COMMISSION REGULATION (EC) No 878/2004

of 29 April 2004

laying down transitional measures in accordance with Regulation (EC) No 1774/2002 for certain animal by-products classified as Category 1 and 2 materials and intended for technical purposes

(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 Articles 4(4), 5(4), 16(3) and 32(1) thereof,

Whereas:

(1) According to the 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], specified risk material intended for food, feed or fertilisers may not be imported into the Community.

(2) However, Category 1 materials, which may contain specified risk material, may be imported into or exported from the Community in accordance with rules laid down in Regulation (EC) No 1774/2002 or to be established under the procedure referred to in its Article 33(2).

(3) Commission Regulation (EC) No 812/2003 of 12 May 2003 on transitional measures under Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards the importation and transit of certain products from third countries [3] provides a temporary derogation until 30 April 2004 from the importation prohibition on certain animal by-products from third countries as set out in Regulation (EC) No 1774/2002.

(4) Certain operators and trading partners have expressed concerns over a prohibition on animal by-products intended for technical uses, outside the feed or food chain.

(5) The Commission has requested scientific advice on a quantitative assessment of the residual risk of bovine spongiform encephalopathy (BSE) in a number of bovine-derived products such as gelatine and tallow, which is expected in the near future. It is also intended to seek further specific advice.

(6) Pending such advice, it is appropriate to provide transitional measures allowing the continued placing on the market, export, import and transit of certain products classified as Category 1 and 2 materials under Regulation (EC) No 1774/2002, intended exclusively for technical uses.

(7) Accordingly, transitional measures should be adopted to allow the technical use of certain, strictly defined, Category 1 and 2 materials. The specific uses of such materials intended for technical purposes should be subject to strict channelling and control measures, further reducing the risk of diversion into the food and feed chains and unintended use in other technical products such as fertilisers and soil improvers, cosmetics, medicinal products and medical devices.

(8) Where the use of Category 1 and 2 animal by-products cannot be avoided for the production of medicinal products, the competent authority may, on the basis of an appropriate case-by-case risk assessment in accordance with relevant Community legislation, derogate from the provisions of the Regulation

(9) With regard to the placing on the market and export of animal by-products intended for a technical use produced in the Community, the rules laid down in Regulation (EC) No 1774/2002 should be generally sufficient, subject to complementing the rules for collection and transport to ensure the strict channelling, identification, and control objectives being pursued; with regard to consignments for imports or in transit, additional certification and channelling requirements should be implemented.

(10) Member States should implement additional verification arrangements as necessary for the implementation of this Regulation and in particular to avoid the risk of diversion, and should cooperate to that effect; they should inform the Commission and other Member States accordingly, and take all necessary measures in the context of the relevant Community legislation in case of non compliance.

[1] OJ L 273, 10.10.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 808/2003 (OJ L 117, 13.5.2003, p. 1).
[2] OJ L 147, 31.5.2001, p. 1. Regulation as last amended by Regulation 2245/2003 (OJ L 333, 20.12.2003, p. 28).
[3] OJ L 117, 13.5.2003, p. 19. Regulation as amended by Regulation (EC) No 2268/2003 (OJ L 336, 23.12.2003, p. 24).

(11) In order to avoid disruption of trade it is appropriate to provide for a reasonable period of time for the continuing acceptance of imported animal by-products arriving at the border inspection posts after 1 May 2004, and which may still be accompanied by old models of health certificates.

(12) 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

Scope

This Regulation shall apply to the following animal by-products, classified as Category 1 or Category 2 material under Regulation (EC) No 1774/2002 and intended exclusively for technical uses:

(a) hides and skins derived from animals which have been treated with certain substances which are prohibited pursuant to Directive 96/22/EC [1];

(b) rendered fats derived from Category 1 materials produced using Method 1 as referred to in Annex V, Chapter III of Regulation (EC) No 1774/2002, and in the case rendered fats from ruminant animals have been purified so that the maximum level of remaining total insoluble impurities does not exceed 0,15 % in weight, and derived fat derivatives meeting at least the standards referred to in Annex VI, Chapter III of Regulation (EC) No 1774/2002;

(c) ruminant intestines (with or without content); and

(d) bone and bone products containing vertebral column and skulls, and bovine horns which have been removed from the skull using a method which left the cranial cavity intact.

However, those animal by-products shall not be derived from animals referred to in Article 4(1)(a)(i) and (ii) of Regulation (EC) No 1774/2002

Article 2

Derogation regarding the placing on the market and export of animal by-products

By way of derogation from Article 20(1) of Regulation (EC) No 1774/2002, the Member States may authorise the placing on the market and export of the animal by-products referred to in Article 1 of this Regulation ('the animal by-products').

However, the derogation provided for in the first sub-paragraph shall not apply to the export of the animal by-products referred to in points (c) and (d) of Article 1 of this Regulation.

[1] OJ L 125, 23.5.1996, p. 3. Directive as amended by Directive 2003/74/EC of the European Parliament and of the Council (OJ L 262, 14.10.2003, p. 17).

Article 3

Derogation regarding the importation and transit of animal by-products

By way of derogation from Article 29(1) of Regulation (EC) No 1774/2002, the Member States may authorise the importation and transit of the animal by-products.

A label similar to that referred to in point (a) of Article 5 of this Regulation shall also be required for the imported animal by-products.

Article 4

Conditions for the placing on the market, export and import of the animal by-products

1. The placing on the market or export of the animal by-products shall be carried out in a way that does not present a risk to animal and public health and the environment.

2. Imports of the animal by-products shall be subjected to sanitary certification requirements in accordance with national legislation.

Imported consignments and consignments in transit shall be channelled in accordance with the monitoring procedure provided for in Article 8 (4) of Council Directive 97/78/EC.

Article 5

Collection and transport of the animal by-products

The collection and transport of the animal by-products shall comply with the following additional requirements:

(a) in addition to the identification requirements provided for in Chapter I of Annex II to Regulation (EC) No 1774/2002, all packages shall bear a label indicating 'PROHIBITED IN FOOD, FEED, FERTILISERS, COSMETICS, MEDICINAL PRODUCTS AND MEDICAL DEVICES';

However, a different label may be used in the case the animal by-products are intended for medicinal products in accordance with Community legislation. Any such label shall make clear that the animal by-products are 'DESTINED FOR MEDICINAL PRODUCTS ONLY';

(b) the by-products shall be delivered to a dedicated technical plant approved in accordance with Article 18 of Regulation (EC) No 1774/2002, and shall be subjected to a treatment which satisfies the competent authority in such a way that the resulting technical product does not pose a risk to animal and public health;

(c) the technical plant referred to in point (b) shall keeps records in accordance with Article 9 of Regulation (EC) No 1774/2002, and shall uses the animal by-products exclusively for technical purposes authorised by the competent authority.

Article 6

Controls

1. With regard to consignments imported or in transit, the competent authority shall carry out documentary checks at regular intervals, and at least twice a year, on the channelling chain from the border inspection posts of first entry to the approved technical plant in case of import, and to the border inspection post of exit in case of transit, for the purpose of reconciliation of the quantities of animal by-products imported, used and disposed of, ensuring compliance with this Regulation and with Regulation (EC) No 1774/2002.

For consignments in transit, the competent authorities responsible for the border inspection post of first entry and of exit respectively shall cooperate as necessary to ensure effective traceability and checks. The competent authorities shall also cooperate in their surveillance to ensure reconciliation of quantities imported in one Member State and used in another, of quantities exported from one Member State but produced in another, and of quantities in transit -in and out.

2. With regard to consignments for placing on the market in the Community or for export, the competent authorities shall carry out the checks provided for in Regulation (EC) No 1774/2002, in particular its Articles 7 and 8, with the same objectives of checking the reconciliation of quantities and compliance.

Article 7

Information to be provided by the Member States

Member States shall immediately inform the Commission and other Member States in the framework of the Standing Committee on the Food Chain and Animal Health of:

(a) the use made of the derogation provided in Articles 2 and 3; and

(b) the verification arrangements provided for in Article 6 to ensure that the animal by-products concerned are used only for purposes authorised in accordance with Article 5(c).

Article 8

Measures to be taken in the event of non-compliance with this Regulation

The competent authority shall take appropriate action immediately in the case of any non-compliance.

Article 9

Entry into force and applicability

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

2. It shall apply from 1 May 2004.

3. However, the certificates drawn up in the format under Commission Regulation (EC) No 812/2003 may be used until 15 June 2004.

4. Member States shall authorise until 15 August 2004 the import of consignments which have left the third country before 15 June 2004, and which may still be accompanied by the certificates referred to in point 3 above.

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

Done at Brussels, 29 April 2004.

For the Commission

David BYRNE

Member of the Commission