Commission Implementing Regulation (EU) No 914/2011 of 13 September 2011 amending Regulation (EU) No 605/2010 laying down animal and public health and veterinary certification conditions for the introduction into the European Union of raw milk and dairy products intended for human consumption (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 914/2011

of 13 September 2011

amending Regulation (EU) No 605/2010 laying down animal and public health and veterinary certification conditions for the introduction into the European Union of raw milk and dairy products intended for human consumption

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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[(1)], and in particular the introductory phrase and point (b) of Article 9(4) thereof,

Whereas:

(1) Regulation (EU) No 605/2010 of 2 July 2010[(2)] laying down animal and public health and veterinary certification conditions for the introduction into the European Union of raw milk and dairy products intended for human consumption provides that consignments of raw milk and dairy products intended for human consumption, authorised for importation into the Union, are to be accompanied by a health certificate drawn up in accordance with the appropriate model set out in Part 2 of Annex II thereto for the commodity concerned ('the model health certificates').

(2) It should be clarified that the requirement regarding the use of the model health certificates provided for in that Regulation is without prejudice to specific certification requirements laid down in other Union acts or in agreements concluded by the Union with third countries.

(3) The model health certificates specify the commodity code for the commodities covered by Regulation (EU) No 605/2010 on the basis of the Harmonised Commodity Description and Coding System ('HS codes') of tariff nomenclature maintained by the World Customs Organization (WCO).

(4) Certain dairy products covered by Regulation (EU) No 605/2010 do not fall within the commodity codes in the model health certificates. In order to allow a more precise identification of those commodities in the model health certificates, it is necessary to amend those models and add the missing HS codes, in particular as regards HS codes 35.01 and 35.02 (casein, caseinates and albumines).

(5) In addition, it should be clarified in the model health certificates that the requirements regarding antibiotic residues, contaminants and pesticide residues may be based on the findings of official monitoring programmes which are at least equivalent to those provided for in Union legislation.

(6) For reasons of clarity and transparency of Union legislation, the model health certificates should be replaced by the model health certificates set out in the Annex to this Regulation.

(7) Regulation (EU) No 605/2010 should therefore be amended accordingly.

(8) 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

Regulation (EU) No 605/2010 is amended as follows:

(1) In Article 1, the following second paragraph is added:

> This Regulation shall apply without prejudice to any specific certification requirements laid down in other Union acts or in agreements concluded by the Union with third countries.

(2) Annex II is amended in accordance with the Annex to this Regulation.

Article 2

For a transitional period until 30 November 2011, consignments of raw milk and dairy products for which the relevant health certificates have been issued in accordance with Regulation (EU) No 605/2010 before the entry into force of this Regulation may continue to be introduced into the Union.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*

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

Done at Brussels, 13 September 2011.

For the Commission

The President

José Manuel BARROSO

ANNEX

In Annex II, parts 2 and 3 to Regulation (EU) No 605/2010 are replaced by the following:

PART 2 Model Milk-RMHealth Certificate for raw milk from third countries or parts thereof authorised in column A of Annex I to Regulation (EU) No 605/2010 intended for further processing in the European Union before being used for human consumption

Model Milk-RMP **Health Certificate for dairy products derived from raw milk for human consumption from third countries or parts thereof authorised in column A of Annex I to Regulation (EU) No 605/2010 intended for importation into the European Union**

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		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	Species (Scientific name)	Net weight	Batch number

Model Milk-RMP

COUNTRY **Dairy products derived from raw milk for human consumption**

Part II: Certification

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

II.1. Animal Health Attestation

I, the undersigned official veterinarian, declare that I am aware of the relevant provisions of Directive 2002/99/EC and of Regulation (EC) No 853/2004 and hereby certify that the dairy products described above has been manufactured from raw milk obtained from animals:

(a) under the control of the official veterinary service,

(b) which were in a country or part thereof that has been free of foot-and-mouth disease and of rinderpest for a period of at least 12 months prior to the date of this certificate, and where vaccination against foot-and-mouth disease has not been carried out during that period,

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

(d) 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;

II.2. Public Health attestation

I, the undersigned official inspector, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004 and hereby certify that the dairy product made with raw milk described above was produced in accordance with those provisions, in particular that:

(a) it was manufactured from raw milk:

(i) which comes from holdings registered in accordance with Regulation (EC) No 852/2004 and checked in accordance with Annex IV to Regulation (EC) No 854/2004,

(ii) which was produced, collected, cooled, stored and transported in accordance with the hygiene conditions laid down in Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004,

(iii) which meets the plate and somatic cell count criteria laid down in Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004,

(iv) which complies with the guarantees on the residues status of raw milk provided by the monitoring plans for the detection of residues or substances submitted in accordance with Council Directive 96/23/EC, and in particular, Article 29 thereof,

(v) which, pursuant to testing for residues of antibacterial drugs carried out by the food business operator in accordance with the requirements of Annex III, Section IX, Chapter I, Part III, point 4 of Regulation (EC) No 853/2004, it complies with the maximum residue limits for residues of antibacterial veterinary medicinal products laid down in the Annex to Regulation (EU) No 37/2010;

(vi) which has been produced under conditions guaranteeing compliance with the maximum residue levels for pesticides laid down in Regulation (EC) No 396/2005, and maximum levels for contaminants laid down in Regulation (EC) No 1881/2006.

(b) it comes from an establishment implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004,

(c) it has been obtained from raw milk that has not undergone any heat treatment or any physical or chemical treatment during the manufacturing process,

(d) it has been wrapped, packaged and labeled in accordance with Chapters III and IV of Section IX of Annex III to Regulation (EC) No 853/2004,

(e) it meets the relevant microbiological criteria laid down in Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs, and

(f) the guarantees covering live animals and products thereof provided by the residue plans submitted in accordance with Directive 96/23/EC, and in particular Article 29 thereof, are fulfilled.

Model Milk-RMP

COUNTRY **Dairy products derived from raw milk for human consumption**

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

Notes

This certificate is intended for dairy products derived from raw milk for human consumption, from third countries or parts thereof authorised in column A of Annex I to Regulation (EU) No 605/2010 intended for importation into the European Union.

Part I:

— Box reference I.7: Provide name and ISO code of the country or part thereof as appearing in Annex I to Regulation (EU) No 605/2010.

— Box reference I.11: Name, address and approval number of the establishment of dispatch.

— 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 the 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 under the following headings: 04.01; 04.02; 04.03; 04.04; 04.05; 04.06; 17.02; 21.05; 22.02; 35.01; 35.02 or 35.04.

— 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) should be included.

— Box reference I.28: Manufacturing plant: introduce the approval number of the production holding(s), collection centre or standardization centre approved for exportation to the European Union.

Part II:

— 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

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

Model Milk-HTB **Health Certificate for dairy products derived from milk of cows, ewes, goats and buffaloes for human consumption from third countries or parts thereof authorised in column B of Annex I to Regulation (EU) No 605/2010 intended for importation into the European Union**

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 Address Approval number		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	Species (Scientific name)	Net weight	Batch number

Model Milk-HTB

COUNTRY

Dairy products derived from milk of cows, ewes, goats and buffaloes for human consumption from third countries authorised in column B

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

Part II: Certification

II.1. Animal Health Attestation

I, the undersigned official veterinarian, declare that I am aware of the relevant provisions of Directive 2002/99/EC and of Regulation (EC) No 853/2004 and hereby certify that the dairy product described above:

(a) has been obtained from animals:

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

(ii) which were in a country or part thereof that has been free of foot-and-mouth disease and of rinderpest for a period of at least 12 months prior to the date of this certificate, and where vaccination against foot-and-mouth disease has not been carried out during that period,

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

(iv) 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,

(b) has undergone or been produced from raw milk which has been submitted to 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.

II.2. Public Health attestation

I, the undersigned official veterinarian, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004 and hereby certify that the dairy product described above was produced in accordance with those provisions, in particular that:

(a) it was manufactured from raw milk:

(i) which comes from holdings registered in accordance with Regulation (EC) No 852/2004 and checked in accordance with Annex IV to Regulation (EC) No 854/2004,

(ii) which was produced, collected, cooled, stored and transported in accordance with the hygiene conditions laid down in Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004,

(iii) which meets the plate and somatic cell count criteria laid down in Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004,

(iv) which complies with the guarantees on the residues status of raw milk provided by the monitoring plans for the detection of residues or substances submitted in accordance with Council Directive 96/23/EC, and in particular, Article 29 thereof,

(v) which, pursuant to testing for residues of antibacterial drugs carried out by the food business operator in accordance with the requirements of Annex III, Section IX, Chapter I, Part III, point 4 of Regulation (EC) No 853/2004, it complies with the maximum residue limits for residues of antibacterial veterinary medicinal products laid down in the Annex to Regulation (EU) No 37/2010,

(vi) which has been produced under conditions guaranteeing compliance with the maximum residue levels for pesticides laid down in Regulation (EC) No 396/2005, and maximum levels for contaminants laid down in Regulation (EC) No 1881/2006.

(b) it comes from an establishment implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004,

(c) it has been processed, stored, wrapped, packaged and transported in accordance with the relevant hygiene conditions laid down in Annex II to Regulation (EC) No 852/2004 and Chapter II of Section IX of Annex III to Regulation (EC) No 853/2004,

(d) it meets the relevant criteria laid down in Chapter II of Section IX of Annex III to Regulation (EC) No 853/2004 and the relevant microbiological criteria laid down in Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs,

(e) the guarantees covering live animals and products thereof provided by the residue plans submitted in accordance with Directive 96/23/EC, and in particular Article 29 thereof, are fulfilled.

Model Milk-HTB

COUNTRY

Dairy products derived from milk of cows, ewes, goats and buffaloes for human consumption from third countries authorised in column B

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

Notes

This certificate is intended for dairy products for human consumption from third countries or parts thereof authorised in column B of Annex I of Regulation (EU) No 605/2010 intended for importation into the European Union.

Part I:

— Box reference I.7: Provide name and ISO code of the country or part thereof as appearing in Annex I to Regulation (EU) No 605/2010.

— Box reference I.11: Name, address and approval number of the establishment of dispatch.

— 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 the 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 under the following headings: 04.01; 04.02; 04.03; 04.04; 04.05; 04.06; 17.02; 21.05; 22.02; 35.01; 35.02 or 35.04.

— 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) should be included.

— Box reference I.28: Manufacturing plant: introduce the approval number of the treatment and/or processing establishment(s) approved for export to the European Union.

Part II:

— 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

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

Model Milk-HTC **Health Certificate for dairy products for human consumption from third countries or parts thereof authorised in column C of Annex I to Regulation (EU) No 605/2010 intended for importation into the European Union**

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 Address Approval number		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	Species (Scientific name)	Net weight	Batch number

Model Milk-HTC

COUNTRY **Dairy products from third countries authorised in column C**

Part II: Certification

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

II.1. Animal Health Attestation

I, the undersigned official veterinarian, declare that I am aware of the relevant provisions of Directive 2002/99/EC and of Regulation (EC) No 853/2004 and hereby certify that the dairy product described above:

(a) has been 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,

(1) either [(b) in the case of dairy products made from raw milk sourced from cows, ewes, goats or buffaloes have undergone, prior to import into the territory of the European Union:

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

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

(1) or [(iii) a high temperature short time pasteurisation treatment (HTST) at 72°C for 15 seconds 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, applied immediately after the heat treatment;]

(1) or [(iv) a treatment with an equivalent pasteurisation effect to point (iii) achieving, where applicable, a negative reaction to a alkaline phosphatase test, applied immediately after the heat treatment;]

(1) or [(v) a HTST treatment with a pH below 7.0;]

(1) or [[(vi) a HTST treatment combined with another physical treatment by

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

(1) or [(vi) (2) additional heating equal to or greater than 72 °C or more, combined with desiccation;]]

(1) or [(b) in the case of dairy products made from raw milk sourced from animals other than cows, ewes, goats or buffaloes have undergone, prior to import into the territory of the European Union:

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

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

II.2. Public Health attestation

I, the undersigned official veterinarian, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004 and hereby certify that the dairy product described above was produced in accordance with provisions, in particular that:

(a) it was manufactured from raw milk:

(i) which comes from holdings registered in accordance with Regulation (EC) No 852/2004 and checked in accordance with Annex IV to Regulation (EC) No 854/2004;

(ii) which was produced, collected, cooled, stored and transported in accordance with the hygiene conditions laid down in Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004;

(iii) which meets the plate and somatic cell count criteria laid down in Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004;

(iv) which complies with the guarantees on the residues status of raw milk provided by the monitoring plans for the detection of residues or substances submitted in accordance with Council Directive 96/23/EC, and in particular, Article 29 thereof;

(v) which, pursuant to testing for residues of antibacterial drugs carried out by the food business operator in accordance with the requirements of Annex III, Section IX, Chapter I, Part III, point 4 of Regulation (EC) No 853/2004, it complies with the maximum residue limits for residues of antibacterial veterinary medicinal products laid down in the Annex to Regulation (EU) No 37/2010;

Model Milk-HTC

COUNTRY **Dairy products from third countries authorised in column C**

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

(vi) which has been produced under conditions guaranteeing compliance with the maximum residue levels for pesticides laid down in Regulation (EC) No 396/2005, and maximum levels for contaminants laid down in Regulation (EC) No 1881/2006.

(b) it comes from an establishment implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004,

(c) it has been processed, stored, wrapped, packaged and transported in accordance with the relevant hygiene conditions laid down in Annex II to Regulation (EC) No 852/2004 and Chapter II of Section IX of Annex III to Regulation (EC) No 853/2004,

(d) it meets the relevant criteria laid down in Chapter II of Section IX of Annex III to Regulation (EC) No 853/2004 and the relevant microbiological criteria laid down in Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs,

(e) the guarantees covering live animals and products thereof provided by the residue plans submitted in accordance with Directive 96/23/EC, and in particular Article 29 thereof, are fulfilled.

Notes

This certificate is intended for dairy products for human consumption from third countries or parts thereof authorised in column C of Annex I to Regulation (EU) No 605/2010 intended for importation into the European Union.

Part I:

— Box reference I.7: Provide name and ISO code of the country or part thereof as appearing in Annex I to Regulation (EU) No 605/2010.

— Box reference I.11: Name, address and approval number of the establishment of dispatch.

— Box reference I.15: Registration number (railway wagons or container and road vehicles), flight number (aircraft) or name (ship) is to be provided. 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 the 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 under the following headings: 04.01; 04.02; 04.03; 04.04; 04.05; 04.06; 17.02; 19.01; 21.05; 21.06.90.98; 22.02; 35.01; 35.02 or 35.04.

— 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) should be included.

— Box reference I.28: Manufacturing plant: introduce the approval number of the treatment and/or processing establishment(s) approved for export to the European Union.

Part II:

(1) Keep as appropriate.

— 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

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

PART 3 Model Milk-T/SAnimal Health Certificate for raw milk or dairy products for human consumption, for [transit] / [storage] (1) (2) in the European Union

(**1**) OJ L 18, 23.1.2003, p. 11.

(**2**) OJ L 175, 10.7.2010, p. 1.

Changes to legislation:
Commission Implementing Regulation (EU) No 914/2011 is up to date with all changes known to be in force on or before 31 August 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

– Regulation implicit repeal by EUR 2020/692 Regulation