COMMISSION IMPLEMENTING REGULATION (EU) No 300/2013

of 27 March 2013

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 of Article 8, the first subparagraph of point (1) and point (4) of Article 8 and Article 9(4) thereof,

Having regard to Regulation (EC) No 854/2004 of the European Parliament and of 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 [2], and in particular Article 11(1) thereof,

Whereas:

(1) Commission Regulation (EU) No 605/2010 [3] lays down the public and animal health conditions and certification requirements for the introduction into the Union of consignments of raw milk and dairy products and the list of third countries from which the introduction into the Union of such consignments is authorised.

(2) Annex I to Regulation (EU) No 605/2010 sets out a list of third countries or parts thereof authorised for the introduction into the Union of consignments of raw milk and dairy products and indicates the type of heat treatment required for such commodities. Article 4 of Regulation (EU) No 605/2010 provides that Member States are to authorise the importation of consignments of dairy products derived from raw milk of cows, ewes, goats or buffaloes from the third countries or parts thereof at risk of foot-and-mouth disease, which are listed in column C of Annex I to that Regulation, provided that such dairy products have undergone, or been produced from raw milk which has undergone, a heat treatment as referred to in that Article.

(3) The risk arising from imports into the Union of dairy products produced from raw milk of camels of the species *Camelus dromedarius* (dromedary camels) from third countries or parts thereof at risk of foot-and-mouth disease listed in column C of Annex I to Regulation (EU) No 605/2010 is not greater than from imports of dairy products derived from raw milk of cows, ewes, goats or buffaloes, provided that such dairy products have undergone, or been produced from raw milk which has undergone, the heat treatments referred to in Article 4 of that Regulation. Accordingly, that Article should be amended to cover dairy products derived from raw milk of that species.

(4) In addition, the Emirate of Dubai of the United Arab Emirates, which is a third country not listed by the World Organisation for Animal Health as being free of foot-and-mouth disease, has expressed an interest in exporting to the Union dairy products produced from raw milk derived from dromedary camels after physical or chemical treatment in accordance with Article 4 of Regulation (EU) No 605/2010 and has submitted information in accordance with Regulation (EC) No 882/2004 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 [4].

(5) The Commission inspection service audited with satisfactory results the animal and public health controls on the production of milk derived from dromedary camels in the Emirate of Dubai. In addition, the recommendations of the Commission inspection service were adequately addressed by the Emirate of Dubai.

(6) Based on that information, it can be concluded that the Emirate of Dubai can provide the necessary guarantees to ensure that dairy products produced in the Emirate of Dubai from raw milk of dromedary camels are in conformity with the applicable animal and public health requirements for imports into the Union of dairy products from third countries or parts thereof at risk of foot-and-mouth disease listed in column C of Annex I to Regulation (EU) No 605/2010.

(7) In order to authorise imports into the Union of dairy products produced from dromedary camel milk from certain parts of the territory of the United Arab Emirates, the Emirate of Dubai should be added to the list of third countries or parts thereof referred to in Annex I to Regulation (EU) No 605/2010, with an indication that the authorisation provided for in Column C of that list applies only to dairy products produced from milk of that species.

[1] OJ L 18, 23.1.2003, p. 11.
[2] OJ L 139, 30.4.2004, p. 206.
[3] OJ L 175, 10.7.2010, p. 1.
[4] OJ L 165, 30.4.2004, p. 1.

(8) The model of health certificate 'Milk-HTC' in Part 2 of Annex II to Regulation (EU) No 605/2010 should be amended in order to include a reference to dairy products produced from milk of dromedary camels.

(9) Certain dairy products covered by Regulation (EU) No 605/2010 do not fall within the commodity codes (HS codes) referred to in the model health certificates for dairy products. In order to allow a more precise identification of those commodities in the model health certificates, it is necessary to add the missing HS codes 15.17 (margarine) and 28.35 (phosphates) in the respective models of the health certificates 'Milk-HTB', 'Milk-HTC' and 'Milk-T/S' in Annex II to that Regulation.

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

(11) 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 4(1), the introductory phrase is replaced by the following:

'Member States shall authorise the importation of consignments of dairy products derived from raw milk of cows, ewes, goats, buffaloes or, where specifically authorised in Annex I, from camels of the species *Camelus dromedarius* from the third countries or parts thereof at risk of foot-and-mouth disease listed in column C of Annex I, provided that such dairy products have undergone, or been produced from raw milk which has undergone, a heat treatment involving:';

(2) Annexes I and II are amended in accordance with the Annex to this Regulation.

Article 2

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

It shall apply from 1 April 2013.

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

Done at Brussels, 27 March 2013.

For the Commission
The President
José Manuel BARROSO

ANNEX

The Annexes to Regulation (EU) No 605/2010 are amended as follows:

(1) Annex I is amended as follows:

(a) the following entry is inserted after the entry for Andorra in the table set out in that Annex:

'AE	The Emirate of Dubai of the United Arab Emirates ([1])	0	0	+ ([2])'

(b) the following footnotes are added to the table set out in that Annex:

'([1]) Only dairy products produced from milk of camels of the species *Camelus dromedarius*.

([2]) Dairy products produced from milk of camels of the species *Camelus dromedarius* are authorised.';

(2) in Annex II, Part 2 is amended as follows:

(a) in Model Milk-HTB, in the Notes, in Part I, Box reference I.19 is replaced by the following:

'— 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; 15.17; 17.02; 21.05; 22.02; 28.35; 35.01; 35.02 or 35.04.';

(b) the Model Milk-HTC is replaced by the following:

'*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 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

Species (scientific name)	Manufacturing plant	Number of packages	Net weight	Batch number

Model Milk-HTC

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

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) 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;

either [(b) the dairy product was made from raw milk sourced from cows, ewes, goats, buffaloes or, where authorised in accordance with footnote (2) of Annex I to Regulation (EC) No 605/2010, from -camels of the species *Camelus dromedarius*, and has 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 an 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 an alkaline phosphatase test, applied immediately after the heat treatment;]

([1]) *or* [(v) a HTST treatment of milk with a pH below 7,0;]

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

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

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

([1]) *or* [(b) the dairy product was made from raw milk sourced from animals other than cows, ewes, goats, buffaloes or camels of the species *Camelus dromedarius*, and has 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 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 described above was produced in accordance with those provisions, and 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;

Model Milk-HTC

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

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

(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 to 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.

Notes

This certificate is intended for dairy products for human consumption from third countries or parts thereof authorised, where applicable for milk from certain animal species only, 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; 15.17; 17.02; 19.01; 21.05; 21.06; 22.02; 28.35; 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:

(c) in Model Milk-T/S, in the Notes, in Part I, Box reference I.19 is replaced by the following:

'— 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; 15.17; 17.02; 19.01; 21.05; 21.06; 22.02; 28.35; 35.01; 35.02 or 35.04.'.