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)

ANNEX I

Model Health Certificate for import into 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.	
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 Documentary 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		

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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 regionalisation by Union legislation for the relevant meat constituents, the region as indicated in Part 1 of Annex II to Decision 2007/777/EC. The country of origin of the meat products must be the same as the country of export in box 1.7.

(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 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.

(1) (E.2) for imports from a country or a region with a controlled 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 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;

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(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 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;

(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

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(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 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 the same as the country of export in box 1.7).

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 is 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 at 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 a 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 a alkaline phosphatase test, immediately followed by

(1) either [lowering the pH below 6 for 1 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 .....(7).]

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

(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) .....]

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 1.7.

— 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: codes of the following headings: 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'. 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.

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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.

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 destination 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

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

Part II: Certification

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 regionalisation by Union legislation for the relevant meat constituents, the region as indicated in Part 1 of Annex II to Decision 2007/777/EC. The country of origin of the meat products must be the same as the country of export in box 1.7.]

(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) originate in the country indicated in box I.7 which is listed in Annex I to Regulation (EU) No 605/2010 and the treatment applied is conform to the treatment provided for in that list for the relevant country. The country of origin of the dairy products must be the same as the country of export in box 1.7;

(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 at 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 a 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 a alkaline phosphatase test, immediately followed by

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

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

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Transit/Storage

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

([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]).]

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 1.7. 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: codes of the following headings: 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.

— 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: