



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 25.7.2001  
COM(2001) 450 final

Proposal for a

**COUNCIL REGULATION**

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

(presented by the Commission)

## EXPLANATORY MEMORANDUM

The purpose of this Regulation is to withdraw the authorisation of certain additives and to replace one animal category for an additive.

Following the procedure laid down in Article 9g (1) and (4) and of Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs<sup>1</sup>, dossiers were submitted before 1 October 2000 for amongst other the coccidiostats meticlorpindol, meticlorpindol/methylbenzoquate, amprolium, amprolium/ethopabate, dimetridazole and nicarbazin and for the antibiotic flavophospholipol with a view to their re-evaluation as additives to be linked to a person responsible for putting them into circulation.

In accordance with the procedure laid down in Article 4 (4) and (5) of Council Directive 70/524/EEC, 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<sup>2</sup> was verified.

The applicants for authorisation of the above mentioned substances were notified by the Commission that their dossiers were not in compliance with Council Directive 87/153/EEC, because compulsory information was missing.

Similarly, the applicant for authorisation of the above mentioned 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.

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

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 given time frame.

Since the requirements of Directive 70/524/EEC have not been met for the following six coccidiostats and other medicinal substances, their authorisation should be withdrawn and their entries deleted from Chapter I of Annex B to the Directive:

- meticlorpindol,
- meticlorpindol/methylbenzoquate,
- amprolium,
- amprolium/ethopabate,
- dimetridazole,
- nicarbazin.

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<sup>1</sup> OJ L 270, 14.12.1970, p. 1.

<sup>2</sup> OJ L 64 du 7.3.1987, p. 19.

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 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”.

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 Feedingstuffs on a draft Commission Regulation, which withdraws the authorisation of the six above-mentioned additives belonging to the group of coccidiostats and other medicinal substances. It also withdraws the use of the antibiotic flavophospholipol for the animal category “animals bred for fur, excluding rabbits” and replaces for the same antibiotic the animal category “other poultry, excluding ducks, geese, pigeons” by the animal category “chickens for fattening”.

Owing to the fact that the Standing Committee for Feedingstuffs failed to deliver an opinion on 9 July 2001, the Commission is required, under the above-mentioned Article, to refer the proposed measures to the Council. The Council will have 3 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.

Proposal for a

## COUNCIL REGULATION

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

**(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<sup>3</sup>, as last amended by Council Directive 1999/20/EC<sup>4</sup>, and in particular Article 9g (4) thereof,

Having regard to the proposal from the Commission<sup>5</sup>,

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 re-evaluation as additives linked to a person responsible for putting them into circulation.
- (2) New applications for authorisation had to be submitted for the above mentioned additives. Further, 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 re-evaluation.
- (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 Directive 87/153/EEC of 16 February 1987 fixing guidelines for the assessment of additives in animal nutrition<sup>6</sup>, as last amended by Commission Directive 95/11/CE<sup>7</sup> within a period of sixty days from the date on which the dossiers were dispatched to them.

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<sup>3</sup> OJ L 270, 14.12.1970, p. 1.

<sup>4</sup> OJ L 80, 25.3.1999, p. 20.

<sup>5</sup> OJ C ..., ..., p. ...

<sup>6</sup> OJ L 64, 7.3.1987, p. 19.

<sup>7</sup> OJ L 106, 11.5.1995, p. 23.

- (5) After consultation of the Standing Committee on Feedingstuffs and in accordance with Article 4 (5) of Directive 70/524/EC, the applicants for authorisation of the above mentioned 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/EC, the applicant for authorisation of the above mentioned 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 above mentioned 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) In the absence of an opinion of the Standing Committee for Feedingstuffs, 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*

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/methylbenzoate,
  - 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,

*For the Council  
The President*