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 and dairy products intended for human consumption (Text with EEA relevance)

Article 1

Subject matter and scope

This Regulation lays down:

- (a) the public and animal health conditions and certification requirements for the introduction into the European Union of consignments of raw milk and dairy products;
- (b) the list of third countries from which the introduction into the European Union of such consignments is authorised.

Article 2

Imports of raw milk and dairy 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 and dairy products from the third countries or parts thereof listed in column A of Annex I.

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 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 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, where applicable, a negative reaction to a alkaline phosphatase test, applied immediately after the heat treatment; or
 - (ii) a treatment with an equivalent pasteurisation effect to point (i) achieving, where applicable, a negative reaction to an alkaline phosphatase test, applied immediately after the heat treatment;
- d a HTST treatment of milk with a pH below 7.0; or
- e a HTST treatment combined with another physical treatment by either:
 - (i) lowering the pH below 6 for one hour, or
 - (ii) additional heating equal to or greater than 72 °C, combined with desiccation.

2 Member States shall authorise the importation of consignments of dairy products derived from raw milk of animals other than those referred to in paragraph 1, 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 treatment involving:

- a a sterilisation process, to achieve an F₀ value equal to or greater than three; or
- b an ultra high temperature (UHT) treatment at not less than 135 °C in combination with a suitable holding time.

Article 5

Certificates

Consignments authorised for importation in accordance with Articles 2, 3 and 4 shall be accompanied by a health certificate drawn up in accordance with the appropriate model set out in Part 2 of Annex II for the commodity concerned and completed in accordance with the explanatory notes set out in Part 1 of that Annex.

However, the requirements laid down in this Article shall not preclude the use of electronic certification or of other agreed systems, harmonised at European Union level.

Article 6

Transit and storage conditions

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 European 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 European Union of consignments of raw milk or dairy products and comply with

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the appropriate heat 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 or dairy product concerned, as laid down in the animal health attestation in Part II.1 of the relevant model health certificate set out 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 Commission Regulation (EC) No 136/2004⁽¹⁾, signed by the official veterinarian of the border inspection post of introduction into the European Union.

Article 7

Derogation concerning transit and storage conditions

1 By way of derogation from Article 6, the transit by road or by rail through the European Union, between designated border inspection posts in Latvia, Lithuania and Poland listed in Commission Decision $2009/821/EC^{(2)}$, of consignments 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 European 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 European Union;
- 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 European Union.

2 Unloading or storage, as defined in Article 12(4) or in Article 13 of Directive 97/78/ EC, of such consignments on European 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 European Union territory matches the number and quantities entering the European Union.

Article 8

Specific treatment

Consignments of dairy 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 Status: This is the original version (as it was originally adopted).

preceding the date 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.

Article 9

Repeal

Decision 2004/438/EC is repealed.

References to Decision 2004/438/EC shall be construed as references to this Regulation.

Article 10

Transitional provisions

For a transitional period until 30 November 2010, consignments of raw milk and milkbased products as defined in Decision 2004/438/EC in respect of which the relevant health certificates have been issued in accordance Decision 2004/438/EC may continue to be introduced into the European Union.

Article 11

Entry into force and applicability

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 August 2010.

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

Done at Brussels, 2 July 2010.

For the Commission The President José Manuel BARROSO Status: This is the original version (as it was originally adopted).

- (**1**) OJ L 21, 28.1.2004, p. 11.
- (**2**) OJ L 296, 12.11.2009, p. 1