Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EU) No 28/2012. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

Commission Regulation (EU) No 28/2012 of 11 January 2012 laying down requirements for the certification for imports into and transit through the Union of certain composite products and amending Decision 2007/275/ EC and Regulation (EC) No 1162/2009 (Text with EEA relevance)

# COMMISSION REGULATION (EU) No 28/2012

of 11 January 2012

laying down requirements for the certification for imports into and transit through the Union of certain composite products and amending Decision 2007/275/EC and Regulation (EC) No 1162/2009

(Text with EEA relevance)

# THE EUROPEAN COMMISSION,

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

Having regard to 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<sup>(1)</sup>, and in particular Article 3(5) thereof;

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<sup>(2)</sup>, and in particular Article 8(5) thereof,

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<sup>(3)</sup>, and in particular the first paragraph of Article 9 thereof,

Having regard to Regulation (EC) No 854/2004 of the European Parliament and 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<sup>(4)</sup>, and in particular the first paragraph of Article 16 thereof,

Having regard to Regulation (EC) No 882/2004<sup>(5)</sup> of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules and in particular Article 48(1) and the first subparagraph of Article 63(1) thereof,

# Whereas:

- (1) Directive 97/78/EC provides that veterinary checks on products from third countries introduced into the Union are to be carried out by Member States in accordance with that Directive and with Regulation (EC) No 882/2004.
- (2) Regulation (EC) No 882/2004 lays down general rules for the performance of official controls to verify compliance with rules aiming, in particular, at preventing, eliminating

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- or reducing to acceptable levels risks to humans and animals, either directly or through the environment.
- (3) Directive 2002/99/EC lays down the general animal health rules governing all stages of the production, processing and distribution within the Union and the introduction from third countries of products of animal origin and products obtained intended for human consumption.
- (4) Regulation (EC) No 853/2004 lays down specific rules on the hygiene of food of animal origin for food business operators. Article 6(4) of that Regulation provides that food business operators importing food containing both products of plant origin and processed products of animal origin (composite products) are to ensure that the processed products of animal origin contained in such food satisfy certain public health requirements laid down therein. In addition, Regulation (EC) No 853/2004 provides that food business operators must be able to demonstrate that they have done so, for example through appropriate documentation or certification.
- (5) Regulation (EC) No 853/2004 applies from 1 January 2006. However, the application of a number of measures laid down therein with immediate effect from that date would have presented practical difficulties in certain cases.
- (6) Commission Regulation (EC) No 2076/2005<sup>(6)</sup> therefore provided that, by way of derogation from Article 6(4) of Regulation (EC) No 853/2004, food business operators importing food containing composite products were to be exempt from the obligation provided for in that Article.
- (7) Commission Regulation (EC) No 1162/2009 of 30 November 2009 laying down transitional measures for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council<sup>(7)</sup> repealed and replaced Regulation (EC) No 2076/2005. Regulation (EC) No 1162/2009 contains the same derogation from Article 6(4) of Regulation (EC) No 853/2004 as did Regulation (EC) No 2076/2005.
- (8) In addition, Regulation (EC) No 1162/2009 provides that imports of composite products are to comply with the harmonised Union rules, where applicable, and with the national rules implemented by the Member States in other cases.
- (9) Regulation (EC) No 1162/2009 applies until 31 December 2013.
- (10) Commission Decision 2007/275/EC of 17 April 2007 concerning lists of animals and products to be subject to controls at border inspection posts under Council Directives 91/496/EEC and 97/78/EC<sup>(8)</sup> provides that certain composite products are to be subject to veterinary checks, when imported into the Union. Pursuant to that Decision, the composite products subjected to veterinary checks are all those containing processed meat products, those containing half or more of their substance of any one processed product of animal origin other than processed meat products and those containing no processed meat products and less than half of their substance of processed milk product where the final products do not meet certain requirements laid down in Decision 2007/275/EC.

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- (11) In addition, Decision 2007/275/EC lays down certain certification requirements regarding the composite products subject to veterinary checks. It provides that composite products containing processed meat products are to be accompanied at introduction into the Union by the relevant certificate for meat products laid down in Union legislation. Composite products containing processed milk products, which are to be subjected to veterinary checks, are to be accompanied at introduction into the Union by the relevant certificate laid down in Union legislation. In addition, composite products containing only processed fishery or egg products which are to be subjected to veterinary checks are to be accompanied at introduction into the Union by the relevant certificate laid down in Union legislation or a commercial document where there is no certificate so required.
- (12) The composite products subjected to veterinary checks pursuant to Decision 2007/275/ EC are, by their very nature, the ones that may present also a higher public health risk. The levels of potential public health risk vary depending on the product of animal origin which is included in the composite product, the percentage in which that product of animal origin is present in the composite product and the treatments applied to it as well as the shelf stability of the composite product.
- (13) It is therefore appropriate that the public health requirements laid down in Regulation (EC) No 853/2004 apply to those composite products even before the expiry of the derogation provided for in Regulation (EC) No 1162/2009.
- (14) In particular, the certification of compliance with public health requirements as laid down in Regulation (EC) No 853/2004 should be provided for in this Regulation for the importation of the composite products containing processed meat products, of those composite products containing half or more of their substance of milk products or of processed fishery or egg products and of those composite products containing no processed meat products and less than half of their substance of processed milk products where the final products are not shelf-stable at ambient temperature or where they have not clearly undergone in their manufacture a complete cooking or heat treatment process throughout their substance, so that any raw product is not denatured.
- (15) As a consequence, the derogation laid down in Regulation (EC) No 1162/2009 should no longer apply for those composite products.
- (16) The animal health requirements concerning those composite products are already laid down in Union legislation. Pursuant to those requirements, those composite products should in particular only be imported from approved third countries.
- (17) A specific model health certificate attesting that such composite products imported into the Union comply with those public and animal health requirements should be laid down in this Regulation. As a consequence, the certification requirements laid down in Decision 2007/275/EC should no longer apply for those composite products.
- (18) For the other composite products containing half or more of their substance of products of animal origin other than milk products or fishery or egg products, the certification requirements laid down in Decision 2007/275/EC should continue to apply. However, for reasons of simplification and clarity of Union legislation, it is appropriate to

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- include those certification requirements in this Regulation, so that the main rules on the certification of composite products be laid down in only one act.
- (19) Decision 2007/275/EC and Regulation (EC) No 1162/2009 should therefore be amended accordingly.
- (20) Due to animal health reasons, a certificate and specific conditions for transit via the Union should be provided for. However these conditions should be applicable only to composite products containing processed meat products or processed dairy products.
- (21) Specific conditions for transit via the Union of consignments to and from Russia should be provided for, owing to the geographical situation of Kaliningrad, which only concerns Latvia, Lithuania and Poland.
- (22) To avoid any disruption of trade, the use of certificates issued in accordance with Decision 2007/275/EC prior to the date of application of this Regulation should be authorised for a transitional period.
- (23) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

### Article 1

## **Subject matter**

This Regulation lays down rules on the certification of consignments of certain composite products introduced into the Union from third countries.

# Article 2

# **Definitions**

For the purposes of this Regulation, the definitions in Article 2 of Decision 2007/275/ EC shall apply.

# Article 3

# Imports of certain composite products

- Consignments of the following composite products introduced into the Union shall come from a third country or part thereof authorised for the introduction into the Union of consignments of the products of animal origin contained in those composite products and the products of animal origin used for the production of such composite products shall originate from establishments in compliance with Article 6.1(b) of Regulation (EC) No 853/2004:
  - a composite products containing processed meat products, as referred to in Article 4(a) of Decision 2007/275/EC;
  - b composite products containing processed milk products and covered by Article 4(b) and (c) of Decision 2007/275/EC;

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- c composite products containing half or more of their substance of processed fishery or egg products and covered by Article 4(b) of Decision 2007/275/EC.
- 2 Consignments of composite products referred to in paragraph 1 shall be accompanied by a health certificate in accordance with the model health certificate set out in Annex I and comply with the conditions established in such certificates.
- Consignments of composite products containing half or more of their substance of products of animal origin other than those referred to in paragraph 1 shall come from a third country or part thereof authorised for the introduction into the Union of consignments of the products of animal origin contained in those composite products and shall be accompanied at introduction into the Union by the relevant certificate laid down in Union legislation for those products of animal origin or by a commercial document where there is no certificate so required.

### Article 4

# Transit and storage of certain composite products

The introduction into the Union of consignments of composite products referred to in Article 3(1)(a) and (b) not intended for importation into the Union but destined for a third country either by immediate transit or after storage in the Union, in accordance with Articles 11, 12 or 13 of Council Directive 97/78/EC, shall only be authorised if the consignments comply with the following conditions:

- (a) they come from a third country or part thereof authorised for the introduction into the Union of consignments of the products of animal origin contained in those composite products and comply with the appropriate treatment conditions for such products, as provided for in Commission Decision 2007/777/EC<sup>(9)</sup> and Commission Regulation (EU) No 605/2010<sup>(10)</sup> for the product of animal origin concerned;
- (b) they are accompanied by a health certificate drawn up in accordance with the model health certificate set out in Annex II;
- (c) they comply with the specific animal health requirements for the importation into the Union of the products of animal origin contained in the composite products concerned, as set out in the animal health attestation in the model health certificate referred to in point (b);
- (d) they are certified as acceptable for transit, including for storage as appropriate, on the common veterinary entry document referred to in Article 2(1) of Commission Regulation (EC) No 136/2004<sup>(11)</sup>, signed by the official veterinarian of the border inspection post of introduction into the Union.

## Article 5

# Derogation for transit of consignments coming from and destined to Russia

- By way of derogation from Article 4, the transit by road or by rail through the Union, between designated border inspection posts in Latvia, Lithuania and Poland, listed in Commission Decision 2009/821/EC<sup>(12)</sup>, of consignments of composite products referred to Article 3 coming from and destined to Russia directly or via another third country shall be authorised provided that the following conditions are complied with:
  - a the consignment is sealed with a serially numbered seal at the border inspection post of introduction into the Union by the veterinary services of the competent authority[F1.]

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$[^{F2}(b)]$	F	2	 																				
(c)	F: F:	2 2	 																				
(d)]		•	 		•		٠		•		•		•	•	•	•	•	•	٠	•	•	•	
F <sup>2</sup> 2																							
F23																							

#### **Textual Amendments**

- F1 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, transhipment 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).
- F2 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, transhipment 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).

# **I**<sup>F3</sup>Article 5a

# Derogation for transit through Croatia of consignments coming from Bosnia and Herzegovina and destined to third countries

- By way of derogation from Article 4, the direct transit by road through the Union, between the border inspection post of Nova Sela and the border inspection post of Ploče, of consignments of composite products referred to Article 3 coming from Bosnia and Herzegovina and destined to third countries shall be authorised provided that the following conditions are complied with:
  - a the consignment is sealed with a serially numbered seal at the border inspection post of introduction into the Union by the official veterinarian at the border inspection post of entry[F1.]

$[^{F2}(b)]$	F2																
(c)																	
(d)]]																	
<sup>F2</sup> 2		 															
F <sup>2</sup> 3		 															

## **Textual Amendments**

**F1** 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, transhipment and onward transportation through the Union, and amending Commission Regulations (EC) No 798/2008, (EC) No 1251/2008,

Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EU) No 28/2012. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

- (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).
- F2 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, transhipment 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).
- **F3** Inserted by Commission Implementing Regulation (EU) No 556/2013 of 14 June 2013 amending Regulations (EC) No 798/2008, (EU) No 206/2010, (EU) No 605/2010 and (EU) No 28/2012 as regards the transit of certain products of animal origin from Bosnia and Herzegovina (Text with EEA relevance).

## Article 6

# Amendment to Decision 2007/275/EC

Article 5 of Decision 2007/275/EC is deleted.

#### Article 7

# Amendment to Regulation (EC) No 1162/2009

In Regulation (EC) No 1162/2009, the first subparagraph of Article 3(2) is replaced by the following:

2. By way of derogation from Article 6(4) of Regulation (EC) No 853/2004, food business operators importing food containing both products of plant origin and processed products of animal origin, other than those referred to in Article 3(1) of Regulation (EU) No 28/2012<sup>(13)</sup>, shall be exempt from the obligation provided for in that Article.

# Article 8

# **Transitional provision**

For a transitional period until 30 September 2012, consignments of composite products in respect of which the relevant certificates have been issued in accordance with Article 5 of Decision 2007/275/EC before 1 March 2012 may continue to be introduced into the Union.

#### Article 9

# Entry into force and application

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 March 2012.

Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EU) No 28/2012. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EU) No 28/2012. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

# [F4ANNEX I

# Model Health Certificate for import into the European Union of composite products intended for human consumption

# **Textual Amendments**

**F4** Substituted by Commission Implementing Regulation (EU) No 468/2012 of 1 June 2012 amending Regulation (EU) No 28/2012 laying down requirements for the certification for imports into and transit through the Union of certain composite products (Text with EEA relevance).

cou	JNTR	1	Veterinary certificate to EU
	l.1.	Consignor Name Address	Certificate reference No     I.2.a.      Central competent authority
		Tel.	I.4. Local competent authority
Ħ	1.5.	Consignee	I.G.
ignme	1.0.	Name Address	
suoo pe		Postcode Tel.	
dispatched consignment	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of destination ISO code I.10.
ğ	1.11.	Place of origin	1.12.
Part I: Details		Name Approval number Address	
Pg		Name Approval number Address	
		Name Approval number Address	
	I.13.	Place of loading	I.14. Date of departure
	I.15.	Means of transport  Aeroplane ☐ Ship ☐ Railway wagon ☐	I.16. Entry BIP in EU
		Road vehicle Other	l.17.
		Identification  Documentation references	
	I.18.	Description of commodity	I.19. Commodity code (HS code)
			I.20. Quantity
	1.21.	Temperature of product  Ambient ☐ Chilled ☐	I.22. Number of packages Frozen □
	1.23.	Seal/Container No	I.24. Type of packaging
	1.25.	Commodities certified for:	<u> </u>
		Human consumption	
	1.26.		I.27. For import or admission into EU
	1.28.	Identification of the commodities	
			ature of Net weight Batch number mmodity

Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EU) No 28/2012. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

#### COUNTRY

#### Composite products intended for human consumption

Health information II.a. Certificate reference No I, the undersigned official veterinarian/official inspector hereby certify that Certification I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004 and (EC) No 853/2004, in particular Article 6.1(b) on the origin of the products of animal origin used in the production of the composite products described above and certify that the composite products described above were produced in accordance with those requirements, in particular that they come from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004: Part the composite products described above contain: (1) either [II.2.A Meat products, treated stomachs, bladders and intestines (2) in any quantity which meet the animal health requirements in Commission Decision 2007/777/EC and contain the following meat constituents which meet the criteria indicated below: Approved Establishment(s) (D) Species (A) Treatment (B) Origin (C)

- (A) Insert the code for the relevant species of meat product, treated stomachs, bladders and intestines where BOV = domestic bovine animals (Bos taurus, Bison bison, Bubalus bubalis and their crossbreds); OVI = domestic sheep (Ovis aries) and goats (Capra hircus); EQI = domestic equine animals (Equus caballus, Equus asinus and their crossbreds), POR = domestic porcine animals (Sus scrofa); RM = domestic rabbits, PFG = domestic poultry and farmed feathered game, RUF farmed non-domestic animals other than suidae and solipeds; RUW = wild non-domestic animals other than suidae and solipeds; SUW = wild non-domestic suidae: EQW = wild non-domestic solipeds, WL = wild lagomorphs, WGB = wild game birds.
- (B) Insert A, B, C, D, E or F for the required treatment as specified and defined in Parts 2, 3 and 4 of Annex II to Decision 2007/777/EC.
- (C) Insert the ISO code of the country of origin of the meat product, treated stomachs, bladders and intestines as listed in Annex II, Part 2 to Decision 2007/777/EC and, in the case of regionalization by Union legislation for the relevant meat constituents, the region as indicated in Part 1 of Annex II to Decision 2007/777/EC or a Member State of the European Union. The country of origin of the meat products must be one the following:
  - the same as the country of export in box I.7.
  - a Member State of the European Union.
  - a third country or parts thereof authorised to export to the Union meat products treated with treatment A as set out in Annex II to Decision 2007/777/EC, where the third country where the composite product is produced is also authorised to export to the Union meat products treated with that treatment.
- (D) Insert EU approval number of the establishments of origin of the meat products, treated stomachs, bladders and intestines contained in the composite product.
- ▶<sup>(1)</sup> (E) If containing material from bovine, ovine or caprine animals, the fresh meat and/or intestines used in the preparation of the meat products and/or treated intestines shall be subject to the following conditions depending on the BSE risk category of the
  - (1)[(E.1) for imports from a country or a region classified in accordance with Decision 2007/453/EC as a country or region posing a negligible BSE risk:
    - 1. the animals, from which the products of bovine, ovine and caprine animal origin are derived, have passed ante mortem and post mortem inspection:
    - 2. the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001 of the European Parliament and of the Council (11);
    - 3. the products of bovine, ovine and caprine animal origin do not contain and are not derived from mechanically separated meat obtained from the bones of bovine, ovine or caprine animals, except for products of bovine, ovine and caprine animal origin derived from animals that were born, continuously reared and slaughtered in a country or region classified in accordance with Decision 2007/453/EC as a country or region posing a negligible BSE risk in which there have been no BSE indigenous cases;
    - 4. the animals, from which the products of bovine, ovine and caprine animal origin are derived, were not slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, except if the animals were born, continuously reared and slaughtered in a country or region classified in accordance with Decision 2007/453/EC as a country or region posing a negligible BSE risk;

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#### COUNTRY

Health information

II.

#### Composite products intended for human consumption

II.b.

or region classified in accordance with De	povine, ovine and caprine animal origin are derived, originate from a country ecision 2007/453/EC as posing an undetermined BSE risk, those animals or greaves, as defined in the Terrestrial Animal Health Code of the World
Organisation for Animal Health, and the	products were produced and handled in a manner which ensures that it

(\*) or [(E.2) for imports from a country or a region classified in accordance with Decision 2007/453/EC as a country or region posing a controlled BSE risk:

II.a. Certificate reference No

did not contain and was not contaminated with nervous and lymphatic tissues exposed during the deboning process.]

- the animals, from which the products of bovine, ovine and caprine animal origin are derived, have passed
  ante mortem and post mortem inspection and were not killed after stunning by laceration of central nervous
  tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of
  gas injected into the cranial cavity;
- the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001, or mechanically separated meat obtained from the bones of bovine, ovine or caprine animals.
- (¹) (⁴) 3. In the case of intestines originally sourced from a country or a region with a negligible BSE risk, imports of treated intestines have been subject to the following conditions:
  - (a) the country or region was classified in accordance with Decision 2007/453/EC as a country or region posing a controlled BSE risk;
  - (b) the animals, from which the products of bovine, ovine and caprine animal origin are derived, were born, continuously reared and slaughtered in the country or region with a negligible BSE risk and have passed ante mortem and post mortem inspections;
  - (1) (c) if the intestines are sourced from a country or region where there have been BSE indigenous cases:
    - (i) the animals were born after the date from which the ban on the feeding of ruminants with meatand-bone meal and greaves derived from ruminants was enforced; or
    - (ii) the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001.]
- (\*) or [(E.3) for imports from a country or a region classified in accordance with Decision 2007/453/EC as a country or region with an undetermined BSE risk:
  - the animals, from which the products of bovine, ovine and caprine animal origin are derived, were not fed
    meat-and-bone meal or greaves derived from ruminants, as defined in the Terrestrial Animal health Code
    of the World Organisation for Animal Health, and have passed ante mortem and post mortem inspections;
  - the animals, from which the products of bovine, ovine and caprine animal origin are derived, were not killed, after stunning, by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity;
  - 3. the products of bovine, ovine and caprine animal origin are not derived from:
    - (a) specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001;
    - (b) nervous and lymphatic tissues exposed during the deboning
    - (c) mechanically separated meat obtained from bones of bovine, ovine or caprine animals.
  - (¹) (⁴) 4. In the case of intestines originally sourced from a country or a region with a negligible BSE risk, imports of treated intestines have been subject to the following conditions:
    - (a) the country or region was classified in accordance with Decision 2007/453/EC as a country or region posing a undetermined BSE risk;
    - (b) the animals, from which the products of bovine, ovine and caprine animal origin are derived, were born, continuously reared and slaughtered in the country or region with a negligible BSE risk and have passed ante mortem and post mortem inspections;

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ΛI		

## Composite products intended for human consumption

II.	Health	nformation		II.a. Certificate reference No	II.b.
			$(^{1})$ (c) if the intestines are sourced	from a country or region where there have b	peen BSE indigenous cases:
				fter the date from which the ban on the feeding derived from ruminants was enforced; or	ng of ruminants with meat-and-
				ovine and caprine animal origin do not cor s defined in point 1 of Annex V to Regulatior	
( <sup>1</sup> ) and/or	[II.2.B	Processed dain products in any		for more of the substance of the composite p	product or not shelf stable dairy
		number of t	he establishments of origin of the o	alairy products contained in the composite pr U). The country of origin of the dairy product	oduct authorised at the time of
		— the sam	e as the country of export in box I.	7,	
		— a Memb	er State of the European Union,		
		No 605/		nion milk and dairy products in Column A or ire the composite product is produced is als dairy products.	
				e listed in Annex I to Regulation (EU) No 605/ in that list for the relevant country;	2010 and the treatment applied
		(b) have been p	produced from milk obtained from a	animals:	
		(i) under th	e control of the official veterinary s	ervice;	
		(ii) belongir	ng to holdings which were not unde	er restrictions due to foot-and-mouth disease	or rinderpest; and
				ensure that they satisfy the animal health cond No 853/2004 and in Directive 2002/99/EC;	ditions laid down in Chapter I of
		(c) are dairy pro	oducts made from raw milk obtaine	d from:	
			, ewes, goats or buffaloes and prio ced from raw milk which has unde	r to import into the territory of the European rgone	Union have undergone or been
		( <sup>1</sup> ) either	achieved by a pasteurisation pro-	ng a single heat treatment with a heating e cess of at least 72 °C for 15 seconds and alkaline phosphatase test applied immedia	where applicable, sufficient to
		( <sup>1</sup> ) or	[a sterilisation process, to achieve	an F <sub>0</sub> value equal to or greater than three;	
		(¹) or	[an ultra high temperature (UHT) to	reatment at not less than 135 °C in combination	on with a suitable holding time;]
		(¹) or		teurisation treatment (HTST) at 72 °C for 15 applied to milk with a pH lower than 7,0 anosphatase test	
		(¹) or	equivalent pasteurisation effect, ap	teurisation treatment (HTST) at 72 °C for 15 opplied twice to milk with a pH equal to or gran an alkaline phosphatase test, immediately for	eater than 7,0 achieving, where
		(1)	either [lowering the pH below 6 for	or one hour;]	
		O	or [additional heating equal to	or greater than 72 °C, combined with desico	cation;]]
			als other than cows, ewes, goats o gone or been produced from raw i	r buffaloes and prior to import into the territo milk which has undergone	ry of the European Union have

Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EU) No 28/2012. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

COUNTRY	1						Composite products	intended for human	consumptio
II.	Health	inform	ation				II.a. Certificate reference No	II.b.	
		(	¹) eiti	her	a steri	lisation process, to achieve	an F <sub>0</sub> value equal to or greater than thr	ee;]	
		(	(1) or		[an ultr	a high temperature (UHT) tre	eatment at not less than 135 °C in comb	ination with a suitable h	holding time;]
							or between		
A) and/or							e approved establishment No (8)		cituatos
(*) anu/or	[11.2.0					]	e approved establishment No (-)		Situatec
(1) and/or	[II.2.D	Proces	sed	egg	produ	cts that originate from the a	pproved country (9)	]	
		(EC) I	No 85	3/20	04 wh		ment which satisfies the requirements of the certificate is free from highly patho		
		either							
	(*)	II.2.D.					where appropriate, the territory of a neignza or Newcastle disease for at least the		has been no
		or							
	(1)	II.2.D.2	2 [the	e eg	g produ	ucts were processed:			
		(	1) eith	ner	[liquid	egg white was treated:			
				(1)	either	[with 55,6 °C for 870 secon	nds.]		
				(1)	or	[with 56,7 °C for 232 secon	nds.]		
		(	1) or		[10 %	salted yolk was treated with	n 62,2 °C for 138 seconds.]		
		(	1) or		[dried	egg white was treated:			
				(1)	either	[with 67 °C for 20 hours.]			
				(1)	or	[with 54,4 °C for 513 hours	.]		
		(	1) or		[whole	e eggs were at least treated:			
				(1)	either	[with 60 °C for 188 seconds	s.]		
				(1)	or	[completely cooked.]			
					[whole	e egg blends were at least tr	reated]:		
				(1)	either	[with 60 °C for 188 seconds	s.]		
				(1)	or	[with 61,1 °C for 94 second	ds.]		
Notes									
Part I:									
intesti No 60	nes as li 5/2010 a	isted in and/or fo	Anne: or pro	x II, cess	Part 2 ed fish	to Decision 2007/777/EC and	composite product containing meat product for processed dairy products in Anr II to Commission Decision 2006/766/EC	nex I to Commission Re	egulation (EU)
						d registration/approval number must be the same as the cou	er if available of the establishments of prountry of origin in box I.7.	oduction of the composi	ite product(s)
transp	ort in co ted in bo	ontainers	s, the	tota	I numb	er of containers and their re-	ner and road vehicles), flight number (ai gistration number and where there is a gnor must inform the border inspection p	serial number of the se	eal it must be
						e Harmonised System (HS) o 05; 21.03; 21.04; 21.05; 21.0	code of the World Customs Organisation 06.	such as: 16.01; 16.02;	16.03; 16.04

- Box reference I.20: Indicate total gross weight and total net weight.

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cou	NTRY	Composite products inte	nded for human consumptio
II.	Health information	II.a. Certificate reference No	II.b.
_	Box reference I.23: For containers or boxes, the container number	and the seal number (if applicable) must be	e included.
	Box reference I.28: Manufacturing plant: insert the name and approproduct(s). Nature of commodity: in case of composite products or "meat product", "treated stomachs", "bladders" or "intestines". In casease of composite product containing processed fishery products containing egg products specify the egg content percentage.	ontaining meat products, treated stomachs, be of composite product containing dairy product	pladders and intestines indicate fucts indicate "dairy product". In
Par	t II:		
(¹)	Keep as appropriate.		
( <sup>2</sup> )	Meat products as laid down in point 7.1 of Annex I to Regulation (E in point 7.9 of Annex I to Regulation (EC) No 853/2004 that have 2007/777/EC.		
( <sup>3</sup> )	By way of derogation from point 4, carcasses, half carcasses or containing no specified risk material other than the vertebral column		
	When removal of the vertebral column is not required, carcasses of shall be identified by a blue stripe on the label referred to in Reg		nals containing vertebral column
	The number of bovine carcasses or wholesale cuts of carcasses, fi where removal of the vertebral column is not required shall be added in case of imports.		
( <sup>4</sup> )	Only applicable to imports of treated intestines.		
( <sup>5</sup> )	By way of derogation from point 3, carcasses, half carcasses or containing no specified risk material other than the vertebral column		
	When removal of the vertebral column is not required, carcasses of shall be identified by a clearly visible blue stripe on the label reference.		nals containing vertebral column
	Specific information on the number of bovine carcasses or wholesa and from which removal of the vertebral column is not required sha 136/2004 in case of imports.		
( <sup>6</sup> )	Raw milk and dairy products means, raw milk and dairy products fr No $853/2004$ .	or human consumption as defined in point 7.	2 of Annex I to Regulation (EC)
(7)	Date or dates of production. Imports of raw milk and dairy product for exportation to the European Union of the third country or par measures have been adopted by the European Union against important the country of the European Union against important the country of the European Union against important the country of th	t thereof mentioned under I.7 and I.8, or du	uring a period where restrictive
(8)	Number of the fishery product establishment authorised to export	to the EU.	
( <sup>9</sup> )	Country of origin authorised to export to the EU.		
(10)	In case of composite products containing only agg or fichery products	tunte the cignature of an official Inchector ca	in he accented

▶<sup>(1)</sup> (¹¹) The removal of specified risk material is not required if the products of bovine, ovine and caprine animal origin derive from animals born, continuously reared and slaughtered in a third country or region of a third country classified in accordance with Decision 2007/453/EC as posing a negligible BSE risk. ◀

- The colour of the signature shall be different to that of the printing. The same rule applies to stamps other than those embossed or watermark.

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COUNTRY	Composite product	Composite products intended for human consumption							
II. Health information	II.a. Certificate reference No	II.b.							
Official veterinarian/Official inspector (10)									
Name (in capital letters):	Qualification and title:								
Date:	Signature:								
Stamp:									

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# ANNEX II

# Model Health Certificate for transit through or storage in the European Union of composite products intended for human consumption]

COL	MIN		veterinary certificate to Eu
	l.1.	Consignor Name	I.2. Certificate reference No I.2.a.
		Address	I.3. Central competent authority
		Tel.	I.4. Local competent authority
signment	1.5.	Consignee Name Address	Rerson responsible for the load in EU     Name     Address
ched con		Postcode Tel.	Postcode Tel.
of dispatched consignment	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of destination ISO code I.10.
Part I: Details	l.11.	Place of origin	I.12. Place of origin
<u>با</u>		Name Approval number Address	Custom warehouse  Ship supplier
P.		Name Approval number Address	Name Approval number Address
		Name Approval number Address	Postcode
	I.13.	Place of loading	I.14. Date of departure
	I.15.	Means of transport	I.16. Entry BIP in EU
		Aeroplane Ship Railway wagon Road vehicle Other	
		Identification  Documentation references	1.17.
	I.18.	Description of commodity	I.19. Commodity code (HS code)
			I.20. Quantity
	1.21.	Temperature of product	I.22. Number of packages
		Ambient ☐ Chilled ☐	Frozen
	1.23.	Seal/Container No	I.24. Type of packaging
	1.25.	Commodities certified for:	
		Human consumption	
	1.26.	For transit through EU to third country	1.27.
		Third country ISO code	
	1.28.	Identification of the commodities	
			re of Net weight Batch number modity
	1		

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# on

0:	UNTRY			Composite products i Transit/Storage	intended for human consumption
	II.	Healt	h information	II.a. Certificate reference No	II.b.
		I, the	undersigned official veterinarian/official inspector herel	by certify that the composite products de	scribed above contain:
Part II: Certification	( <sup>1</sup> ) either	II.1.A	Meat products, treated stomachs, bladders and intest and intestines have been produced according to Con and meet the criteria indicated below:		
ë.			Species (A)	Treatment (B)	Origin (C)
Par			(A) Insert the code for the relevant species of meat bovine animals ( <i>Bos taurus, Bison bison, Bubalus</i> ( <i>Capra hircus</i> ); EQI = domestic equine animals ( <i>Eus scrota</i> ); RM = domestic rabbits, PFC animals other than suidae and solipeds; RUW = v domestic suidae: EQW = wild non-domestic solidae:	bubalis and their crossbreds); OVI = don iquus caballus, Equus asinus and their cro a = domestic poultry and farmed featherer wild non-domestic animals other than suic	nestic sheep ( <i>Ovis aries</i> ) and goat ossbreds), POR = domestic porcin d game, RUF farmed non-domesti dae and solipeds; SUW = wild nor
			(B) Insert A, B, C, D, E or F for the required treatment 2007/777/EC.	nent as specified and defined in Parts 2	, 3 and 4 of Annex II to Decisio
			(C) Insert the ISO code of the country of origin of the Part 2 to Decision 2007/777/EC and, in the case region as indicated in Part 1 of Annex II to Decis origin of the meat products must be one the folio	of regionalization by Union legislation for ion 2007/777/EC or a Member State of the	the relevant meat constituents, th
			— the same as the country of export in box I.7,		
			— a Member State of the European Union,		
			<ul> <li>a third country or parts thereof authorised to Annex II to Decision 2007/777/EC, where the export to the Union meat products treated wi</li> </ul>	third country where the composite produc	
	( <sup>1</sup> ) and/or	[II.1.B	Processed dairy products $(^3)$ in an amount of half or products in any quantity that	r more of the substance of the composit	e product or not shelf stable dair
			(a) have been produced in the countryfollowing:	The country of origin of the	dairy products must be one of th
			— the same as the country of export in box I.7,		
			— a Member State of the European Union,		
			<ul> <li>a third country or parts thereof authorised to Annex II to Decision 2007/777/EC, where the export to the Union meat products treated wi</li> </ul>	third country where the composite produc	
			The country of origin indicated in box I.7 must be must be conform to the treatment provided for in		605/2010 and the treatment applie
			(b) have been produced from milk obtained from ani	mals:	
			(i) under the control of the official veterinary ser	vice;	
			(ii) belonging to holdings which were not under	restrictions due to foot-and-mouth diseas	e or rinderpest; and
			(iii) subject to regular veterinary inspections to en Section IX of Annex III to Regulation (EC) No		onditions laid down in Chapter I o
			(c) are dairy products made from raw milk obtained	from	

(1) either [cows, ewes, goats or buffaloes and prior to import into the territory of the European Union have undergone or been produced from raw milk which has undergone

(¹) either [a pasteurisation treatment involving a single heat treatment with a heating effect at least equivalent to that achieved by a pasteurisation process of at least 72 °C for 15 seconds and where applicable, sufficient to ensure a negative reaction to an alkaline phosphatase test applied immediately after the heat treatment;]

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# COUNTRY

# Composite products intended for human consumption Transit/Storage

II. Health information	II.a. Certificate reference number	II.b.
(1) or [a sterilisation process, to achieve	an F <sub>0</sub> value equal to or greater than three	:]
( <sup>1</sup> ) or [an ultra high temperature (UHT) tre	atment at not less than 135 °C in combinati	on with a suitable holding time;]
	urisation treatment (HTST) at 72 °C for 15 plied to milk with a pH lower than 7,0 a sphatase test];	
equivalent pasteurisation effect, app	urisation treatment (HTST) at 72 °C for 15 i lied twice to milk with a pH equal to or gra n alkaline phosphatase test, immediately f	eater than 7,0 achieving, where
(1) either [lowering the pH below 6 fo	r one hour;]	
(1) or [additional heating equal to	or greater than 72 °C, combined with desi	ccation;]]
(1) or [animals other than cows, ewes, goats or to undergone or been produced from raw mi		ry of the European Union have
(1) either [a sterilisation process, to achieve	an F <sub>0</sub> value equal to or greater than three	:]
(1) or [an ultra high temperature (UHT) ti time;]]	eatment at not less than 135 °C in comb	pination with a suitable holding
(d) were produced on or	between and .	(4).]
and/or [II.1.C Processed egg products that originate from the appro	oved country (5)	
Were produced from eggs coming from an establishm (EC) No 853/2004 which at the date of issue of the Regulation (EC) No 798/2008 and		
either		
( <sup>1</sup> ) [II.1.C.1 [within a 10 km radius of which [including, w no outbreak of highly pathogenic avian influ		
or		
(1) [II.1.C.2 [the egg products were processed:		
(1) either [liquid egg white was treated:		
(1) either [with 55,6 °C for 870 second	ls.]	
(1) or [with 56,7 °C for 232 second	ds.]	
(1) or [10 % salted yolk was treated with (	62,2 °C for 138 seconds.]	
(1) or [dried egg white was treated:		
(1) either [with 67 °C for 20 hours.]		
(1) or [with 54,4 °C for 513 hours.]		
(1) or [whole eggs were at least treated:		
(1) either [with 60 °C for 188 seconds	]	
( <sup>1</sup> ) or [completely cooked.]		
[whole egg blends were at least trea	ated]:	
(1) either [with 60 °C for 188 seconds	]	
(1) or [with 61,1 °C for 94 seconds	.]	

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# COUNTRY

# Composite products intended for human consumption Transit/Storage

II.	Health information	II.a. Certificate reference number	II.b.	
Notes				
Part I:				
	<ul> <li>Box reference I.7: Insert the ISO code of the country of origin of the meat product, treated stomachs, bladders and intestines as listed in Annex II, Part 2 to Decision 2007/777/EC and/or for processed dairy product in Annex I to Commission Regulation (EU) No 605/2010.</li> </ul>			
	Box reference I.11: Name, address of the establishments of production of the composite product(s). Name of the country of origin which must be the same as the country of origin in box I.7.			
	Approval number is not applicable.			
1	Box reference I.15: Registration number (railway wagons or container and road vehicles), flight number (aircraft) or name (ship). In the case of transport in containers, the total number of containers and their registration number and where there is a serial number of the seal it must be indicated in box I.23. In case of unloading and reloading, the consignor must inform the border inspection post of introduction into the European Union.			
	Box reference I.19: Use the appropriate Harmonised System (HS) code of the World Customs Organisation such as: 16.01; 16.02; 16.03; 16.04; 16.05; 19.01; 19.02; 19.05; 20.04; 20.05; 21.03; 21.04; 21.05; 21.06.			
- I	<ul> <li>Box reference I.20: Indicate total gross weight and total net weight.</li> </ul>			
— I	<ul> <li>Box reference I.23: For containers or boxes, the container number and the seal number (if applicable) must be included.</li> </ul>			
	<ul> <li>Box reference I.28: Manufacturing plant: insert the name and approval number if available of the establishments of production of the composite product(s). Nature of commodity: in case of composite products containing meat products, treated stomachs, bladders and intestines indicate "meat product", "treated stomachs", "bladders" or "intestines". In case of composite product containing dairy products indicate "dairy product".</li> </ul>			
Part II:				
(1)	Keep as appropriate.			
` ′	Meat products as laid down in point 7.1 of Annex I to Regulation (EC) No 853/2004 and treated stomachs, bladders and intestines as laid down in point 7.9 of Annex I to Regulation (EC) No 853/2004 that have undergone one of the treatments laid down in Annex II part 4 to Decision 2007/777/EC.			
	Raw milk and dairy products means, raw milk and dairy products for No 853/2004.	human consumption as defined in point	7.2 of Annex I to Regulation (EC)	
``	Date or dates of production. Imports of raw milk and dairy products shall not be allowed when obtained either prior to the date of authorisation for exportation to the European Union of the third country or part thereof mentioned under I.7 and I.8, or during a period where restrictive measures have been adopted by the European Union against imports of raw milk and dairy products from this third country or part thereof.			
( <sup>5</sup> )	5) Country of origin authorised to export to the EU.			
— The colour of the signature shall be different to that of the printing. The same rule applies to stamps other than those embossed or watermark.				
Official veterinarian/Official inspector				
	Name (in capital letters):	Qua	lification and title:	
	Date:	Sign	ature:'	
	Stamp:			

Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EU) No 28/2012. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

- **(1)** OJ L 24, 30.1.1998, p. 9.
- (2) OJ L 18, 23.1.2003, p. 11.
- (**3**) OJ L 139, 30.4.2004, p. 55.
- (4) OJ L 139, 30.4.2004, p. 206.
- (5) OJ L 165, 30.4.2004, p. 1.
- (**6**) OJ L 338, 22.12.2005, p. 83.
- (7) OJ L 314, 1.12.2009, p. 10.
- (8) OJ L 116, 4.5.2007, p. 9.
- **(9)** OJ L 312, 30.11.2007, p. 49.
- (10) OJ L 175, 10.7.2010, p. 1.
- (11) OJ L 21, 28.1.2004, p. 11.
- (12) OJ L 296, 12.11.2009, p. 1.
- (13) OJ L 12, 14.1.2012, p. 1.'

# **Status:**

Point in time view as at 31/12/2020.

# **Changes to legislation:**

There are outstanding changes not yet made to Commission Regulation (EU) No 28/2012. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.