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POINT 35

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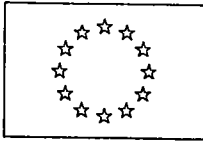
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(Amendment of Regulation (EC) No 878/2004)

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
C(2004)

Draft

COMMISSION REGULATION

of

**amending Regulation (EC) No 878/2004 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**

Draft

COMMISSION REGULATION

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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 consumption¹, and in particular Articles 4(4), 5(4) and 32(1) thereof,

Whereas:

- (1) Regulation (EC) No 1774/2002 lays down health rules concerning animal by-products not intended for human consumption. That Regulation defines animal by-products as Categories 1, 2 and 3 material, depending on the risk arising from such products.
- (2) In accordance with that Regulation, animal by-products other than Category 1 or 3 material are defined as Category 2 material, irrespective of any further considerations regarding the risk arising from such products. The permitted use of animal by-products for feeding purposes is dependent on whether such material is defined as Category 1, 2 or 3 material. While certain Category 3 material may be used for feeding purposes, Category 2 material is generally excluded from such use.
- (3) However, certain animal by-products which may be considered as posing a low risk do not come within the definition of Category 3 material in Regulation (EC) No 1774/2002. The definition of such material, by default, as Category 2 material does not correspond with the risks arising from such products.
- (4) 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 purposes² was adopted in order to permit the continued placing on the market, export, import and transit of certain animal by-products defined as Category 1 and 2 material, intended exclusively for technical uses.

¹ OJ L 273, 10.10.2002, p.1. Regulation as last amended by Commission Regulation (EC) No 208/2006 (OJ L 36, 8.2.2006, p. 25).

² OJ L 162, 30.4.2004, p. 62.

- (5) The Report on animal by-products³ adopted by the Commission on 21 October 2005 and presented to the Council on 24 October 2005 reflects the difficulties concerning the definition of certain material as Category 2 material and envisages a number of amendments to Regulation (EC) No 1774/2002 in the course of the review of that legislation scheduled to start from the end of 2006.
- (6) Pending those amendments it should be possible to use certain low risk animal by-products presently defined as Category 2 material for certain feeding and for technical purposes. Accordingly, the scope of Regulation (EC) No 878/2004 should be extended in order to permit the use of certain Category 2 low risk material for the manufacture of technical products and for certain feeding purposes.
- (7) Regulation (EC) No 878/2004 should therefore be amended accordingly.
- (8) 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

Commission Regulation (EC) No 878/2004 is amended as follows:

- (1) The title is replaced by the following:

‘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’

- (2) Article 1 is replaced by the following:

‘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 other than fertilisers, cosmetics and medical devices:
 - (a) hides and skins derived from animals which have been treated with substances which are prohibited pursuant to Directive 96/22/EC⁴;
 - (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

³ COM(2005) 521 Final.

⁴ OJ L 125, 23.5.1996, p. 3.

derivatives complying with at least the standards in Chapter III of Annex VI to Regulation (EC) No 1774/2002;

- (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 and for feeding to farmed fur animals and for technical uses, such as fishing baits.

- (a) animals of the zoological class *Insecta (Hexapoda)*, including any of their transformation forms, such as larvae;
- (b) worms of the zoological *phyla Aschelminthes* and *Annelida*;
- (c) aquatic animals, except sea mammals, if not originating from aquaculture;
- (d) aquaculture animals bred specifically for the purpose of using them as fishing bait provided the bait are not used in aquaculture without prior processing;
- (e) animals belonging to the zoological orders of *Rodentia* and *Lagomorpha*; and
- (f) products derived from or produced by the animals referred to in (a) to (e), such as meal or fish eggs.

(3) The following Article 1a is inserted:

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.'

(4) Article 5 is replaced by the following:

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;
- (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 of 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 products⁵, to the manufacturing establishment of 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 use⁶ or to the manufacturing site of medical devices in accordance with Council Directive 93/42/EEC of 14 June 1993 concerning medical devices⁷; or

⁵ Official Journal L 262, 27.9.1976, p. 169m, as last amended by _____

⁶ Official Journal L 311, 28/11/2001 p. 67 - 128, as last amended by _____

⁷ Official Journal L 169, 12.7.1993, as last amended by _____

- (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)(c) or (d) deep frozen;

Without prejudice to Commission Regulation (EC) No 811/2003 of 12 May 2003 as regards the intra-species recycling ban for fish, the burial and burning of animal by-products and certain transitional measures⁸, the animal by-products referred to in Article 1(2)(c) 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 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.

Article 2

This Regulation shall enter into force from the third 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, [...]

For the Commission
Markos Kyprianou
Member of the Commission

⁸ OJ L 117, 13.5.2003, p. 14.

