II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 790/2010

of 7 September 2010

amending Annexes VII, X and XI to Regulation (EC) No 1774/2002 of the European Parliament and of the Council laying down health rules concerning animal by-products not 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 Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption [1], and in particular the first and second subparagraphs of Article 32(1) thereof,

Whereas:

(1) Regulation (EC) No 1774/2002 lays down animal and public health rules concerning animal by-products not intended for human consumption.

(2) Article 19 of that Regulation provides that processed animal protein and other processed products that could be used as feed material are to be placed on the market only if they comply with certain requirements. In this respect, Annex VII to that Regulation sets out specific hygiene requirements for the processing and placing on the market of such products.

(3) In addition, Article 29 of Regulation (EC) No 1774/2002 provides that the importation into, and the transit through the Union of the products referred to in Annex VII may take place only if such products comply with certain requirements. Those requirements include that the products must come from a third country or parts of third countries on a list to be drawn up and updated in accordance with the procedure referred to in that Article, except where Annex VII to Regulation (EC) No 1774/2002 provides otherwise.

(4) Colostrum is a feed material of animal origin, within the meaning of the definition laid down in point 23 of Annex I to Regulation (EC) No 1774/2002.

(5) Part A of Chapter V of Annex VII to that Regulation does not set out any specific requirements for the production of colostrum or colostrum products. That Part only sets out the general principle that colostrum must be produced under conditions offering adequate guarantees as regards animal health.

(6) In addition, Part B of Chapter V of Annex VII to Regulation (EC) No 1774/2002 does not set out specific requirements for the importation of colostrum and colostrum products and the Commission has not laid down any list of third countries or parts of third countries from which imports of colostrum are accepted. Accordingly, the importation of colostrum or colostrum products into the European Union is currently not authorised.

(7) There is an interest to import into the Union colostrum and colostrum products as feed material for farmed animals and for technical purposes. Economic operators have indicated their interest in the use of colostrum and colostrum products for the production of feed material and for technical purposes.

(8) The demand for such products from economic operators should be met and rules should therefore be laid down for the importation of such animal by-products. However, colostrum is an animal by-product which may pose a risk for the transmission of certain diseases, such as foot-and-mouth disease, tuberculosis, brucellosis and enzootic-bovine-leukosis to susceptible animals. In order to safeguard animal health, the importation of colostrum and colostrum products should therefore be subject to certain conditions.

[1] OJ L 273, 10.10.2002, p. 1.

(9) In accordance with the first paragraph of Article 28 of Regulation (EC) No 1774/2002 the provisions applicable to the importation of products referred to in Annex VII to that Regulation from third countries are not to be more favourable or less favourable than those applicable to the production and marketing of those products in the Union. The specific requirements set out for the importation of whey and colostrum or colostrum products should therefore also apply to the production and placing on the market of those animal by-products in the Union.

(10) The opinion of the European Food Safety Authority, adopted on 29 March 2006, related to the animal health risks of feeding animals with ready-to-use dairy products without further treatment [1], confirmed that specific hygiene requirements and treatments for milk and milk-based products are to be established to limit the risk of transmitting infectious diseases, in particular through feeding of milk or milk products to animals of species susceptible to foot-and-mouth disease. In the absence of suitable scientific data, the aforementioned opinion does not recommend any treatment which would provide the necessary guarantees that the considered pathogens are effectively inactivated in colostrum while preserving antibodies contained therein.

(11) In the absence of approved treatments and in order to prevent the transmission of possible animal diseases through colostrum and colostrum products, it is appropriate to establish health requirements for those animal by-products based on guarantees at origin.

(12) In particular, as regards foot-and-mouth disease prevention, colostrum and colostrum products should be obtained from animals free of foot-and-mouth disease and not at risk of contracting this disease. Imports of colostrum and colostrum products should therefore be limited to bovine colostrum and its products from countries approved for imports of raw milk. Imports of colostrum and colostrum products should be limited to bovine colostrum and its products from countries where the risk of foot-and-mouth disease is limited.

(13) 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 [2] provides that Member States are to authorise imports of raw milk and raw milk-based products only from the third countries listed in column A of Annex I thereto. The list of third countries from which the importation into the Union of colostrum and colostrum products should be authorised should therefore be the same as the list of third countries set out in column A of Annex I to Decision 2004/438/EC. Chapter V of Annex VII to Regulation (EC) No 1774/2002 should therefore refer to that list.

(14) The health status with regard to bovine tuberculosis, bovine brucellosis and enzootic-bovine-leukosis of the herds from which colostrum and colostrum products originate should also be taken into account, in particular where such animal by-products are intended for feeding animals or the production of certain technical products. The herds from which colostrum and colostrum products originate should be free of those diseases.

(15) Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine [3] applies to intra-Union trade in bovine animals and sets out provisions for recognising herds as being disease-free. It lays down the definitions for officially tuberculosis-free bovine herds, officially brucellosis-free bovine herds and officially enzootic-bovine-leukosis-free herds. The requirements for placing on the market and importation of colostrum and colostrum products should therefore take account of those definitions.

(16) Colostrum and colostrum products should have undergone a primary high temperature short term treatment for their preservation. In addition, the placing on the market, including the importation, of such animal by-products should only be allowed if they originate from animals that do not show clinical signs of any disease communicable through colostrum to humans or animals. Colostrum and colostrum products should therefore be produced from bovine animals kept in areas for which guarantees can be provided that foot-and-mouth disease has not occurred within at least one incubation period of 21 days after the collection and before such colostrum or colostrum products are placed on the market in Member States.

(17) Part A of Chapter V of Annex VII to Regulation (EC) No 1774/2002 provides that whey to be fed to animals of species susceptible to foot-and-mouth disease and produced from milk treated in accordance with the rules set out therein must be collected at least 16 hours after milk clotting and its pH must be recorded as below 6,0 before transport to animal holdings.

(18) Chapter 2 of Annex X to Regulation (EC) No 1774/2002 sets out a single model health certificate for milk and milk products not intended for human consumption originating in third countries for dispatch to or for transit through the European Union. That model certificate should be amended in order to cover also colostrum and colostrum products, as well as to reflect the new rules concerning whey.

[1] The EFSA Journal (2006) 347, p. 1.
[2] OJ L 154, 30.4.2004, p. 72.
[3] OJ 121, 29.7.1964, p. 1977/64.

(19) Annex XI to Regulation (EC) No 1774/2002 sets out lists of third countries from which Member States may authorise imports of certain animal by-products not intended for human consumption. Part I of that Annex should be amended to take account of the rules for the importation of colostrum and colostrum products.

(20) Cameroon applied for the authorisation for imports of apiculture animal by-products. Cameroon is already authorised for the imports of honey for human consumption. Part XII of Annex XI should be amended appropriately and Cameroon should be authorised for the imports of apiculture animal by-products.

(21) Annexes VII, X and XI to Regulation (EC) No 1774/2002 should therefore be amended accordingly.

(22) A transitional period should be provided for after the date of entry into force of this Regulation, in order to provide the necessary time for stakeholders to comply with the new rules and to allow for the continued importation into the European Union of the animal by-products concerned, as provided for in Regulation (EC) No 1774/2002, before the amendments introduced by this Regulation.

(23) 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

Annexes VII, X and XI to Regulation (EC) No 1774/2002 are amended in accordance with the Annex to this Regulation.

Article 2

Consignments of milk and milk products not intended for human consumption accompanied by a health certificate completed and signed in accordance with the appropriate model set out in Chapter 2 of Annex X to Regulation (EC) No 1774/2002 before the date of entry into force of this Regulation shall continue to be accepted for importation into the Union until 30 September 2010, where those certificates were completed and signed before 31 August 2010.

Article 3

This Regulation shall enter into force on the 20th day following 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, 7 September 2010.

For the Commission
The President
José Manuel BARROSO

ANNEX

Annexes VII, X and XI to Regulation (EC) No 1774/2002 are amended as follows:

1. in Annex VII, Chapter V is amended as follows:

(a) the heading is replaced by the following:

'CHAPTER V

Specific requirements for milk, milk products, colostrum and colostrum products';

(b) Part A is amended as follows:

(i) paragraph 3 is replaced by the following:

'3. Whey to be fed to animals of species susceptible to foot-and-mouth disease and produced from milk treated in accordance with paragraph 1 must:

(a) either be collected at least 16 hours following milk clotting and its pH must be recorded as below 6,0 before transport to animal holdings; or

(b) have been produced at least 21 days before shipping and during that period no case of foot-and-mouth disease has been detected in the Member State of origin.';

(ii) the following paragraph 6 is added:

'6. Colostrum and colostrum products must:

6.1. be obtained from bovine animals kept on a holding on which all bovine herds are recognised as officially tuberculosis-free, officially brucellosis-free and officially enzootic-bovine-leukosis-free as defined in Article 2(2)(d), (f) and (j) of Directive 64/432/EEC;

6.2. have been produced at least 21 days before shipping and during that period no case of foot-and-mouth disease has been detected in the Member State of origin;

6.3. have undergone a single HTST treatment (*);

6.4. comply with the requirements set out in paragraph 4.

(*) HTST = High Temperature Short Time pasteurisation at 72 °C for at least 15 seconds or equivalent pasteurisation effect achieving a negative reaction to a phosphatase test in bovine milk.'

(c) Part B is amended as follows:

(i) paragraph 1.1 is replaced by the following:

'1.1. they come from third countries appearing on the list in Part I(A) of Annex XI;';

(ii) paragraph 2 is replaced by the following:

'2. By way of derogation from paragraph 1.4, Member States shall authorise imports of milk and milk products from third countries so authorised in Column "A" of Annex I to Commission Decision 2004/438/EC (*) provided that the milk and milk products have undergone a single HTST treatment and:

(a) have not been shipped before a period of at least 21 days has elapsed after production and during that period no case of foot-and-mouth disease has been detected in the exporting third country; or

(b) have been presented at an EU border inspection post at least 21 days after production and during that period no case of foot-and-mouth disease has been detected in the exporting third country.

(*) OJ L 154, 30.4.2004, p. 72.';

(iii) the following paragraph 2a is inserted:

'2a. Member States shall authorise imports of colostrum or colostrum products of bovine animals provided that:

2a.1. they come from a third country appearing on the list in Part I(B) of Annex XI;

2a.2. they comply with the conditions set out in paragraphs 1.2 and 1.3;

2a.3. they have undergone a single HTST treatment (*) and:

(a) have not been shipped before a period of at least 21 days has elapsed after production and during that period no case of foot-and-mouth disease has been detected in the exporting third country; or

(b) have been presented at an EU border inspection post at least 21 days after production and during that period no case of foot-and-mouth disease has been detected in the exporting third country;

2a.4. they have been obtained from bovine animals subject to regular veterinary inspections to ensure that animals come from holdings on which all bovine herds are:

(a) either recognised as officially tuberculosis free and officially brucellosis free as defined in Article 2(2)(d) and (f) of Directive 64/432/EEC or not restricted under the national legislation of the third country of origin of the colostrum regarding eradication of tuberculosis and brucellosis; and

(b) either recognised as official enzootic-bovine-leukosis-free as defined in Article 2(2)(j) of Directive 64/432/EEC or included in an official system for the control of enzootic-bovine-leukosis and there has been no evidence as a result of clinical and laboratory testing of this disease in the herd during the past two years;

2a.5. after completion of the processing, every precaution has been taken to prevent contamination of the colostrum or colostrum products;

2a.6. the final product has been labelled so as to indicate that it contains Category 3 material and is not intended for human consumption, and that it has been:

(a) packed in new containers; or

(b) transported in bulk in containers or other means of transport that before use were thoroughly cleansed and disinfected using a disinfectant approved for the purpose by the competent authority.

(*) HTST = High Temperature Short Time pasteurisation at 72 °C for at least 15 seconds or equivalent pasteurisation effect achieving a negative reaction to a phosphatase test in bovine milk.';

2. in Annex X, Chapter 2 is replaced by the following:

'CHAPTER 2

Health certificate

For milk, milk products, colostrum and colostrum products not intended for human consumption for dispatch to or transit through (*) the European Union

COUNTRY: **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor Name Address Tel.	I.2. Certificate reference number I.2.a. I.3. Central competent authority I.4. Local competent authority
I.5. Consignee Name Address Postal code Tel.	I.6. Person responsible for the load in EU Name Address Postal code Tel.
I.7. Country of origin ISO code I.8. Region of origin Code	I.9. Country of destination ISO code I.10. Region of destination Code
I.11. Place of origin Name Approval number Address	I.12. Place of destination Custom warehouse ☐ Name Approval number Address Postal code
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. No(s) of CITIES
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. Identification of container/Seal number	I.24. Type of packaging
I.25. Commodities certified for: Animal feedingstuff ☐ Further process ☐ Technical use ☐ Other ☐	
I.26. For transit through the EU to a 3rd country ☐ 3rd country ISO code	I.27. For import or admission into the EU ☐
I.28. Identification of the commodities Species Approval number of establishments Manufacturing plant Net weight Batch number	

(*) Delete as appropriate.

COUNTRY:

Milk, milk products, colostrum and colostrum products not for human consumption

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

Part II: Certification

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002 [1], and in particular Article 6 and Chapter V of Annex VII thereto, and certify that the milk [2], the milk products [2] the colostrum [2] or the colostrum products [2] referred to in box I.28 comply with the following conditions:

II.1. they were produced and derived in ..... *(name of exporting country)* [3], ... *(insert name of region)* [3], which is listed in the Annex to Decision 2004/438/EC, and which has been free from foot-and-mouth disease (FMD) and rinderpest for 12 months immediately prior to export and has not practiced vaccination against rinderpest during that period;

II.2. they were produced from raw milk or colostrum derived from animals which at the time of milking did not show clinical signs of any disease transmissible through milk or colostrum to humans or animals, and which had been kept for at least 30 days prior to production on holdings that were not subject to official restrictions due to foot and mouth disease or rinderpest;

II.3. they are milk or milk products that:

([2]) *either* [have undergone one of the treatments or combinations thereof described in point II. 4]

([2]) *or* [comprise whey to be fed to animals of species susceptible to foot-and-mouth disease, and that whey was collected from milk subjected to one of the treatments described in point II. 4 and

([2]) *either* [the whey was collected at least 16 hours after clotting and has a pH below 6;]

([2]) ([4]) *or* [the whey has been produced at least 21 days before the shipping and during that period no cases of FMD have been detected in the exporting country;]

([2]) ([4]) *or* [the whey has been produced on .../.../..., this date, in consideration of the foreseen voyage duration, being at least 21 days before the consignment is presented to a Border Inspection Post of the European Union;]]

II.4. they have been subject to one of the following treatments:

([2]) *either* [High Temperature Short Time pasteurisation at 72 °C for at least 15 seconds, or an equivalent pasteurisation achieving a negative reaction to a phosphatase test in bovine milk, in combination with:

([2]) *either* [a subsequent second High Temperature Short Time pasteurisation at 72 °C for at least 15 seconds or an equivalent pasteurisation which itself achieves a negative reaction to a phosphatase test in bovine milk;]

([2]) *or* [a subsequent drying process that in the case of milk intended for feeding is combined with additional heating to 72 °C or higher;]

([2]) *or* [a subsequent process by which the pH is reduced and kept for at least one hour at a level below 6;]

([2]) ([4]) *or* [the condition that the milk/milk product has been produced at least 21 days before the shipping and during that period no cases of FMD have been detected in the exporting country;]

([2]) ([4]) *or* [the milk/milk product has been produced on .../.../..., this date, in consideration of the foreseen voyage duration, being at least 21 days before the consignment is presented to a Border Inspection Post of the European Union;]

([2]) *or* [sterilisation at a level of at least $F_0 3$;]]

([2]) *or* [Ultra High Temperature treatment at 132 °C for at least one second in combination with:

([2]) *either* [a subsequent drying process that in the case of milk intended for feeding is combined with additional heating to 72 °C or higher,]

([2]) *or* [a subsequent process by which the pH is reduced and kept for at least one hour at a level below 6;]

([2]) ([4]) *or* [the condition that the milk/milk product has been produced at least 21 days before the shipping and during that period no cases of FMD has been detected in the exporting country;]

([2]) ([4]) *or* [the milk/milk product has been produced on .../.../... this date, in consideration of the foreseen voyage duration, being at least 21 days before the consignment is presented to a Border Inspection Post of the European Union;]]

II.5. they are colostrum or colostrum products of bovine animals that have been subject to High Temperature Short Time pasteurisation at 72 °C for at least 15 seconds, or an equivalent pasteurisation achieving a negative reaction to a phosphatase test in bovine milk, in combination with:

([2]) ([4]) *either* [the condition that the colostrum or colostrum products have been produced at least 21 days before the shipping and in this period no cases of FMD have been detected in the exporting country;]

([2]) ([4]) *or* [the colostrum or colostrum products have been produced on .../.../..., this date, in consideration of the foreseen voyage duration, being at least 21 days before the consignment is presented to a Border Inspection Post of the European Union;]

COUNTRY: **Milk, milk products, colostrum and colostrum products not for human consumption**

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

and have been obtained from animals subject to regular veterinary inspections to ensure that animals come from holdings on which all bovine herds are:

(2) (4) *either* [recognised as officially tuberculosis and brucellosis free (5),]

(2) (4) *or* [not restricted under the national legislation of the third country of origin regarding eradication of tuberculosis and brucellosis,]

and (2) (4) *either* [recognised as official enzootic-bovine-leukosis free (5);]

(2) (4) *or* [included in an official system for the control of enzootic bovine leukosis and there has been no evidence as result of clinical and laboratory testing of this disease in the herd during the past two years;]

II.6. every precaution was taken to avoid contamination of the milk/milk product/colostrum/colostrum product after processing;

II.7. the milk/milk product/colostrum/colostrum product was packed:

(2) *either* [in new containers,]

(2) *or* [in vehicles or bulk containers disinfected prior to loading using a product approved by the competent authority,]

and the containers are marked so as to indicate the nature of the milk/milk product/colostrum and bear labels indicating that the product is Category 3 material and not intended for human consumption.

Notes

Part I:

— Box reference I.6: Person responsible for the load in EU: this box is to be filled in only if it is a certificate for transit commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship) is to be provided. In case of unloading and reloading, the consignor must inform the Border Inspection Post of the European Union.

— Box reference I.19: Use the appropriate Harmonised System (HS) code of the World Customs Organisation: 23.09.10, 23.09.90, 35.01, 35.02 or 35.04.

— Box reference I.23: For bulk containers, the container number and the seal number (if applicable) must be included.

— Box reference I.26 and I.27: Fill in according to whether it is a transit or an import certificate.

— Box reference I.28: "Manufacturing plant": provide the registration number of treatment or processing establishment.

Part II:

(1) OJ L 273, 10.10.2002, p. 1.

(2) Delete as appropriate.

(3) For completion if the authorisation to import into the European Union is restricted to certain regions of the third country concerned.

(4) This condition applies only to third countries listed in column "A" of Annex I to Decision 2004/438/EC.

COUNTRY:	**Milk, milk products, colostrum and colostrum products not for human consumption**	
II. Health information	II.a. Certificate reference No	II.b.

(5) Officially tuberculosis and brucellosis free herd as laid down in Annex A to Council Directive 64/432/EEC; and officially enzootic-bovine-leukosis free herd as laid down in Chapter I of Annex D to Council Directive 64/432/EEC.

— The signature and the seal must be in a different colour from that of the printing

— Note for the importer: this certificate is only for veterinary purposes and must accompany the consignment until it reaches the Border Inspection Post of the European Union.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:'

Stamp:

3. Annex XI is amended as follows:

(a) Part I is replaced by the following:

'***PART I***

List of third countries from which Member States may authorise imports of milk, milk products, colostrum and colostrum products (health certificate Chapter 2)

A. Milk and milk products:

Third countries listed as authorised in any of the columns of Annex I to Decision 2004/438/EC.

B. Colostrum and colostrum products:

Third countries listed as authorised in column "A" of Annex I to Decision 2004/438/EC.';

(b) Part XII is replaced by the following:

'***PART XII***

List of third countries from which Member States may authorise imports of apiculture products (health certificate Chapter 13)

Third countries listed in part 1 of Annex II to Regulation (EU) No 206/2010, and the following country:

— "(CM) Cameroon" '.