COMMISSION REGULATION (EC) No 79/2005

of 19 January 2005

implementing Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards the use of milk, milk-based products and milk-derived products, defined as Category 3 material in that Regulation

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 Article 6 (2) (i) thereof,

Whereas:

(1) Regulation (EC) No 1774/2002 lays down the public and animal health rules for the collection, transport, storage, handling, processing and use or disposal of animal by-products in order to prevent those products from presenting a risk to public or animal health.

(2) Regulation (EC) No 1774/2002 lays down rules for the use of certain animal by-products derived from the production of products intended for human consumption and former foodstuffs of animal origin, falling within the definition of Category 3 material in that Regulation, including milk and milk-based products no longer intended for human consumption. Regulation (EC) No 1774/2004 also provides for the possibility to use Category 3 material in other ways, in accordance with the procedure laid down in that Regulation and after consultation of the appropriate scientific committee.

(3) According to opinions of the Scientific Steering Committee of 1996, 1999 and 2000, there is no evidence that milk transmits bovine spongiform encephalopathy (BSE) and any risk from milk is considered to be negligible. In its state of affairs report of 15 March 2001, the TSE/BSE *ad hoc* Group upheld that advice.

(4) On the basis of those opinions, milk, milk-based products and colostrum are derogated from the prohibition on the feeding of animal protein to farmed animals, which are kept, fattened or bred for the production of food, in accordance with Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies [2].

(5) Regulation (EC) No 1774/2002 does not apply to liquid milk and colostrum disposed of or used on the farm of origin. That Regulation also permits the application to land of milk and colostrum as a fertiliser or soil improver, if the competent authority does not consider them to present a risk of spreading any serious transmissible disease, given that farmed animals could have access to such land and therefore could be exposed to such a risk.

(6) Under Regulation (EC) No 1774/2002, Category 3 material is to be used in accordance with strict conditions and the feeding of such material to farmed animals is allowed only after processing in an approved Category 3 processing plant.

(7) Animal by-products derived from the production of dairy products intended for human consumption and former dairy foodstuffs are generally produced in establishments approved in accordance with 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 [3]. Ready-to-use dairy products are generally wrapped and, therefore, the possibility for subsequent contamination of the product is minimal.

(8) The Commission is to seek the advice of the European Food Safety Authority on the possibility to feed to farmed animals, and under the required conditions to minimise risks, ready-to-use milk, milk-based products and milk-derived products, falling within the definition of Category 3 material in Regulation (EC) No 1774/2002, (the products), without further treatment.

[1] OJ L 273, 10.10.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 668/2004 (OJ L 112, 19.4.2004, p. 1).

[2] OJ L 147, 31.5.2001, p. 1. Regulation as last amended by Regulation (EC) No 1993/2004 (OJ L 344, 20.11.2004, p. 12).

[3] OJ L 268, 14.9.1992, p. 1. Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

(9) Pending that advice and in the light of the current scientific opinions and of the Scientific Committee on Animal Health and Animal Welfare report on the strategy for emergency vaccination against foot-and-mouth disease of 1999, it is appropriate to lay down, on a provisional basis, specific measures for the collection, transportation, processing, and use of these products.

(10) Appropriate control systems should be put in place in the Member States to ensure compliance with this Regulation and to take appropriate actions in case of non-compliance. Member States should also take into account their risk assessment for the best and worst case scenarios carried out in preparation of their contingency plans for epizootic diseases, when deciding on the number of registered holdings that may be authorised to use the products concerned.

(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

General authorisation by Member States

Member States shall authorise the collection, transportation, processing, use and storage of milk, milk-based products and milk-derived products, falling within the definition of Category 3 material, as referred to in Articles 6(1)(e), 6(1)(f) and 6(1)(g) of Regulation (EC) No 1774/2002, that have not been processed in accordance with Chapter V of Annex VII to that Regulation (the products), provided that these activities and products comply with the requirements set out in this Regulation.

Article 2

Use as feed of processed products and whey and unprocessed products

1. Processed products and whey, as referred to in Annex I, may be used as feed in accordance with the requirements laid down in that Annex.

2. Unprocessed products and other products, as referred to in Annex II, may be used as feed in accordance with the requirements laid down in that Annex.

Article 3

Collection, transportation and storage

1. The products shall be collected, transported and identified in accordance with the requirements set out in Annex II to Regulation (EC) No 1774/2002.

However, the first subparagraph shall not apply to operators of milk-processing establishments approved in accordance with Article 10 of Directive 92/46/EEC when collecting and returning to their establishment products which they have previously delivered to their customers.

2. The storage of the products shall take place at an appropriate temperature to avoid any risk to public or animal health, either:

(a) in a dedicated storage plant approved for that purpose in accordance with Article 11 of Regulation (EC) No 1774/2002; or

(b) in a dedicated, separate storage area in an establishment approved in accordance with Article 10 of Directive 92/46/EEC.

3. Samples of the final products taken during storage or at the time of withdrawal from storage, shall at least comply with the microbiological standards set out in Chapter I(D)(10) of Annex VII to Regulation (EC) No 1774/2002.

Article 4

Authorisation, registration and control measures

1. The milk processing establishments approved in accordance with Article 10 of Directive 92/46/EEC and the holdings, which are authorised as provided for in the Annexes to this Regulation, shall be registered by the competent authority for that purpose.

2. The competent authority shall take the necessary measures to control compliance by operators of registered establishments and holdings with the requirements set out in this Regulation.

Article 5

Suspension of authorisation and registration in case of non-compliance

Any authorisation and registration issued by the competent authority in accordance with this Regulation shall be immediately suspended if the requirements of this Regulation are no longer fulfilled.

The authorisation and registration may be reinstated only after appropriate corrective measures have been taken as instructed by the competent authority.

Article 6

Review

The Commission shall review the provisions of this Regulation and adapt them as appropriate in the light of the opinion of the European Food Safety Authority.

Article 7

Entry into force

This Regulation shall enter into force on the 20th day following that of 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, 19 January 2005.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX I

OTHER USE OF PROCESSED PRODUCTS AND WHEY, AS PROVIDED FOR IN ARTICLE 6 (2)(i) OF REGULATION (EC) No 1774/2002

CHAPTER I

A. Products concerned

The products, including cleaning water that have been in contact with raw milk and/or milk pasteurised in accordance with Chapter I(A)(4)(a) of Annex C to Directive 92/46/EEC, subjected to at least one of the following treatments:

(a) 'ultra high temperature' (UHT) in accordance with Chapter I(A)(4)(b) of Annex C to Directive 92/46/EEC;

(b) sterilisation whereby either an Fc value equal to or greater than 3 is achieved, or which was carried out in accordance with Chapter I(A)(4)(c) of Annex C to Directive 92/46/EEC at a temperature of at least 115°C for 20 minutes or equivalent;

(c) pasteurisation in accordance with Chapter I, A, 4(a) or sterilisation, other than that referred to in paragraph (b) of this Section, in accordance with Chapter I(A)(4)(c) of Annex C to Directive 92/46/EEC, followed by:

(i) in the case of dried milk or dried milk products, a drying process; or

(ii) in the case of an acidified milk product, a process by which the pH is reduced and kept for at least one hour at a level below 6.

B. Use

The products, referred to in Section A, may be used as feed material in the Member State concerned, and may be used in cross-border areas where the Member States concerned have a mutual agreement to that effect. The establishment concerned must ensure traceability of the products.

CHAPTER II

A. Products concerned

1. the products, including cleaning water that has been in contact with milk that has only been pasteurised in accordance with Chapter I(A)(4)(a) of Annex C to Directive 92/46/EEC; and

2. whey produced from non heat-treated milk-based products, which must be collected at least 16 hours after milk clotting and where the pH must be recorded as < 6,0 before being sent directly to authorised animal holdings.

B. Use

The products and whey, referred to in Section A, may be used as feed material in the Member State concerned subject to the following conditions:

(a) they are sent from an establishment approved in accordance with Article 10 of Directive 92/46/EEC, which guarantees the traceability of those products; and

(b) they are sent to a limited number of authorised animal holdings, fixed on the basis of the risk assessment for the best and worst case scenarios carried out by the Member State concerned in preparation of the contingency plans for epizootic diseases, in particular foot-and-mouth disease.

ANNEX II

OTHER USES OF UNPROCESSED PRODUCTS AND OTHER PRODUCTS

A. Products concerned:

Raw products, including cleaning water that has been in contact with raw milk, and other products for which the treatments referred to in the Chapters I and II of Annex I cannot be ensured.

B. Use

The products referred to in Section A, may be used as feed material in the Member State concerned subject to the following conditions:

(a) they are sent from an establishment approved in accordance with Article 10 of Directive 92/46/EEC, which guarantees the traceability of those products; and

(b) they are sent to a limited number of authorised animal holdings, fixed on the basis of the risk assessment for the best and worst case scenarios carried out by the Member State concerned in preparation of the contingency plans for epizootic diseases, in particular foot-and-mouth disease, and provided that the animals present in the authorised animal holdings can only be moved:

(i) either directly to a slaughterhouse located in the same Member State; or

(ii) to another holding in the same Member State, for which the competent authority guarantees that animals susceptible to foot-and-mouth disease may leave the holding only:

(a) either in accordance with point (i); or

(b) if the animals have been dispatched to a holding not feeding the products referred to in this Annex, after a 21-day standstill period has elapsed from the introduction of the animals.