►B ►M1 **COMMISSION REGULATION (EC) No 878/2004**

of 29 April 2004

laying down transitional measures for certain animal by-products defined as Category 1 and 2 materials, in accordance with Regulation (EC) No 1774/2002 of the European Parliament and of the Council. ◄

(Text with EEA relevance)

(OJ L 162, 30.4.2004, p. 62)

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(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.

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[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).

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(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.

(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:

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Article 1

Scope

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

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

(b) rendered fats derived from Category 1 material produced using Method 1 as referred to in Chapter III of Annex V to Regulation (EC) No 1774/2002, which in the case of 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 complying with at least the standards in Chapter III of Annex VI to Regulation (EC) No 1774/2002;

([1]) OJ L 125, 23.5.1996, p. 3.

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

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

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

2. This Regulation shall apply to the following animal by-products, defined as Category 2 material in Regulation (EC) No 1774/2002 in accordance with Article 5(1)(g) of that Regulation, which are intended for feeding to animals other than farmed land animals, for feeding to farmed fur animals or for technical uses, including fishing baits:

(a) terrestrial invertebrates other than species pathogenic to animals or to humans, including any of their transformation forms, such as larvae;

(b) aquatic animals, except sea mammals, if not originating from aquaculture;

(c) aquaculture animals bred specifically for the purpose of using them as fishing bait provided the bait are not used in aquaculture without prior processing;

(d) animals belonging to the zoological orders of *Rodentia* and *Lagomorpha*, including those kept as farmed animals for the production of products of animal origin; and

(e) products derived from or produced by the animals referred to in (a) to (d), such as fish eggs, but excluding meal derived from animals referred to in (d).

Article 1a

Derogation regarding commercial documents and health certificates

By way of derogation from point 1 of Chapter III of Annex II to Regulation (EC) No 1774/2002, animal by-products referred to in Article 1(2) of the present Regulation may be supplied by retailers to final users other than business operators without being accompanied during transportation by a commercial document or, when required by Regulation (EC) No 1774/2002, a health certificate.

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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 ►M1 points (c) and (d) of Article 1(1) ◄ of this Regulation.

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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 ►M1 paragraphs (1) or (2), as appropriate, 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.

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As regards animal by-products referred to in Article 1 (1), 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 ([1]).

Article 5

Labelling, delivery, record keeping and treatment requirements

1. In addition to the identification requirements provided for in Chapter I of Annex II to Regulation (EC) No 1774/2002, all packages of animal by-products referred to in Article 1(1) of the present Regulation, shall bear a label indicating 'PROHIBITED IN FOOD, FEED, FERTILISERS, COSMETICS, MEDICINAL PRODUCTS AND MEDICAL DEVICES'.

However, in case of animal by-products intended for medicinal products in accordance with Community legislation a different label may be used which shall indicate 'DESTINED FOR MEDICINAL PRODUCTS ONLY'.

2. All packages of animal by-products referred to in Article 1(2), shall bear a label indicating 'NOT FOR HUMAN CONSUMPTION', unless they are dispatched in ready-to-sell packages, indicating that the content is destined for the feeding to pets only or for the use as fishing bait.

3. The animal by-products referred to in Article 1 of the present Regulation shall be delivered to a technical plant dedicated to the use of such materials and which has been approved in accordance with Article 18(1) of Regulation (EC) No 1774/2002.

The animal by-products referred to in Article 1(2) may also be delivered:

(a) to an intermediate plant approved in accordance with Article 10(1) of Regulation (EC) No 1774/2002;

(b) to a storage plant approved in accordance with Article 11(1) of Regulation (EC) No 1774/2002;

([1]) OJ L 24, 30.1.1998, p. 9.

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(c) to a petfood plant approved in accordance with Article 18(1) of Regulation (EC) No 1774/2002;

(d) to a holding or establishment keeping animals in accordance with the requirements referred to in Article 23(2)(c) of Regulation (EC) No 1774/2002;

(e) to the place of manufacture or the manufacturing establishment, as appropriate, of

(i) cosmetic products in accordance with Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products [1],

(ii) veterinary medicinal products in accordance with Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products [2],

(ii i) medicinal products in accordance with Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [3],

(iv) medical devices in accordance with Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [4] or

(v) in vitro diagnostic devices in accordance with Directive 98/79/EC of the European Parliament and the Council of 27 October 1998 on in vitro diagnostic medical devices [5]; or

(f) directly for retail sale where the animal by-products are:

(i) dispatched in ready-to-sell packages bearing a label with a clear indication that the content is only destined for:

— the feeding to pets; or fishing bait

(ii) dried by a treatment sufficient to destroy pathogenic organisms, including *salmonella*; or

(iii) in the case of animal by-products referred to in Article 1(2)(b), (c) and, as regards *Rodentia*, (d) deep frozen;

Without prejudice to Commission Regulation (EC) No 811/2003 of 12 May 2003 implementing Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards the intra-species recycling ban for fish, the burial and burning of animal by-products and certain transitional measures [6], the animal by-products referred to in Article 1(2)(b) of the present Regulation may also be delivered for the use as feed material to a holding or establishment keeping aquatic animals.

4. The owner, operator or their representative of the plants, holdings or establishments referred to in paragraph 3 of this Article shall:

(a) keep records in accordance with Article 9 of Regulation (EC) No 1774/2002;

(b) ensure that the animal by-products are subjected, where appropriate, to a treatment which satisfies the competent authority in such a way

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[1] OJ L 262, 27.9.1976, p. 169. Directive as last amended by Commission Directive (EC) No 2006/78, (OJ L 271, 30.9.2006, p. 56).
[2] OJ L 311, 28.11.2001, p. 1. Directive as last amended by Directive 2004/28/EC (OJ L 136, 30.4.2004, p. 58).
[3] OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).
[4] OJ L 169, 12.7.1993, p. 1. Directive as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).
[5] OJ L 331, 7.12.1998, p. 1. Directive as amended by Regulation (EC) No 1882/2003.
[6] OJ L 117, 13.5.2003, p. 14.

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that the resulting material does not pose a risk to animal and public health;

(c) further dispatch or use the animal by-products exclusively for purposes authorised by the competent authority.

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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 ►M1 Article 5(3) ◄.

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.

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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.