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⁽¹⁾, 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⁽²⁾, 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⁽³⁾, 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⁽⁴⁾, and in particular the first paragraph of Article 16 thereof,

Having regard to Regulation (EC) No 882/2004⁽⁵⁾ 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

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⁽⁶⁾ 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⁽⁷⁾ 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⁽⁸⁾ 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 do not meet certain requirements laid down in Decision 2007/275/EC.

- (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

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

1 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;

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.

3 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⁽⁹⁾ and Commission Regulation (EU) No 605/2010⁽¹⁰⁾ 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⁽¹¹⁾, 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

1 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 $2009/821/EC^{(12)}$, 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}.]

 $\begin{bmatrix} F^{2}(b) & F^{2} & & \\ (c) & F^{2} & & \\ (d) \end{bmatrix} \quad F^{2} & & \\ \end{array}$

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).

[^{F3}Article 5a

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

1 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
• • •	F2
(d)]]	F2
^{F2} 2	
^{F2} 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,

(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 $28/2012^{(13)}$, 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.

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

[^{F4}ANNEX I

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

	extı F4		ulation (EU) No 468/2012 of 1 June 2012 amending rements for the certification for imports into and transit 5 (Text with EEA relevance).		
ou	NTR	(Veterinary certificate to E		
	I.1.		I.2. Certificate reference No I.2.a.		
		Name Address	I.3. Central competent authority		
		Tel.	I.4. Local competent authority		
dispatched consignment	1.5.	Consignee Name Address Postcode	1.6.		
tche		Tel.			
of dispa	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO code I.10.		
etails o	l.11.	Place of origin	1.12.		
Part I: Details		Name Approval number Address			
Ч		Name Approval number Address			
		Name Approval number Address			
	I.13.	Place of loading	I.14. Date of departure		
	l.15.	Means of transport	I.16. Entry BIP in EU		
		Aeroplane Ship Railway wagon Road vehicle Other	1.17.		
		Identification Documentation references			
	l.18.	Description of commodity	I.19. Commodity code (HS code)		
			I.20. Quantity		
	I.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:	1		
		Human consumption 🔲			
	1.26.		I.27. For import or admission into EU		
	1.28.	Identification of the commodities	1		
			Nature of Net weight Batch number ommodity		

СС	UNTRY			Composite products i	intended for human consumption			
	П.	Healt	h information	II.a. Certificate reference No	II.b.			
		I, the	undersigned official veterinarian/official inspector herel	by certify that				
Part II: Certification		II.1.	I am aware of the relevant provisions of Regulations Article 6.1(b) on the origin of the products of animal of certify that the composite products described above v come from (an) establishment(s) implementing a prog No 852/2004;	origin used in the production of the compo were produced in accordance with those	osite products described above and requirements, in particular that they			
II.2. 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 require Commission Decision 2007/777/EC and contain the following meat constituents which meet the criteria indicated below:							
			Species (A) Treatment (B)	Origin (C)	Approved Establishment(s) (D)			
			(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>E</i> animals (<i>Sus scrofa</i>); RM = domestic rabbits, PFC animals other than suidae and solipeds; RUW = v domestic suidae: EQW = wild non-domestic solip	bubalis and their crossbreds); OVI = don quus caballus, Equus asinus and their cro a = domestic poultry and farmed feathere wild non-domestic animals other than suic	nestic sheep (<i>Ovis aries</i>) and goats ossbreds), POR = domestic porcine d game, RUF farmed non-domestic dae and solipeds; SUW = wild non-			
			(B) Insert A, B, C, D, E or F for the required treatm 2007/777/EC.	nent as specified and defined in Parts 2	e, 3 and 4 of Annex II to Decision			
			(C) Insert the ISO code of the country of origin of the I 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 following the series of the series o	of regionalization by Union legislation for ion 2007/777/EC or a Member State of the	the relevant meat constituents, the			
			- 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 ex II to Decision 2007/777/EC, where the third co to the Union meat products treated with that 	ountry where the composite product is pro				
			(D) Insert EU approval number of the establishments contained in the composite product.	s of origin of the meat products, treated	stomachs, bladders and intestines			
		▶ ⁽¹⁾	(E) If containing material from bovine, ovine or capri meat products and/or treated intestines shall be s country of origin:	ne animals, the fresh meat and/or intesti subject to the following conditions depend	nes used in the preparation of the ing on the BSE risk category of the			
			(¹) [(E.1) for imports from a country or a region classifiant a negligible BSE risk:	ied in accordance with Decision 2007/45	3/EC as a country or region posing			
			 the animals, from which the products of mortem and post mortem inspection; 	f bovine, ovine and caprine animal orig	in are derived, have passed ante			
 the products of bovine, ovine and caprine animal origin do not contain and are not derived from spe as defined in point 1 of Annex V to Regulation (EC) No 999/2001 of the European Parliament and content of the European Parliament and conte								
	re not derived from mechanically teept for products of bovine, ovine ared and slaughtered in a country agion posing a negligible BSE risk							
			 the animals, from which the products of after stunning by means of gas injected eration after stunning of central nervous the cranial cavity, except if the animals classified in accordance with Decision 2 	into the cranial cavity or killed by the sa s tissue by means of an elongated rod-s s were born, continuously reared and s	me method or slaughtered by lac- haped instrument introduced into laughtered in a country or region			

COUNTRY Composite products intended for human consumption Health information II.a. Certificate reference No Ш. II.b. 5. if the animals, from which the products of bovine, ovine and caprine animal origin are derived, originate from a country or region classified in accordance with Decision 2007/453/EC as posing an undetermined BSE risk, those animals were not fed with meat-and-bone meal 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 did not contain and was not contaminated with nervous and lymphatic tissues exposed during the deboning process.] (1) 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: 1. 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; 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, 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.] (1) 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: 1. 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; 2. 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 in troduced 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;

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. (See end of Document for details)

COUNTRY		Composite products intended for human consumption						
II. Health info	ormation II.a.	Certificate reference No	II.b.					
	(1) (c) if the intestines are sourced from	a country or region where there have b	een BSE indigenous cases:					
	.,	ne date from which the ban on the feedir ved from ruminants was enforced; or	ng of ruminants with meat-and-					
		e and caprine animal origin do not cor ined in point 1 of Annex V to Regulation						
	Processed dairy products (⁶) in an amount of half or more of the substance of the composite product or not shelf stable dairy products in any quantity that:							
(a)	 have been produced in the countrynumber of the establishments of origin of the dairy production for export of dairy products to the EU). The product of the second se	products contained in the composite pro-	oduct authorised at the time of					
	- the same as the country of export in box I.7,							
	 a Member State of the European Union, 							
	 a third country authorised to export to the Union No 605/2010, where the third country where the conditions, to export to the Union milk and dairy 	e composite product is produced is als						
	The country of origin indicated in box I.7 must be liste must be conform to the treatment provided for in the		2010 and the treatment applied					
(b)) have been produced from milk obtained from anima	ls:						
	(i) under the control of the official veterinary service	9;						
	(ii) belonging to holdings which were not under rest	trictions due to foot-and-mouth disease	or rinderpest; and					
	(iii) subject to regular veterinary inspections to ensure Section IX of Annex III to Regulation (EC) No 8		ditions laid down in Chapter I of					
(c)	e) are dairy products made from raw milk obtained from	n:						
Ċ	i) either [cows, ewes, goats or buffaloes and prior to in produced from raw milk which has undergone		Union have undergone or been					
	(¹) either [a pasteurisation treatment involving a achieved by a pasteurisation process ensure a negative reaction to an alka	of at least 72 °C for 15 seconds and	where applicable, sufficient to					
	(1) or [a sterilisation process, to achieve an F	F_0 value equal to or greater than three;						
	(1) or [an ultra high temperature (UHT) treatm	ent at not less than 135 °C in combination	on with a suitable holding time;]					
	(¹) or [a high temperature short time pasteuris equivalent pasteurisation effect, applie negative reaction to an alkaline phosph	d to milk with a pH lower than 7,0 a	seconds, or a treatment with an achieving, where applicable, a					
	(¹) or [a high temperature short time pasteuris equivalent pasteurisation effect, applied applicable, a negative reaction to an al	I twice to milk with a pH equal to or gre	eater than 7,0 achieving, where					
	(1) either [lowering the pH below 6 for one	e hour;]						
	(1) or [additional heating equal to or gr	reater than 72 °C, combined with desico	eation;]]					
Ć)	 or [animals other than cows, ewes, goats or buff undergone or been produced from raw milk v 		ry of the European Union have					

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. (See end of Document for details)

COUNTRY	Y	Composite products inter	nded for human consumption
П.	Health information	II.a. Certificate reference No	II.b.
	(1) either [a sterilisation process, to achieve a	an F_0 value equal to or greater than three;]	
	(¹) or [an ultra high temperature (UHT) tre	atment at not less than 135 °C in combination	n with a suitable holding time;]
	(d) were produced on and		
(1) and/or	r [II.2.C Processed fishery products that originate from the	approved establishment No (8)	situated
.,	in the country (⁹)]		
(¹) and/or	r [II.2.D Processed egg products that originate from the ap	oproved country (⁹)]
	were produced from eggs coming from an establishr (EC) No 853/2004 which at the date of issue of t Regulation (EC) No 798/2008 and		
	either		
	(¹) II.2.D.1 [within a 10 km radius of which [including, v outbreak of highly pathogenic avian influen	where appropriate, the territory of a neighbouri za or Newcastle disease for at least the prev	
	or		
	(⁷) II.2.D.2 [the egg products were processed:		
	(¹) either [liquid egg white was treated:		
	(¹) either [with 55,6 °C for 870 secon	ds.]	
	(¹) or [with 56,7 °C for 232 secon	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	5.]	
	(¹) or [completely cooked.]		
	[whole egg blends were at least tr	eated]:	
	(¹) either [with 60 °C for 188 seconds	5.]	
	(¹) or [with 61,1 °C for 94 second	s.]	
Notes			
Part I:			
intesti No 60	reference I.7: Insert the ISO code of the country of origin of the tines as listed in Annex II, Part 2 to Decision 2007/77/EC and 52/2010 and/or for processed fishery products in Annex I and II x I part 1 to Commission Regulation (EC) No 798/2008.	I/or for processed dairy products in Annex I to	Commission Regulation (EU
	reference I.11: Name, address and registration/approval numbe e of the country of origin which must be the same as the cou		on of the composite product(s)
transp	reference I.15: Registration number (railway wagons or contair port in containers, the total number of containers and their req ated in box I.23. In case of unloading and reloading, the consig n.	sistration number and where there is a serial	number of the seal it must be
	reference I.19: Use the appropriate Harmonised System (HS) c 5; 19.01; 19.02; 19.05; 20.04; 20.05; 21.03; 21.04; 21.05; 21.0		as: 16.01; 16.02; 16.03; 16.04

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

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. (See end of Document for details)

COUNTRY	Composite products inte	ended for human consumption
II. Health information	II.a. Certificate reference No	II.b.
- Box reference I.23: For containers or boxes, the container number	er and the seal number (if applicable) must be	e included.
— Box reference I.28: Manufacturing plant: insert the name and appr product(s). Nature of commodity: in case of composite products "meat product", "treated stomachs", "bladders" or "intestines". In ca case of composite product containing processed fishery product containing egg products specify the egg content percentage.	containing meat products, treated stomachs, l ase of composite product containing dairy prod	bladders and intestines indicate ducts indicate "dairy product". In
Part II:		
(¹) Keep as appropriate.		
(²) Meat products as laid down in point 7.1 of Annex I to Regulation (in point 7.9 of Annex I to Regulation (EC) No 853/2004 that hav 2007/777/EC.		
(³) By way of derogation from point 4, carcasses, half carcasses of containing no specified risk material other than the vertebral colu		
When removal of the vertebral column is not required, carcasses shall be identified by a blue stripe on the label referred to in Re		nals containing vertebral column
The number of bovine carcasses or wholesale cuts of carcasses, where removal of the vertebral column is not required shall be add in case of imports.		
(4) Only applicable to imports of treated intestines.		
(5) By way of derogation from point 3, carcasses, half carcasses of containing no specified risk material other than the vertebral colu		
When removal of the vertebral column is not required, carcasses shall be identified by a clearly visible blue stripe on the label re		nals containing vertebral column
Specific information on the number of bovine carcasses or whole and from which removal of the vertebral column is not required sh 136/2004 in case of imports.		
(⁶) Raw milk and dairy products means, raw milk and dairy products No 853/2004.	for 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 production for exportation to the European Union of the third country or particle measures have been adopted by the European Union against in	art thereof mentioned under I.7 and I.8, or di	uring a period where restrictive
(⁸) Number of the fishery product establishment authorised to export	t to the EU.	
(⁹) Country of origin authorised to export to the EU.		
(10) In case of composite products containing only egg or fishery pro	oducts the signature of an official Inspector ca	an be accepted.
(1) (11) The removal of specified risk material is not required if the born, continuously reared and slaughtered in a third cou 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.

COUNTRY	Composite products inte	nded 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:		

ANNEX II

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

COL	OUNTRY 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				
gnment	1.5.	Consignee Name Address	 Person responsible for the load in EU Name Address 				
consi		Postcode	Postcode				
tched		Tel.	Tel.				
of dispatched consignment	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO code I.10.				
etails	l.11.	Place of origin	I.12. Place of origin				
Part I: Details		Name Approval number Address	Custom warehouse D Ship supplier D				
4		Name Approval number Address	Name Approval number Address				
		Name Approval number Address	Postcode				
	I.13.	Place of loading	I.14. Date of departure				
	l.15.	Means of transport	I.16. Entry BIP in EU				
		Aeroplane Arip Railway wagon Road vehicle Other	1.17.				
		Identification Documentation references	617.				
	l.18.	Description of commodity	I.19. Commodity code (HS code)				
			I.20. Quantity				
	I.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					
			rre of Net weight Batch number modity				

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. (See end of Document for details)

:01	JNT	RY			Composite products in Transit/Storage	ntended for human consumption
	Π.		Healt	h information	II.a. Certificate reference No	II.b.
			I, the	undersigned official veterinarian/official inspector hereb	y certify that the composite products des	scribed above contain:
Part II: Certification	(*)	either	ll.1.A	Meat products, treated stomachs, bladders and intestin and intestines have been produced according to Com and meet the criteria indicated below:		
t II: Cerl				Species (A)	Treatment (B)	Origin (C)
Par				(A) Insert the code for the relevant species of meat p bovine animals (<i>Bos taurus, Bison bison, Bubalus</i> (<i>Capra hircus</i>); EQI = domestic equine animals (<i>Ec</i> animals (<i>Sus scrofa</i>); RM = domestic rabbits, PFG animals other than suidae and solipeds; RUW = w domestic suidae: EQW = wild non-domestic solip	bubalis and their crossbreds); OVI = dom guus caballus, Equus asinus and their cro = domestic poultry and farmed feathered rild non-domestic animals other than suid	estic sheep (<i>Ovis aries</i>) and goats ssbreds), POR = domestic porcine I game, RUF farmed non-domestic ae and solipeds; SUW = wild non-
				(B) Insert A, B, C, D, E or F for the required treatm 2007/777/EC.	ent as specified and defined in Parts 2,	3 and 4 of Annex II to Decision
				(C) Insert the ISO code of the country of origin of the n Part 2 to Decision 2007/777/EC and, in the case or region as indicated in Part 1 of Annex II to Decision origin of the meat products must be one the following the set of	of regionalization by Union legislation for t on 2007/777/EC or a Member State of th	the relevant meat constituents, the
				— 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 Annex II to Decision 2007/777/EC, where the t export to the Union meat products treated with 	hird country where the composite produc	
	(*)	and/or	[II.1.B	Processed dairy products $(^3)$ in an amount of half or products in any quantity that	more of the substance of the composite	product or not shelf stable dairy
				(a) have been produced in the country following:	The country of origin of the o	dairy products must be one of the
				— 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 Annex II to Decision 2007/777/EC, where the t export to the Union meat products treated with 	hird 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		05/2010 and the treatment applied
				(b) have been produced from milk obtained from anim	nals:	
				(i) under the control of the official veterinary serv	vice;	
				(ii) belonging to holdings which were not under re	estrictions due to foot-and-mouth disease	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 of
				(c) are dairy products made from raw milk obtained f	rom	
				(¹) either [cows, ewes, goats or buffaloes and prior t produced from raw milk which has undergo		n Union have undergone or been
					a single heat treatment with a heating s of at least 72 °C for 15 seconds and wh nosphatase test applied immediately after	ere applicable, sufficient to ensure

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. (See end of Document for details)

COUNTRY				Composite products intended for human consumption Transit/Storage			
н.	Health info	rmation				II.a. Certificate reference number	II.b.
		(1) or	[a ste	rilisation process, to achieve a	an F_0 value equal to or greater than three	a;]
		(1) or	[an ul	tra high temperature (UHT) trea	atment at not less than 135 °C in combinal	ion with a suitable holding time;
		(1) or	equiv		urisation treatment (HTST) at 72 °C for 15 plied to milk with a pH lower than 7,0 sphatase test];	
		(1) or	equiv	alent pasteurisation effect, app	urisation treatment (HTST) at 72 °C for 15 lied twice to milk with a pH equal to or g n alkaline phosphatase test, immediately	eater than 7,0 achieving, where
				(¹) either	[lowering the pH below 6 for	r one hour;]	
				(¹) or	[additional heating equal to a	or greater than 72 °C, combined with des	siccation;]]
		(1) or			er than cows, ewes, goats or b r been produced from raw mil	ouffaloes and prior to import into the territ k which has undergone	ory of the European Union have
		(1) eith	<i>her</i> [a ste	rilisation process, to achieve a	an F_0 value equal to or greater than three	ə:]
		((¹) or	[an u time;]		eatment at not less than 135 °C in com	bination with a suitable holding
		(d) were	e prod	luced on .	or I	between and	(4).]
and	/or [II.1.C	Process	ed eg	g product	s that originate from the appro	oved country (5)	
		(EC) No	853/2	2004 whic		ent which satisfies the requirements of Sec certificate is free from highly pathogeni	
		either					
	Ċ,) [II.1.C.1				here appropriate, the territory of a neight enza or Newcastle disease for at least th	
		or					
	Ċ.) [II.1.C.2	[the	egg prod	ucts were processed:		
		(*)	eithe	r [liquid	egg white was treated:		
			((¹) either	[with 55,6 °C for 870 second	ls.]	
			((¹) or	[with 56,7 °C for 232 second	ls.]	
		()	or	[10 %	salted yolk was treated with 6	2,2 °C for 138 seconds.]	
		(*)	or	[dried	egg white was treated:		
			((¹) either	[with 67 °C for 20 hours.]		
			((1) or	[with 54,4 °C for 513 hours.]		
		C)	or	[whole	eggs were at least treated:		
			((¹) either	[with 60 °C for 188 seconds.]	
			((1) 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	1	

COUNTRY	Composite products inte Transit/Storage	ended for human consumption					
II. Health information	II.a. Certificate reference number	II.b.					
Notes	1						
Part I:							
	— 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 Anr II, Part 2 to Decision 2007/777/EC and/or for processed dairy product in Annex I to Commission Regulation (EU) No 605/2010.						
 Box reference I.11: Name, address of the establishments of production the same as the country of origin in box I.7. 	n of the composite product(s). Name of the	e country of origin which must be					
Approval number is not applicable.							
 Box reference I.15: Registration number (railway wagons or container transport in containers, the total number of containers and their regis indicated in box I.23. In case of unloading and reloading, the consigned Union. 	stration number and where there is a seria	al number of the seal it must be					
 Box reference I.19: Use the appropriate Harmonised System (HS) cod 16.05; 19.01; 19.02; 19.05; 20.04; 20.05; 21.03; 21.04; 21.05; 21.06 		h as: 16.01; 16.02; 16.03; 16.04;					
- Box reference I.20: Indicate total gross weight and total net weight.							
- Box reference I.23: For containers or boxes, the container number a	nd the seal number (if applicable) must b	be included.					
 Box reference I.28: Manufacturing plant: insert the name and approva product(s). Nature of commodity: in case of composite products con "meat product", "treated stomachs", "bladders" or "intestines". In case 	taining meat products, treated stomachs,	bladders and intestines indicate					
Part II:							
(¹) Keep as appropriate.							
(²) Meat products as laid down in point 7.1 of Annex I to Regulation (EC) in point 7.9 of Annex I to Regulation (EC) No 853/2004 that have u 2007/777/EC.							
(³) Raw milk and dairy products means, raw milk and dairy products for No 853/2004.	human consumption as defined in point 7	2.2 of Annex I to Regulation (EC)					
(4) Date or dates of production. Imports of raw milk and dairy products s for exportation to the European Union of the third country or part t measures have been adopted by the European Union against impo-	thereof mentioned under I.7 and I.8, or c	luring a period where restrictive					
(⁵) Country of origin authorised to export to the EU.							
- The colour of the signature shall be different to that of the printing. The	he same rule applies to stamps other than	n those embossed or watermark.					
Official veterinarian/Official inspector							
Name (in capital letters):	Qualit	fication and title:					
Date:	Signa	ture:'					
Stamp:							

- (**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:

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