COMMISSION REGULATION (EC) No 2205/2001

of 14 November 2001

amending Council Directive 70/524/EEC concerning additives in feedingstuffs as regards withdrawal of the authorisation of certain additives

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

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 Directive 2001/46/EC of the European Parliament and of the Council [2], and in particular Article 9g(4) thereof,

Whereas:

(1) As provided for in Article 9g(1) of Directive 70/524/EEC, antibiotics and coccidiostats included in Annex I to that Directive before 1 January 1988 were provisionally authorised as from 1 April 1998 and transferred to Chapter I of Annex B with a view to their reevaluation as additives linked to a person responsible for putting them into circulation.

(2) New applications for authorisation had to be submitted for the abovementioned additives. Furthermore, Article 9g(4) of Directive 70/524/EEC required that the dossiers in respect of these applications be submitted, as provided for in Article 4 of that Directive and no later than 30 September 2000, with a view to reevaluation.

(3) Dossiers were submitted before 1 October 2000 for the coccidiostats meticlorpindol, meticlorpindol/methylbenzoquate, amprolium, amprolium/ethopabate, dimetridazole and nicarbazin and for the antibiotic flavophospholipol.

(4) In accordance with Article 4(4) of Directive 70/524/EEC, Member States checked the compliance of the dossiers with Council Directive 87/153/EEC of 16 February 1987 fixing guidelines for the assessment of additives in animal nutrition [3], as last amended by Commission Directive 2001/79/EC [4], within a period of 60 days from the date on which the dossiers were dispatched to them.

(5) After consultation of the Standing Committee on Feedingstuffs and in accordance with Article 4(5) of Directive 70/524/EEC, the applicants for authorisation of the abovementioned coccidiostats were notified by the Commission that the rules on administrative presentation of the dossiers had not been complied with, in so far as data ranging from substance identification to important toxicological information were missing.

(6) Similarly, after consultation of the Standing Committee on Feedingstuffs and in accordance with Article 4(5) of Directive 70/524/EEC, the applicant for authorisation of the abovementioned antibiotic was notified by the Commission that the rules on administrative presentation of the dossier had not been complied with for certain animal categories, in so far as efficacy data and data related to tolerance tests were missing for these categories.

(7) In order to ensure that the deficiencies in submitting the necessary data were not due to unforeseen delivery reasons, an extra time of three weeks was given to allow the above referred applicants to submit the missing information.

(8) For several substances, complementary information was submitted but this was not sufficient to comply with Directive 87/153/EEC, while for the other substances concerned, no complementary data were sent to the Commission within the extra time given.

(9) Since the requirements of Directive 70/524/EEC have not been met for the abovementioned coccidiostats, the authorisation granted to these additives should be withdrawn and their entries deleted from Chapter I of Annex B to the Directive.

(10) Since the requirements of Directive 70/524/EEC have not been met for the antibiotic flavophospholipol as regards certain animal categories, the entry of the antibiotic in Chapter I of Annex B to the Directive should be amended accordingly.

(11) It is appropriate to allow a limited period of time within which existing stocks of the coccidiostats and the antibiotic covered by this Regulation may be used.

(12) The Standing Committee for Feedingstuffs has not given an opinion, the Commission has therefore proposed these measures to the Council on 25 July 2001 in accordance with Article 23 of Directive 70/524/EEC, the Council being required to act within three months.

(13) The Council has not acted within the required time limit. The Council has not decided against the proposed measures by simple majority within the same time limit. These measures should now be adopted by the Commission,

[1] OJ L 270, 14.12.1970, p. 1.
[2] OJ L 234, 1.9.2001, p. 55.
[3] OJ L 64, 7.3.1987, p. 19.
[4] OJ L 267, 6.10.2001, p. 1.

HAS ADOPTED THIS REGULATION:

Article 1

Chapter I of Annex B to Directive 70/524/EEC shall be amended as follows:

1. The following substances belonging to the group of coccidiostats and other medicinal substances shall be deleted:
   — meticlorpindol,
   — meticlorpindol/methylbenzoquate,
   — amprolium,
   — amprolium/ethopabate,
   — dimetridazole,
   — nicarbazin.

2. The entries in relation to flavophospholipol are amended as follows:

   (a) the animal category 'Animals bred for fur, excluding rabbits' is deleted;

   (b) the animal category 'Other poultry, excluding ducks, geese, pigeons' is replaced by the animal category 'Chickens for fattening'.

Article 2

This Regulation shall enter into force six months after its publication in the *Official Journal of the European Communities*.

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

Done at Brussels, 14 November 2001.

For the Commission

David BYRNE

Member of the Commission