# 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)

## 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)

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 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin[(2)], and in particular the second paragraph of 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[(3)], and in particular Articles 11(1) and the second paragraph of Article 16 thereof,

Whereas:

(1) 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 and colostrum and colostrum-based products intended for human consumption are to comply with the relevant provisions of Annex III thereto.

(2) In addition, Regulation (EC) No 853/2004 provides that food business operators importing products of animal origin from third countries are to ensure that importation takes place only, if the third country of dispatch appears on a list drawn up in accordance with Regulation (EC) No 854/2004 and the products satisfy, inter alia, the requirements of Regulation (EC) No 853/2004 and any import conditions laid down in accordance with Union legislation governing import controls for products of animal origin.

(3) Commission Regulation (EU) No 605/2010[(4)] lays down the public and animal health conditions and the certification requirements for the introduction of consignments of

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raw milk and dairy products into the Union. It also lays down the list of third countries from which the introduction of such consignments into the Union is authorised.

(4) Regulation (EU) No 605/2010 establishes different import conditions depending on the animal health status of the exporting third country as regards foot-and-mouth disease (FMD) and rinderpest. Third countries which are free from FMD without vaccination and rinderpest for the period for at least 12 months prior to import are listed in column A of Annex I to Regulation (EU) No 605/2010 and imports into the Union of raw milk and dairy products, derived from raw milk from those third countries, are authorised without having undergone a specific treatments.

(5) The Commission received several requests from some Member States and trade partners to establish animal health conditions for the imports of colostrum and colostrum-based products for human consumption into the Union.

(6) Regulation (EU) No 605/2010 does not apply to colostrum and colostrum-based products. However, colostrum represents the same animal health risks as raw milk for FMD. Colostrum can therefore be safely imported from countries which are already authorised for import of raw milk and listed in listed in column A of Annex I to Regulation (EU) No 605/2010.

(7) Several commercial products are made of pasteurised or sterilised colostrum. However, since the effects of pasteurisation and sterilisation have not been validated for colostrum which has a high cell content, pasteurised or sterilised colostrum and colostrum-based products should only be imported from those third countries which are free from FMD without vaccination, listed in column A of Annex I to Regulation (EU) No 605/2010.

(8) Articles 11, 12 and 13 of Council Directive 97/78/EC[(5)] lay down the rules and conditions for the checks to be applied to consignment of products of animal origin imported into the Union but destined for a third country either by immediate transit or after storage in the Union.

(9) In order to allow the introduction of colostrum and colostrum-based products into the Union, a new model health certificate for such commodities should be added in Part 2 of Annex II to Regulation (EU) No 605/2010 and the model health certificate for raw milk and dairy products for human consumption intended for transit through or storage in the Union set out in Part 3 of Annex II to that Regulation should be amended in order to cover colostrum and colostrum-based products.

(10) In order to include colostrum and colostrum-based products in the scope of the Common Veterinary Entry Document referred to in Article 2(1) of Commission Regulation (EC) No 136/2004[(6)], it is necessary to provide in the model of health certificates covering such products the appropriate Harmonised System code listed in Chapter 4 of Annex I to Commission Decision 2007/275/EC[(7)].

(11) To avoid any disruption in trade, the use of animal health certificate for raw milk and dairy products for human consumption, intended for transit through or storage in the Union, issued in accordance with Regulation (EU) No 605/2010, should be authorised during a transitional period.

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

(13) 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*

**Amendments to Regulation (EU) No 605/2010**

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

(1) the title is replaced by the following:
**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;**

(2) in Article 1, point (a) of the first paragraph is replaced by the following:

(a) the 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;;

(3) Article 2 is replaced by the following:

*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.;

(4) Article 6 is replaced by the following:

*Article 6*

**Transit and storage conditions**

The introduction into the European Union of consignments of raw milk, dairy products, colostrum and colostrum-based products not intended for importation into the European 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 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 listed in Annex I for the introduction into the European Union of consignments of raw milk, dairy products, colostrum or colostrum-based products and comply with the

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appropriate treatment conditions for such consignments, as provided for in Articles 2, 3 and 4;

(b) they comply with the specific animal health conditions for importation into the European Union of the raw milk, dairy products, colostrum or colostrum-based products concerned, as laid down in the animal health attestation in point II.1 of the relevant model health certificate set out in Part 2 of Annex II;

(c) they are accompanied by a health certificate drawn up in accordance with the appropriate model set out in Part 3 of Annex II for the consignment concerned and completed in accordance with the explanatory notes set out in Part 1 of that Annex;

(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 Regulation (EC) No 136/2004, signed by the official veterinarian of the border inspection post of introduction into the Union.;

(5) Article 8 is replaced by the following:

*Article 8*

**Specific treatment**

Consignments of dairy products and colostrum-based products authorised for introduction into the European Union in accordance with Articles 2, 3, 4,6 or 7 from third countries or parts thereof where an outbreak of foot-and-mouth disease has occurred within the period of 12 months preceding the date of signature of the health certificate, or which have carried out vaccination against that disease during that period, shall only be authorised for introduction into the European Union if such products have undergone one of the treatments listed in Article 4.;

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

*Article 2*

**Transitional provisions**

For a transitional period until 6 September 2014 the introduction into the European Union of consignments of raw milk and dairy products not intended for importation into the European 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 Directive 97/78/EC, accompanied by a health certificate conforming to the model set out in Part 2 of Annex II to Regulation (EU) No 605/2010, in its version prior to the entry into force of this Regulation, shall be authorised, provided that the certificate has been signed within 26 July 2014.

*Article 3*

**Entry into force**

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

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

Done at Brussels, 5 March 2014.

*For the Commission*

*The President*

José Manuel BARROSO