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(Acts whose publication is obligatory)

COUNCIL REGULATION (EC) No 1756/2002

of 23 September 2002

amending Directive 70/524/EEC concerning additives in feedingstuffs as regards withdrawal of the authorisation of an additive and amending Commission Regulation (EC) No 2430/1999

(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs ([1]), and in particular Article 9m thereof,

Having regard to the proposal from the Commission,

Whereas:

(1) The coccidiostat Nifursol, a nitrofuran, was authorised for use as an additive in feedingstuffs for the first time by Commission Directive 82/822/EEC ([2]). This authorisation was linked to a person responsible for putting it into circulation for a period of ten years by means of Commission Regulation (EC) No 2430/1999 ([3]), without a re-evaluation.

(2) Article 9m provides for the withdrawal of the authorisation of an additive if any of the conditions for its authorisation set out in Article 3a of Directive 70/524/EEC is no longer satisfied.

(3) During the period between 1990 and 1995, both the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Committee for Veterinary Medicinal Products (CVMP) gave opinions on the use of veterinary medicinal products in food-producing animals of the group of substances known as nitrofurans. They concluded that it was not possible, because of the genotoxicity and carcinogenicity of the substance, to identify an acceptable daily intake (i.e. a level of intake by humans of residues of the substances which could be regarded as safe). Accordingly, it was not possible to set maximum residue levels for the substances. All nitrofurans were therefore inserted into Annex IV to Council Regulation (EEC) No 2377/90 ([4]), with the effect of prohibiting throughout the Community the administration of these substances, as veterinary medicinal products, to food-producing animals.

(4) The Commission therefore asked the Scientific Committee for Animal Nutrition (SCAN) to make a new scientific risk assessment of Nifursol, which belongs also to the group of nitrofurans.

(5) The SCAN adopted an opinion concerning Nifursol on 11 October 2001, which concluded that on the basis of the mutagenicity, genotoxicity and carcinogenicity studies provided by the person responsible for putting Nifursol into circulation, and because of the lack of data on developmental toxicity, it was not possible to derive an acceptable daily intake for the consumers. The SCAN confirmed this opinion on 18 April 2002 after having examined complementary data.

(6) Therefore, it cannot be guaranteed that Nifursol does not present a risk for human health.

(7) Article 3a(b) of Directive 70/524/EEC states that Community authorisation of an additive shall be given only if, taking into account the conditions of use, it does not adversely affect human or animal health or the environment, nor harm the consumer by impairing the characteristics of animal products.

(8) Consequently, as a condition laid down in Article 3a of that Directive is no longer met for the coccidiostat Nifursol, the use of the substance as an additive in feedingstuff should no longer be permitted. Regulation (EC) No 2430/1999 and the entry of this coccidiostat in Chapter II of Annex B to Directive 70/524/EEC should be amended accordingly.

([1]) OJ L 270, 14.12.1970, p. 1. Directive as last amended by Commission Regulation (EC) No 2205/2001 (OJ L 297, 15.11.2001, p. 3).
([2]) Forty-first Commission Directive 82/822/EEC of 19 November 1982 amending the Annexes to Council Directive 70/524/EEC concerning additives in feedingstuffs (OJ L 347, 7.12.1982, p. 16).
([3]) OJ L 296, 17.11.1999, p. 3.
([4]) Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ L 224, 18.8.1990, p. 1). Regulation as last amended by Commission Regulation (EC) No 1530/2002 (OJ L 230, 28.8.2002, p. 3).

(9) In the absence of a favourable opinion of the Standing Committee on the Food Chain and Animal Health, the Commission has been unable to adopt the provisions it envisaged under the procedure laid down in Article 23 of Directive 70/524/EEC,

HAS ADOPTED THIS REGULATION:

Article 1

1. In Annex I to Commission Regulation (EC) No 2430/1999 the entry relating to the additive E 769, Nifursol, shall be deleted.

2. In Chapter II of Annex B to Directive 70/524/EEC, the entry relating to Nifursol, a substance belonging to the group of coccidiostats and other medicinal substances, shall be deleted.

Article 2

This Regulation shall enter into force on the seventh day following its publication in the *Official Journal of the European Communities*.

It shall apply from 31 March 2003.

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

Done at Brussels, 23 September 2002.

For the Council

The President

M. FISCHER BOEL