Proposal for a Council Regulation amending Council 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

(2002/C 262 E/24)

COM(2002) 367 final

(Submitted by the Commission on 8 July 2002)

EXPLANATORY MEMORANDUM

The purpose of this Regulation is to withdraw the authorisation for use as an additive in feedingstuffs of the coccidiostat Nifursol, a histomonostat belonging to the nitrofuran group.

In October 2001 the Scientific Committee for Animal Nutrition adopted an opinion which concluded that, on the basis of the mutagenicity, genotoxicity and carcinogenicity studies provided by the person responsible for putting the substance into circulation, it was not possible to derive an Acceptable Daily Intake for the consumers.

The company submitted then a further set of data, which have been evaluated by the Scientific Committee for Animal Nutrition. In its opinion of April 2002, the Committee has confirmed the previous one.

Therefore it is not possible to guarantee that the product is safe for the human health.

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

Under the procedure laid down in Article 23 of Council Directive 70/524/EEC, concerning additives in feedingstuffs, the Commission sought the opinion of the Standing Committee on the Food Chain and Animal Health on a draft Commission Regulation, which withdraws the authorisation of the additive 'Nifursol' belonging to the group of coccidiostats and other medicinal substances.

Owing to the fact that the Standing Committee on the Food Chain and Animal Health failed to deliver a favourable opinion on 23 May 2002, the Commission is required, under the abovementioned Article, to refer the proposed measures to the Council. The Council will have three months to decide. If the Council fails to reach a decision, the Commission will adopt the measures, except where the Council has voted by a simple majority against such measures.

This proposal has no financial impact on the budget of the European Communities.

It is based on an exclusive Community competence.

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], as last amended by Commission Regulation (EC) No 2205/2001 [2], 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 [3]. 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 [4], without a re-evaluation.

[1] OJ L 270, 14.12.1970, p. 1.

[2] OJ L 297, 15.11.2001, p. 3.

[3] OJ L 347, 7.12.1982, p. 16.

[4] OJ L 296, 17.11.1999, p. 3.

(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 of Council Regulation (EEC) No 2377/90, 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 to 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) It cannot be guaranteed that Nifursol does not present a risk for human health.

(7) Article 3a(b) 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 Directive 70/524/EEC 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.

(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. Annex I to Commission Regulation (EC) No 2430/1999 is amended as follows:

   The entry relating to the additive E 769, Nifursol, is deleted.

2. Chapter II of Annex B to Directive 70/524/EEC is amended as follows:

   The following substance belonging to the group of coccidiostats and other medicinal substances shall be deleted:

   — Nifursol.

Article 2

This Regulation shall enter into force on the 7th day following its publication in the *Official Journal of the European Communities*.

It shall apply from 30 November 2002.

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