Commission Regulation (EU) No 605/2010 of 2 July 2010 laying down animal and public health and veterinary certification conditions for the introduction into the European Union of raw milk, dairy products, colostrum and colostrum-based products intended for human consumption (Text with EEA relevance)

[[F1]COMMISSION REGULATION (EU) No 605/2010

of 2 July 2010

laying down animal and public health and veterinary certification conditions for the introduction into the European Union of raw milk, dairy products, colostrum and colostrum-based 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 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs[(2)], and in particular Article 12 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 Article 9 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[(4)], and in particular Articles 11(1) and 14 (4) and Article 16 thereof,

Having regard to 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[(5)], and in particular Article 48 (1) thereof,

Whereas:

(1) Council Directive 92/46/EEC of 16 June 1992 laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products[(6)] provided for a list to be drawn up of third countries or parts thereof from which Member States were to authorise the introduction of milk or milk-based products and for such commodities to be accompanied by a health certificate and comply with certain requirements, including heat treatment requirements, and guarantees.

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EU) No 605/2010. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(2) Accordingly, Commission Decision 2004/438/EC of 29 April 2004 laying down animal and public health and veterinary certifications conditions for introduction in the Community of heat-treated milk, milk-based products and raw milk intended for human consumption[(7)] was adopted.

(3) Since the date of adoption of that Decision, a number of new animal health and public health requirements have been laid down, constituting a new regulatory framework in this area, which should be taken into account in this Regulation. In addition, Directive 92/46/EEC was repealed by Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain Directive concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption[(8)].

(4) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[(9)] lays down the general principles governing food and feed in general, and food and feed safety in particular, at European Union and national level.

(5) Directive 2002/99/EC lays down rules governing the introduction from third countries of products of animal origin intended for human consumption. It provides that such products are only to be introduced into the European Union if they comply with the requirements applicable to all stages of the production, processing and distribution of those products in the European Union or if they offer equivalent animal health guarantees.

(6) Regulation (EC) No 852/2004 lays down the general rules for food business operators on the hygiene of foodstuffs at all stages of the food chain, including at primary production level.

(7) Regulation (EC) No 853/2004 lays down specific rules for food business operators on the hygiene of food of animal origin. That Regulation provides that food business operators producing raw milk and dairy products intended for human consumption are to comply with the relevant provisions of Annex III thereto.

(8) Regulation (EC) No 854/2004 lays down specific rules for the organisation of official controls on products of animal origin.

(9) Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs[(10)] lays down the microbiological criteria for certain micro-organisms and the implementing rules to be complied with by food business operators when implementing the general and specific hygiene measures referred to in Article 4 of Regulation (EC) No 852/2004. Regulation (EC) No 2073/2005 provides that food business operators are to ensure that foodstuffs comply with the relevant microbiological criteria set out in that Regulation.

(10) Under the scope of Council Directive 92/46/EEC, raw milk and products thereof could only be obtained from cows, ewes, goats or buffaloes. However, the definitions of raw milk and dairy products set out in Annex I to Regulation (EC) No 853/2004 broadens

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the scope of milk hygiene rules to all mammalian species and defines raw milk as milk produced by the secretion of the mammary gland of farmed animals that has not been heated to more than 40 °C or undergone any treatment that has an equivalent effect. In addition, it defines dairy products as processed products resulting from the processing of raw milk or from further processing of such processed products.

(11) In view of the entry into application of Regulations (EC) Nos 852/2004, 853/2004 and 854/2004 and the acts implementing those Regulations, it is necessary to amend and update European Union public and animal health conditions and certification requirements for the introduction into the European Union of raw milk and dairy products intended for human consumption.

(12) In the interests of consistency of Union law, this Regulation should also take into account the rules laid down in Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council[(11)] and its implementing rules laid down in Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin[(12)] and Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC[(13)].

(13) Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products[(14)] lays down the rules to be observed in issuing certificates required by veterinary legislation to prevent misleading or fraudulent certification. It is appropriate to ensure that certification requirements at least equivalent to those laid down in that Directive are applied by the competent authorities of exporting third countries.

(14) In addition, Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the intenal market[(15)], provides for a computerized system linking veterinary authorities which has been developed in the Europena Union. The format of all model health certificates need to be amended to take into account their compatibility with possible electronic certification under the Trade Control and Expert System (TRACES) provided for in Directive 90/425/EEC. According, the rules laid down in this Regulation should take account of TRACES.

(15) 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[(16)] lays down rules concerning veterinary checks on products of animal origin introduced into the European Union from third countries for their importation or transit, including certain certification requirements. Those rules are applicable to the commodities covered by this Regulation.

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(16) Specific conditions for transit via the European 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.

(17) In the interests of clarity of European law, Commission Decision 2004/438/EC should be repealed and replaced by this Regulation.

(18) To avoid any disruption in trade, the use of health certificates issued in accordance with Decision 2004/438/EC should be authorised during a transitional period.

(19) 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:

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) No 209/2014 of 5 March 2014 amending Regulation (EU) No 605/2010 as regards animal and public health and veterinary certification conditions for the introduction of colostrum and colostrum-based products intended for human consumption into the Union (Text with EEA relevance).

Article 1

Subject matter and scope

This Regulation lays down:

(a) **[**F1the public and animal health conditions and certification requirements for the introduction into the European Union of consignments of raw milk, dairy products, colostrum and colostrum-based products;**]**

(b) the list of third countries from which the introduction into the European Union of such consignments is authorised.

[F2This 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.**]**

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) No 209/2014 of 5 March 2014 amending Regulation (EU) No 605/2010 as regards animal and public health and veterinary certification conditions for the introduction of colostrum and colostrum-based products intended for human consumption into the Union (Text with EEA relevance).

F2 Inserted by 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).

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[F1 Article 2

Importation of raw milk, dairy products, colostrum and colostrum-based products from third countries or parts thereof listed in column A of Annex I

Member States shall authorise the importation of consignments of raw milk, dairy products, colostrum and colostrum-based products from the third countries or parts thereof listed in column A of Annex I.**]**

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) No 209/2014 of 5 March 2014 amending Regulation (EU) No 605/2010 as regards animal and public health and veterinary certification conditions for the introduction of colostrum and colostrum-based products intended for human consumption into the Union (Text with EEA relevance).

Article 3

Imports of certain dairy products from third countries or parts thereof listed in column B of Annex I

Member States shall 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 not at risk from foot-and-mouth disease listed in column B of Annex I, provided that such dairy products have undergone, or been produced from raw milk which has undergone a pasteurisation treatment involving a single heat treatment:

(a) with a heating effect at least equivalent to that achieved by a pasteurisation process of at least 72 °C for 15 seconds;

(b) where applicable, sufficient to ensure a negative reaction to an alkaline phosphatase test applied immediately after the heat treatment.

Article 4

Imports of certain dairy products from third countries or parts thereof listed in column C of Annex I

1 **[**F3Member 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:**]**

a a sterilisation process, to achieve an F_0 value equal to or greater than three;

b an ultra high temperature (UHT) treatment at not less than 135 °C in combination with a suitable holding time;

c (i) 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,