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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)

(OJ L 12, 14.1.2012, p. 1)

Amended by:

Official Journal

| | | No | page | date |
|-------------|---|-------|------|-----------|
| ► <u>M1</u> | Commission Implementing Regulation (EU) No 468/2012 of 1 June 2012 | L 144 | 1 | 5.6.2012 |
| ► <u>M2</u> | Commission Implementing Regulation (EU) No 556/2013 of 14 June 2013 | L 164 | 13 | 18.6.2013 |

COMMISSION REGULATION (EU) No 28/2012

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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:

Directive 97/78/EC provides that veterinary checks on products (1) 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.

⁽¹⁾ OJ L 24, 30.1.1998, p. 9.

^{(&}lt;sup>2</sup>) OJ L 18, 23.1.2003, p. 11.
(³) OJ L 139, 30.4.2004, p. 55.

^{(&}lt;sup>4</sup>) OJ L 139, 30.4.2004, p. 206.

⁽⁵⁾ OJ L 165, 30.4.2004, p. 1.

- (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 (¹) 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 (²) 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.

^{(&}lt;sup>1</sup>) OJ L 338, 22.12.2005, p. 83.
(²) OJ L 314, 1.12.2009, p. 10.

- (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 (¹) 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

^{(&}lt;sup>1</sup>) OJ L 116, 4.5.2007, p. 9.

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 (¹) and Commission Regulation (EU) No 605/2010 (²) 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 (³), 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 (⁴), 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;

⁽¹⁾ OJ L 312, 30.11.2007, p. 49.

⁽²⁾ OJ L 175, 10.7.2010, p. 1.

^{(&}lt;sup>3</sup>) OJ L 21, 28.1.2004, p. 11.

^{(&}lt;sup>4</sup>) OJ L 296, 12.11.2009, p. 1.

- (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.

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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.

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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 (*), shall be exempt from the obligation provided for in that Article.

(*) OJ L 12, 14.1.2012, p. 1.'

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.

ANNEX I

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

| cοι | NTR | Y | | | | | | | | | Veteri | nary certificate to EU |
|---|-------|-------------------------------|-------------------|--------------------------------------|----------------------------------|-------------------------|-----------------------|--------------|-------------|------------|-----------|------------------------|
| | l.1. | Consignor Name | | I.2. Certificate reference No I.2.a. | | | | | | | | |
| | | Address | | | I.3. Central competent authority | | | | | | | |
| | | Tel. | | | 1.4. | Local co | mpete | nt authority | , | | | |
| gnment | 1.5. | Consignee Name | 1.6. | | | | | | | | | |
| Part I: Details of dispatched consignment | | Address Postcode Tel. | | | | | | | | | | |
| dispatch | 1.7. | Country of origin | ISO code | I.8. Region of origin | Code | | Country destinatio | | ISO coo | le l | .10. | |
| ð | | | | | | | | | | | | |
| Details | 1.11. | Place of origin | | | | l.12. | | | | | | |
| Ξ | | Name Address | | Approval number | | | | | | | | |
| Ра | | Name Address | | | | | | | | | | |
| | | Name Address | | Approval number | | | | | | | | |
| | l.13. | Place of loading | | | | I.14. Date of departure | | | | | | |
| | l.15. | 5. Means of transport | | | | | Entry BIF | P in El | U | | | |
| | | Aeroplane 🗌 Road vehicle 🔲 | Ship [Other [| | | | | | | | | |
| | | Identification | - | | | l.17. | | | | | | |
| | l.18. | Description of con | | I.19. Commodity code (HS code) | | | | | | | | |
| | | | | | | | I | | | 1.20. | Quantity | |
| | I.21. | Temperature of pr | oduct | | | | | | | 1.22. | Number of | packages |
| | | Ambient 🔲 | | Chilled | | Froz | en 🗌 | | | | | |
| | 1.23. | Seal/Container No | 1 | | | | | | 1.24. | Type of pa | ckaging | |
| | 1.25. | Commodities certi | fied for: | | | | | | | | | |
| | | Human consumpti | on 🗖 | | | | | | | | | |
| | 1.26. | | | | | 1.27. | For impo | ort or a | admission i | nto EL | J | |
| | 1.28 | Identification of the | e commodities | 3 | | | | | | | | |
| | | Manufacturing plan | | umber of packages | | ature of | | | Net w | eight | | Batch number |
| | | | | | | | | | | | | |

| COUNTRY Composite products intended for human consu | | | | | | | | | | |
|---|--|---|--|---|---|--|--|--|--|--|
| | П. | Healt | h information | II.a. Certificate reference No | II.b. | | | | | |
| | | I, the | undersigned official veterinarian/official inspector her | eby certify that | | | | | | |
| Part II: Certification | | II.1. | I am aware of the relevant provisions of Regulation Article 6.1(b) on the origin of the products of animal certify that the composite products described above come from (an) establishment(s) implementing a pro 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 | | | | | |
| Part | | 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 requirement 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 mea bovine animals (<i>Bos taurus, Bison bison, Bubalu</i> (<i>Capra hircus</i>); EQI = domestic equine animals (<i>Sus scrofa</i>); RM = domestic rabbits, Pf animals other than suidae and solipeds; RUW = domestic suidae: EQW = wild non-domestic so | is bubalis and their crossbreds); OVI = dor Equus caballus, Equus asinus and their cri FG = domestic poultry and farmed feathere wild non-domestic animals other than suit | 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 trea 2007/777/EC. | tment as specified and defined in Parts 2 | 2, 3 and 4 of Annex II to Decision | | | | | |
| | | | (C) Insert the ISO code of the country of origin of the Part 2 to Decision 2007/777/EC and, in the cas region as indicated in Part 1 of Annex II to Dec origin of the meat products must be one the for | e of regionalization by Union legislation for ision 2007/777/EC or a Member State of t | the relevant meat constituents, the | | | | | |
| | | | - the same as the country of export in box 1.7 | , | | | | | | |
| | | | — a Member State of the European Union, | | | | | | | |
| | | | a third country or parts thereof authorised to II to Decision 2007/777/EC, where the third to the Union meat products treated with that | country where the composite product is pr | | | | | | |
| | | | (D) Insert EU approval number of the establishmer contained in the composite product. | ts of origin of the meat products, treated | stomachs, bladders and intestines | | | | | |
| | | | (E) If containing material from bovine, ovine or cap meat products and/or treated intestines shall be country of origin: | | | | | | | |
| | | | (¹) (E.1) for imports from a country or a region with as amended: | a negligible BSE risk as listed in Annex to | Commission Decision 2007/453/EC | | | | | |
| | | | the country or region is classified in a Parliament and of the Council as a co | ccordance with Article 5(2) of Regulation untry or region posing a negligible BSE rise | | | | | | |
| | | | (2) the animals from which the products of reared and slaughtered in the country w | bovine, ovine and caprine animal origin w ith negligible BSE risk and passed ante-m | | | | | | |
| | | | $(^{1})$ (3) if in the country or region there have b | peen BSE indigenous cases: | | | | | | |
| | | | (¹) (a) the animals were born after the da and greaves derived from ruminan | | uminants with meat-and-bone meal | | | | | |
| | | | (¹) (b) the products of bovine, ovine and material as defined in Annex V to bones of bovine, ovine or caprine | Regulation (EC) No 999/2001, or mechani | | | | | | |

| COUNTR | RΥ | | Composite products i | ntended for human consumptior |
|--------|---------------------------------------|--|--|--------------------------------------|
| II. | Health informatio | on | II.a. Certificate reference No | II.b. |
| | | r imports from a country or a region wit 007/453/EC as amended: | th a controlled BSE risk as listed in th | e Annex to Commission Decision |
| | (1) |) the country or region is classified in acc region posing a controlled BSE risk; | cordance with Article 5(2) of Regulation (| EC) No 999/2001 as a country or |
| | (2) |) the animals from which the products of and post-mortem inspections; | bovine, ovine and caprine animal origin | were derived passed ante-mortem |
| | (3) | | ne, ovine and caprine animal origin destine ans of gas injected into the cranial cavity of central nervous tissue by means of ar | or killed by the same method or |
| | (¹) (³) (4) |) the products of bovine, ovine and caprine as defined in Annex V to Regulation (E bovine, ovine or caprine animals; | e animal origin do not contain and are not C) No 999/2001, or mechanically separa | |
| | (¹) (⁴) (5) |) in the case of intestines originally source intestines shall be subject to the following | | ligible BSE risk, imports of treated |
| | | (a) the country or region is classified in a region posing a controlled BSE risk; | accordance with Article 5(2) of Regulation | (EC) No 999/2001 as a country or |
| | | | cts of bovine, ovine and caprine anima d in the country or region with a negli s; | |
| | Ċ, |) (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 data and greaves derived from ruminal | ate from which the ban on the feeding of r ants had been enforced; or | uminants with meat-and-bone meal |
| | | (¹) (ii) the products of bovine, ovine and material as defined in Annex V to | l caprine animal origin do not contain and o Regulation (EC) No 999/2001. | are not derived from specified risk |
| | | r imports from a country or a region with 007/453/EC: | an undetermined BSE risk as listed in th | ne Annex to Commission Decision |
| | (1) |) the animals from which the products of b and-bone meal or greaves derived from | ovine, ovine and caprine animal origin we ruminants and passed ante-mortem and | |
| | (2) | | of bovine, ovine and caprine animal or of gas injected into the cranial cavity of of central nervous tissue by means of ar | or killed by the same method or |
| | (¹) (⁵) (3) |) the products of bovine, ovine and caprir | ne animal origin are not derived from: | |
| | | (i) specified risk material as defined in | Annex V to Regulation (EC) No 999/200 | 1; |
| | | (ii) nervous and lymphatic tissues expo | sed during the deboning process; | |
| | | (iii) mechanically separated meat obtain | ed from bones of bovine, ovine or caprin | e animals; |
| | (1) (4) (4) |) in the case of intestines originally source intestines shall be subject to the followir | | ligible BSE risk, imports of treated |
| | | (a) the country or region is classified in a region posing an undetermined BSE | accordance with Article 5(2) of Regulation risk; | (EC) No 999/2001 as a country or |
| | | | cts of bovine, ovine and caprine anima d in the country or region with a negli s; | |

| COUNTRY | Composite products intended for human consumptio |
|---------------------------------|---|
| II. Health | II.a. Certificate reference No II.b. |
| | (⁷) (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 meand 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 ris 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 dair products in any quantity that: |
| | (a) have been produced in the country |
| | — 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 sam 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 applie 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 bee 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 the achieved by a pasteurisation process of at least 72 °C for 15 seconds and where applicable, sufficient t 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 a equivalent pasteurisation effect, applied to milk with a pH lower than 7,0 achieving, where applicable, 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 a equivalent pasteurisation effect, applied twice to milk with a pH equal to or greater than 7,0 achieving, wher 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 hav undergone or been produced from raw milk which has undergone |

| COUNTRY | ' | | | | | Composite produ | icts intended for h | uman consumption |
|-------------------------|---------|----------|----------|-----------------------|---------------------------------|---|----------------------|------------------------|
| П. | Health | informa | tion | | | II.a. Certificate reference No | II.b. | |
| | | Ċ |) eithe | r [a ster | ilisation process, to achieve a | an F_0 value equal to or greater than | three;] | |
| | | Ċ |) or | [an ult | ra high temperature (UHT) tre | atment at not less than 135 °C in co | mbination with a sui | itable holding time;]] |
| | | | | | | or between | | |
| (¹) and/or | [II.2.C | | | | oducts that originate from the | e approved establishment No (⁸) | | situated |
| (¹) and/or | [II.2.D | Proces | sed eg | g prod | ucts that originate from the a | pproved country (⁹) |] | |
| | | (EC) N | o 853/2 | 2004 wł | | ment which satisfies the requirement the certificate is free from highly pa | | |
| | | either | | | | | | |
| | (') | II.2.D.1 | | | | where appropriate, the territory of a n iza or Newcastle disease for at leas | | |
| | | or | | | | | | |
| | (†) | II.2.D.2 | [the e | egg proc | ucts were processed: | | | |
| | | Ċ |) either | [liquio | d egg white was treated: | | | |
| | | | (| 1) eithe | r [with 55,6 °C for 870 secon | ds.] | | |
| | | | (| 1) or | [with 56,7 °C for 232 secon | ds.] | | |
| | | Ċ, |) or | [10 % | salted yolk was treated with | 1 62,2 °C for 138 seconds.] | | |
| | | Ċ, |) or | [driec | l egg white was treated: | | | |
| | | | (| 1) eithei | [with 67 °C for 20 hours.] | | | |
| | | | (| 1) or | [with 54,4 °C for 513 hours. |] | | |
| | | Ċ |) or | [whol | e eggs were at least treated: | | | |
| | | | (| ¹) eithei | [with 60 °C for 188 seconds | s.] | | |
| | | | (| 1) or | [completely cooked.] | | | |
| | | | | [whol | e egg blends were at least tr | eated]: | | |
| | | | (| ¹) eithe | r [with 60 °C for 188 seconds | s.] | | |
| | | | (| 1) or | [with 61,1 °C for 94 second | s.] | | |

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 inte | nded for human consumption | | | | | | | |
|---|---|----------------------------------|--|--|--|--|--|--|--|
| II. Health information | II.a. Certificate reference No | ll.b. | | | | | | | |
| - Box reference I.23: For containers or boxes, the container number | - Box reference I.23: For containers or boxes, the container number and the seal number (if applicable) must be included. | | | | | | | | |
| - Box reference I.28: <i>Manufacturing plant</i> : 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 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 (E in point 7.9 of Annex I to Regulation (EC) No 853/2004 that have 2007/777/EC. | | | | | | | | | |
| (³) By way of derogation from point 4, carcasses, half carcasses or containing no specified risk material other than the vertebral colur | | | | | | | | | |
| When removal of the vertebral column is not required, carcasses o shall be identified by a blue stripe on the label referred to in Reg | | nals containing vertebral column | | | | | | | |
| The number of bovine carcasses or wholesale cuts of carcasses, fi where removal of the vertebral column is not required shall be adde in case of imports. | | | | | | | | | |
| (⁴) Only applicable to imports of treated intestines. | | | | | | | | | |
| (⁵) By way of derogation from point 3, carcasses, half carcasses or containing no specified risk material other than the vertebral colur | | | | | | | | | |
| When removal of the vertebral column is not required, carcasses o shall be identified by a clearly visible blue stripe on the label refe | | nals containing vertebral column | | | | | | | |
| Specific information on the number of bovine carcasses or wholesa and from which removal of the vertebral column is not required sha 136/2004 in case of imports. | | | | | | | | | |
| (⁶) Raw milk and dairy products means, raw milk and dairy products for No 853/2004. | or human consumption as defined in point 7. | 2 of Annex I to Regulation (EC) | | | | | | | |
| (⁷) Date or dates of production. Imports of raw milk and dairy products for exportation to the European Union of the third country or par measures have been adopted by the European Union against important. | t 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 | to the EU. | | | | | | | | |
| (⁹) Country of origin authorised to export to the EU. | | | | | | | | | |
| (¹⁰) In case of composite products containing only egg or fishery prod | lucts the signature of an official Inspector ca | an 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 product | Composite products intended for human consumption | | | | |
|---|--------------------------------|---|--|--|--|--|
| II. Health information | II.a. Certificate reference No | II.b. | | | | |
| Official veterinarian/Official inspector (10) | | | | | | |
| Name (in capital letters): | Qualification and title: | 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 | | | | | | | | | |
|------------------------|----------------------------------|---|---|--|--|--|--|--|--|--|
| | l.1. | Consignor Name | I.2. Certificate reference No I.2.a. | | | | | | | |
| | | Address | I.3. Central competent authority | | | | | | | |
| | | Tel. | I.4. Local competent authority | | | | | | | |
| dispatched consignment | 1.5. | Consignee Name Address Postcode Tel. | I.6. Person responsible for the load in EU Name Address Postcode Tel. | | | | | | | |
| of dispate | 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 | I.12. Place of origin | | | | | | | |
| Part I: Details | | Name Approval number Address | Custom warehouse D Ship supplier D | | | | | | | |
| ۵. | | Name Approval number Address | Name Approval number Address | | | | | | | |
| | | Name Approval number Address | Postcode | | | | | | | |
| | l.13. | Place of loading | I.14. Date of departure | | | | | | | |
| | l.15. | Means of transport | I.16. Entry BIP in EU | | | | | | | |
| | | Aeroplane A Ship Railway wagon Road vehicle Other | 1.17. | | | | | | | |
| | | Identification Documentation references | 1.17. | | | | | | | |
| | 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 | | | | | | | | |
| | I.28. | Identification of the commodities | | | | | | | | |
| | | | ure of Net weight Batch number modity | | | | | | | |
| | | | | | | | | | | |

| co | UNI | ſRY | | | Composite products intended for human consumption Transit/Storage | | | | | | |
|------------------------|-----|---|----------------------|--|---|---|--|--|--|--|--|
| | II. | | Healt | h information | II.a. Certificate reference No | II.b. | | | | | |
| | | | I, the | undersigned official veterinarian/official inspector here | by certify that the composite products de | scribed above contain: | | | | | |
| Part II: Certification | (') | either | ll.1.A | Meat products, treated stomachs, bladders and intesti and intestines have been produced according to Corr and meet the criteria indicated below: | | | | | | | |
| t II: Cert | | | | Species (A) | Treatment (B) | Origin (C) | | | | | |
| Par | | | | (A) Insert the code for the relevant species of meat bovine animals (<i>Bos taurus, Bison bison, Bubalus</i> (<i>Capra hircus</i>); EQI = domestic equine animals (<i>E</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 quus caballus, Equus asinus and their cro G = domestic poultry and farmed feathered wild non-domestic animals other than suid | nestic sheep (<i>Ovis aries</i>) and goats ssbreds), POR = domestic porcine d 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. | nent 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 r 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 second s | of regionalization by Union legislation for sion 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 export to the Union meat products treated with | third 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 | r more of the substance of the composite | e 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 export to the Union meat products treated with | third country where the composite produc | | | | | | |
| | | | | The country of origin indicated in box I.7 must be must be conform to the treatment provided for in | | 05/2010 and the treatment applied | | | | | |
| | | | | (b) have been produced from milk obtained from ani | mals: | | | | | | |
| | | | | (i) under the control of the official veterinary ser | vice; | | | | | | |
| | | | | (ii) belonging to holdings which were not under r | restrictions due to foot-and-mouth disease | e or rinderpest; and | | | | | |
| | | subject to regular veterinary inspections to ensure that they satisfy the animal health conditions laid down in Chapter 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 produced from raw milk which has undergo | | an Union have undergone or been | | | | | |
| | | | | | g a single heat treatment with a heating ss of at least 72 °C for 15 seconds and wh shosphatase test applied immediately afte | nere applicable, sufficient to ensure | | | | | |

cou

н.

| COUNTRY | | | | | | Composite products inte Transit/Storage | nded for human consumption |
|---------|-------------|---------------------|----------|-----------------|--|---|------------------------------------|
| ۱۱. | Health info | rmation | | | | II.a. Certificate reference number | II.b. |
| | | († |) or | [a ste | rilisation process, to achieve a | an F ₀ value equal to or greater than three | »;] |
| | | Ċ |) or | [an ul | tra high temperature (UHT) trea | atment at not less than 135 °C in combinat | 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 psphatase test]; | |
| | | († | ') or | equiv | alent pasteurisation effect, app | urisation treatment (HTST) at 72 °C for 15 lied twice to milk with a pH equal to or gr n alkaline phosphatase test, immediately | eater than 7,0 achieving, where |
| | | | Ċ, | either | [lowering the pH below 6 for | r one hour;] | |
| | | | Ċ) | or | additional heating equal to a | or greater than 72 °C, combined with des | iccation;]] |
| | | (¹) or | | | er than cows, ewes, goats or b r been produced from raw mil | ouffaloes and prior to import into the territo k which has undergone | ory of the European Union have |
| | | C |) either | [a ste | rilisation process, to achieve a | an F_0 value equal to or greater than three | ə;] |
| | | Ċ | ') or | [an u time;] | | reatment at not less than 135 °C in com | bination with a suitable holding |
| | | (d) were | produc | ed on . | or I | between and | (4).] |
| and/c | or [II.1.C | Processe | ed egg p | roduct | s that originate from the appro | oved country (⁵) | |
| | | (EC) No | 853/200 | 04 whic | | ent which satisfies the requirements of Sec e certificate is free from highly pathogeni | |
| | | either | | | | | |
| | (†) | [II.1.C.1 | | | | here appropriate, the territory of a neighb enza or Newcastle disease for at least th | |
| | | or | | | | | |
| | () | [II.1.C.2 | [the eg | g prodi | ucts were processed: | | |
| | | (†) | either | [liquid | egg white was treated: | | |
| | | | (†) | 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 | 62,2 °C for 138 seconds.] | |
| | | (†) | or | [dried | egg white was treated: | | |
| | | | (1) | either | [with 67 °C for 20 hours.] | | |
| | | | (†) | or | [with 54,4 °C for 513 hours.] | | |
| | | (*) | or | [whole | eggs were at least treated: | | |
| | | | (†) | 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. |] | |
| | | | (†) | or | [with 61,1 °C for 94 seconds | 3.] | |

| COUNTRY Composite products intended for human consu 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 the same as the country of origin in box I.7. | 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. | | | | | | | | |
| transport in containers, the total number of containers and their regis | — 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) cod 16.05; 19.01; 19.02; 19.05; 20.04; 20.05; 21.03; 21.04; 21.05; 21.06. | | n 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 | e included. | | | | | | |
| Box reference I.28: Manufacturing plant: insert the name and approva product(s). Nature of commodity: in case of composite products cont "meat product", "treated stomachs", "bladders" or "intestines". In case | aining 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 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 import | hereof mentioned under I.7 and I.8, or d | uring 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 transmission ${\sf T}$ | ne same rule applies to stamps other than | those embossed or watermark. | | | | | | |
| Official veterinarian/Official inspector | | | | | | | | |
| Name (in capital letters): | Qualif | ication and title: | | | | | | |
| Date: | Signa | ture: | | | | | | |
| Stamp: | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |