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 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.

(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;

b the documents accompanying the consignment and referred to in Article 7 of Directive 97/78/EC are stamped 'ONLY FOR TRANSIT TO RUSSIA VIA THE EU' on each page by the official veterinarian of the competent authority responsible for the border inspection post of introduction into the Union;

c the procedural requirements provided for in Article 11 of Directive 97/78/EC are complied with;

d the consignment is certified as acceptable for transit on the common veterinary entry document by the official veterinarian of the border inspection post of introduction into the Union.

2 Unloading or storage, as defined in Article 12(4) or in Article 13 of Directive 97/78/EC, of such consignments on Union territory shall not be allowed.

3 Regular audits shall be made by the competent authority to ensure that the number of consignments and the quantities of products leaving the Union territory matches the number and quantities entering the Union.

[F1 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;

b the documents accompanying the consignment and referred to in Article 7 of Directive 97/78/EC are stamped 'ONLY FOR TRANSIT TO THIRD COUNTRIES VIA THE EU' on each page by the official veterinarian at the border inspection post of entry;

c the procedural requirements provided for in Article 11 of Directive 97/78/EC are complied with;

d the consignment is certified as acceptable for transit on the Common Veterinary Entry Document referred to in Article 2(1) of Regulation (EC) No 136/2004 by the official veterinarian at the border inspection post of entry.

2 Unloading or storage, as defined in Article 12(4) or in Article 13 of Directive 97/78/EC, of such consignments in the Union shall not be allowed.

3 Regular audits shall be made by the competent authority to ensure that the number of consignments and the quantities of products leaving the Union matches the number and quantities entering the Union.**]**

Textual Amendments

F1 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.

[F2 ANNEX I

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

Textual Amendments

F2 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).

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor Name Address Tel.	I.2. Certificate reference No	I.2.a.
	I.3. Central competent authority	
	I.4. Local competent authority	
I.5. Consignee Name Address Postcode Tel.	I.6.	
I.7. Country of origin ISO code	I.8. Region of origin Code	I.9. Country of destination ISO code / I.10.
I.11. Place of origin Name Approval number Address Name Approval number Address Name Approval number Address	I.12.	
I.13. Place of loading	I.14. Date of departure	
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification Documentation references	I.16. Entry BIP in EU	
	I.17.	
I.18. Description of commodity	I.19. Commodity code (HS code)	
	I.20. Quantity	
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐	I.22. Number of packages	
I.23. Seal/Container No	I.24. Type of packaging	
I.25. Commodities certified for: Human consumption ☐		
I.26.	I.27. For import or admission into EU ☐	
I.28. Identification of the commodities Manufacturing plant / Number of packages / Nature of commodity / Net weight / Batch number		

COUNTRY **Composite products intended for human consumption**

Part II: Certification

II. **Health information**	II.a. Certificate reference No	II.b.

I, the undersigned official veterinarian/official inspector hereby certify that

II.1. 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;

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 requirements in 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 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.

(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 country of origin:

(1) (E.1) for imports from a country or a region with a negligible BSE risk as listed in Annex to Commission Decision 2007/453/EC as amended:

(1) the country or region is classified in accordance with Article 5(2) of Regulation (EC) No 999/2001 of the European Parliament and of the Council as a country or region posing a negligible BSE risk;

(2) the animals from which the products of bovine, ovine and caprine animal origin were derived were born, continuously reared and slaughtered in the country with negligible BSE risk and passed ante-mortem and post-mortem inspections;

(1) (3) if in the country or region there have been BSE indigenous cases:

(1) (a) the animals were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been enforced; or

(1) (b) the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in Annex V to Regulation (EC) No 999/2001, or mechanically separated meat obtained from bones of bovine, ovine or caprine animals.

COUNTRY **Composite products intended for human consumption**

II. **Health information**	II.a. Certificate reference No	II.b.

[1] (E.2) for imports from a country or a region with a controlled BSE risk as listed in the Annex to Commission Decision 2007/453/EC as amended:

(1) the country or region is classified in accordance with Article 5(2) of Regulation (EC) No 999/2001 as a country or region posing a controlled BSE risk;

(2) the animals from which the products of bovine, ovine and caprine animal origin were derived passed ante-mortem and post-mortem inspections;

(3) animals from which the products of bovine, ovine and caprine animal origin destined for export were derived have not been 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;

[1] [3] (4) the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in Annex V to Regulation (EC) No 999/2001, or mechanically separated meat obtained from bones of bovine, ovine or caprine animals;

[1] [4] (5) in the case of intestines originally sourced from a country or a region with a negligible BSE risk, imports of treated intestines shall be subject to the following conditions:

(a) the country or region is classified in accordance with Article 5(2) of Regulation (EC) No 999/2001 as a country or region posing a controlled BSE risk;

(b) the animals from which the products of bovine, ovine and caprine animal origin were derived were born, continuously reared and slaughtered in the country or region with a negligible BSE risk and 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:

[1] (i) the animals were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been enforced; or

[1] (ii) the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in Annex V to Regulation (EC) No 999/2001.

[1] (E.3) for imports from a country or a region with an undetermined BSE risk as listed in the Annex to Commission Decision 2007/453/EC:

(1) the animals from which the products of bovine, ovine and caprine animal origin were derived have not been fed meat-and-bone meal or greaves derived from ruminants and passed ante-mortem and post-mortem inspections;

(2) the animals from which the products of bovine, ovine and caprine animal origin were derived have not been 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;

[1] [5] (3) the products of bovine, ovine and caprine animal origin are not derived from:

(i) specified risk material as defined in Annex V to Regulation (EC) No 999/2001;

(ii) nervous and lymphatic tissues exposed during the deboning process;

(iii) 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 shall be subject to the following conditions:

(a) the country or region is classified in accordance with Article 5(2) of Regulation (EC) No 999/2001 as a country or region posing an undetermined BSE risk;

(b) the animals from which the products of bovine, ovine and caprine animal origin were derived were born, continuously reared and slaughtered in the country or region with a negligible BSE risk and passed ante-mortem and post-mortem inspections;

COUNTRY **Composite products intended for human consumption**

II. **Health information**	II.a. Certificate reference No	II.b.

(1) (c) if the intestines are sourced from a country or region where there have been BSE indigenous cases:

(1) (i) the animals were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been enforced; or

(1) (ii) the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in Annex V to Regulation (EC) No 999/2001.]

(1) *and/or* [II.2.B **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 country ..... in the establishment .....(approval number of the establishments of origin of the dairy products contained in the composite product authorised at the time of production for export of dairy products to the EU). The country of origin of the dairy products must be one of the following:

— 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 milk and dairy products in Column A or B of Annex I to Regulation (EU) No 605/2010, where the third country where the composite product is produced is also authorised, under the same conditions, to export to the Union milk and dairy products.

The country of origin indicated in box I.7 must be listed in Annex I to Regulation (EU) No 605/2010 and the treatment applied must be conform to the treatment provided for in that list for the relevant country;

(b) have been produced from milk obtained from animals:

(i) under the control of the official veterinary service;

(ii) belonging to holdings which were not under restrictions due to foot-and-mouth disease or rinderpest; and

(iii) subject to regular veterinary inspections to ensure that they satisfy the animal health conditions laid down in Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004 and in Directive 2002/99/EC;

(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;]

(1) *or* [a sterilisation process, to achieve an F_0 value equal to or greater than three;]

(1) *or* [an ultra high temperature (UHT) treatment at not less than 135 °C in combination with a suitable holding time;]

(1) *or* [a high temperature short time pasteurisation treatment (HTST) at 72 °C for 15 seconds, or a treatment with an equivalent pasteurisation effect, applied to milk with a pH lower than 7,0 achieving, where applicable, a negative reaction to an alkaline phosphatase test

(1) *or* [a high temperature short time pasteurisation treatment (HTST) at 72 °C for 15 seconds, or a treatment with an equivalent pasteurisation effect, applied twice to milk with a pH equal to or greater than 7,0 achieving, where applicable, a negative reaction to an alkaline phosphatase test, immediately followed by

(1) *either* [lowering the pH below 6 for one hour;]

(1) *or* [additional heating equal to or greater than 72 °C, combined with desiccation;]]

(1) *or* [animals other than 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

COUNTRY **Composite products intended for human consumption**

II. **Health information**	II.a. Certificate reference No	II.b.

(1) *either* [a sterilisation process, to achieve an F_0 value equal to or greater than three;]

(1) *or* [an ultra high temperature (UHT) treatment at not less than 135 °C in combination with a suitable holding time;]]

(d) were produced on ..... or between ..... and ..... (7).]

(1) *and/or* [II.2.C **Processed fishery products** that originate from the approved establishment No (8) ..... situated in the country (9) .....]

(1) *and/or* [II.2.D **Processed egg products** that originate from the approved country (9) .....]

were produced from eggs coming from an establishment which satisfies the requirements of Section X of Annex III to Regulation (EC) No 853/2004 which at the date of issue of the certificate is free from highly pathogenic avian influenza as defined in Regulation (EC) No 798/2008 and

either

(1) II.2.D.1 [within a 10 km radius of which [including, where appropriate, the territory of a neighbouring country,] there has been no outbreak of highly pathogenic avian influenza or Newcastle disease for at least the previous 30 days.]

or

(1) II.2.D.2 [the egg products were processed:

(1) *either* [liquid egg white was treated:

(1) *either* [with 55,6 °C for 870 seconds.]

(1) *or* [with 56,7 °C for 232 seconds.]

(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.]

(1) *or* [completely cooked.]

[whole egg blends were at least treated]:

(1) *either* [with 60 °C for 188 seconds.]

(1) *or* [with 61,1 °C for 94 seconds.]

Notes

Part I:

— Box reference I.7: Insert the ISO code of the country of origin of the composite product containing meat product, treated stomachs, bladders and intestines as listed in Annex II, Part 2 to Decision 2007/777/EC and/or for processed dairy products in Annex I to Commission Regulation (EU) No 605/2010 and/or for processed fishery products in Annex I and II to Commission Decision 2006/766/EC and/or for processed egg products in Annex I part 1 to Commission Regulation (EC) No 798/2008.

— Box reference I.11: Name, address and registration/approval number if available 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.

— 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.

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

COUNTRY **Composite products intended for human consumption**

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 included.

— 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". In case of composite product containing processed fishery products specify whether aquaculture or wild origin. In case of composite product containing egg products specify the egg content percentage.

Part II:

(1) Keep as appropriate.

(2) 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.

(3) By way of derogation from point 4, carcasses, half carcasses or half carcasses cut into no more than three wholesale cuts, and quarters containing no specified risk material other than the vertebral column, including dorsal root ganglia, may be imported.

When removal of the vertebral column is not required, carcasses or wholesale cuts of carcasses of bovine animals containing vertebral column shall be identified by a blue stripe on the label referred to in Regulation (EC) No 1760/2000.

The number of bovine carcasses or wholesale cuts of carcasses, from which removal of the vertebral column is required as well as the number where removal of the vertebral column is not required shall be added to the document referred to in Article 2(1) of Regulation (EC) No 136/2004 in case of imports.

(4) Only applicable to imports of treated intestines.

(5) By way of derogation from point 3, carcasses, half carcasses or half carcasses cut into no more than three wholesale cuts, and quarters containing no specified risk material other than the vertebral column, including dorsal root ganglia, may be imported.

When removal of the vertebral column is not required, carcasses or wholesale cuts of carcasses of bovine animals containing vertebral column shall be identified by a clearly visible blue stripe on the label referred to in Regulation (EC) No 1760/2000.

Specific information on the number of bovine carcasses or wholesale cuts of carcasses, from which removal of the vertebral column is required and from which removal of the vertebral column is not required shall be added to the document referred to in Article 2(1) of Regulation (EC) No 136/2004 in case of imports.

(6) Raw milk and dairy products means, raw milk and dairy products for human consumption as defined in point 7.2 of Annex I to Regulation (EC) No 853/2004.

(7) 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.

(8) Number of the fishery product establishment authorised to export to the EU.

(9) Country of origin authorised to export to the EU.

(10) In case of composite products containing only egg or fishery products the signature of an official Inspector can be accepted.

— 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 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:		

ANNEX II

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

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor Name Address Tel.	I.2. Certificate reference No / I.2.a. I.3. Central competent authority I.4. Local competent authority
I.5. Consignee Name Address Postcode Tel.	I.6. Person responsible for the load in EU Name Address Postcode Tel.
I.7. Country of origin ISO code / I.8. Region of origin Code	I.9. Country of destination ISO code / I.10.
I.11. Place of origin Name Approval number Address Name Approval number Address Name Approval number Address	I.12. Place of origin Custom warehouse ☐ Ship supplier ☐ Name Approval number Address Postcode
I.13. Place of loading	I.14. Date of departure
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification Documentation references	I.16. Entry BIP in EU I.17.
I.18. Description of commodity	I.19. Commodity code (HS code) I.20. Quantity
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐	I.22. Number of packages
I.23. Seal/Container No	I.24. Type of packaging
I.25. Commodities certified for: Human consumption ☐	
I.26. For transit through EU to third country ☐ Third country ISO code	I.27.
I.28. Identification of the commodities Manufacturing plant Number of packages Nature of commodity Net weight Batch number	

COUNTRY

Composite products intended for human consumption
Transit/Storage

Part II: Certification

II. **Health information**	II.a. Certificate reference No	II.b.

I, the undersigned official veterinarian/official inspector hereby certify that the composite products described above contain:

(1) either II.1.A Meat products, treated stomachs, bladders and intestines (2) in any quantity and such meat products, treated stomachs, bladders and intestines have been produced according to Commission Decision 2007/777/EC and contain the following meat constituents and meet the criteria indicated below:

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.

(1) and/or [II.1.B Processed dairy products (3) 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 country ..... The country of origin of the dairy products must be one of 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.

The country of origin indicated in box I.7 must be listed in Annex I to Regulation (EU) No 605/2010 and the treatment applied must be conform to the treatment provided for in that list for the relevant country;

(b) have been produced from milk obtained from animals:

(i) under the control of the official veterinary service;

(ii) belonging to holdings which were not under restrictions due to foot-and-mouth disease or rinderpest; and

(iii) subject to regular veterinary inspections to ensure that they satisfy the animal health conditions laid down in Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004 and in Directive 2002/99/EC;

(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;]

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_0 value equal to or greater than three;]

(1) *or* [an ultra high temperature (UHT) treatment at not less than 135 °C in combination with a suitable holding time;]

(1) *or* [a high temperature short time pasteurisation treatment (HTST) at 72 °C for 15 seconds, or a treatment with an equivalent pasteurisation effect, applied to milk with a pH lower than 7,0 achieving, where applicable, a negative reaction to an alkaline phosphatase test];

(1) *or* [a high temperature short time pasteurisation treatment (HTST) at 72 °C for 15 seconds, or a treatment with an equivalent pasteurisation effect, applied twice to milk with a pH equal to or greater than 7,0 achieving, where applicable, a negative reaction to an alkaline phosphatase test, immediately followed by

(1) *either* [lowering the pH below 6 for one hour;]

(1) *or* [additional heating equal to or greater than 72 °C, combined with desiccation;]]

(1) *or* [animals other than 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 sterilisation process, to achieve an F_0 value equal to or greater than three;]

(1) *or* [an ultra high temperature (UHT) treatment at not less than 135 °C in combination with a suitable holding time;]]

(d) were produced on ..... or between ..... and .....(4).]

and/or [II.1.C Processed egg products that originate from the approved country (5)

Were produced from eggs coming from an establishment which satisfies the requirements of Section X of Annex III to Regulation (EC) No 853/2004 which at the date of issue of the certificate is free from highly pathogenic avian influenza as defined in Regulation (EC) No 798/2008 and

either

(1) *[II.1.C.1 [within a 10 km radius of which [including, where appropriate, the territory of a neighbouring country,] there has been no outbreak of highly pathogenic avian influenza or Newcastle disease for at least the previous 30 days.]*

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 seconds.]

(1) *or* [with 56,7 °C for 232 seconds.]

(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.]

(1) *or* [completely cooked.]

[whole egg blends were at least treated]:

(1) *either* [with 60 °C for 188 seconds.]

(1) *or* [with 61,1 °C for 94 seconds.]

COUNTRY **Composite products intended for human consumption**
Transit/Storage

II. Health information	II.a. Certificate reference number	II.b.

Notes

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 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.

— 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.

— 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.

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

— Box reference I.23: For containers or boxes, the container number and the seal number (if applicable) must be included.

— 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".

Part II:

([1]) Keep as appropriate.

([2]) 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.

([3]) Raw milk and dairy products means, raw milk and dairy products for human consumption as defined in point 7.2 of Annex I to Regulation (EC) No 853/2004.

([4]) 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.

([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): Qualification and title:

Date: Signature:'

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:
Point in time view as at 01/07/2013.

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.