COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 26.07.1999
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99/0168 (CNS)

Proposal for a

COUNCIL DIRECTIVE

amending Directive 70/524/EEC concerning additives in feedingstuffs

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs[1], as amended by Directive 96/51/EC[2], establishes for high technology additives with a very specific composition (antibiotics, coccidiostats and other medicinal substances, and growth promoters) a system where the authorisation will be linked to a person responsible for putting the additive into circulation, in order to protect for a period fixed at ten years, scientific data or information which require costly investment. It is provided for that the Commission replaces the existing authorisations by authorisations linked to a person responsible for putting the additive into circulation through the adoption of a regulation.

   The purpose of this proposed amendment is to ensure that these replacements can take place at the same time for all additives concerned, independently of the date when their authorisation was granted.

2. Actually, Directive 70/524/EEC foresees different treatment of high technology additives depending on the date of authorisation. In difference to those which were authorised after 31 December 1987, high technology additives authorised before that date have to undergo a re-evaluation procedure. But, beyond that distinction, while the replacement of the authorisations granted after 31 December 1987 is foreseen for 1 October 1999, a legal basis for a replacement of the authorisations granted before 1 January 1988 is missing. Article 9g provides only for a replacement after completion of the re-evaluation in 2003.

   According to this legal situation, the consequence would be that copies may remain in circulation after 1 October 1999, which have been evaluated according to standards lower than those which were applied to substances authorised more recently (after 31 December 1987). Moreover, this applies not only to substances but also to uses of substances, authorised subsequently to those authorised at the first authorisation of the substance. Therefore it may occur in many cases, that a copy may still be put into circulation because a certain use of the substance was authorised before 1988, while the authorisation of the same substance authorised subsequently for another use would be linked to a person responsible for putting it into circulation.

3. This is not acceptable, is contrary to the intentions of the legislator and should be corrected. To re-establish a coherent legal situation, the Commission proposes to introduce a legal basis in Directive 70/524/EEC for the replacement of the authorisations of those additives authorised before 1 January 1988 already on 1 October 1999.

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

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1 OJ L 270, 14.12.1970, p. 1. Directive as last amended by Commission Regulation (EC) No 1411/99 (OJ L 164,30.6.1999, p. 56).

2 OJ L 235, 17.9.1996,p. 39.

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THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 37 thereof,

Having regard to the proposal from the Commission[3],

Having regard to the opinion of the European Parliament[4],

Having regard to the opinion of the Economic and Social Committee[5],

(1) Whereas Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs[6], as amended by Directive 96/51/EC[7], establishes for high technology additives with a very specific composition (antibiotics, coccidiostats and other medicinal substances, and growth promotors) a system where the authorisation will be linked to a person responsible for putting the additive into circulation, in order to protect for a period fixed at ten years, scientific data or information which require costly investment;

(2) Whereas it is therefore laid down in Directive 70/524/EEC that the Commission replaces the existing authorisations by authorisations linked to a person responsible for putting the additive into circulation through the adoption of a regulation; whereas in the case of additives included in Annex I of Directive 70/524/EEC after the 31 December 1987 and in the case of additives included in Annex II of the said Directive before April 1998 it is laid down in Article 9h and 9i respectively that these regulations take effect no later than 1 October 1999;

(3) Whereas, in contrast, in the case of additives included in Annex I of Directive 70/524/EEC before 1 January 1988, according to Article 9g of the said Directive, authorisations will have to be linked to the person responsible for putting the additive into circulation by 1 October 2003 in order to enable their evaluation in accordance with Article 4 of the directive;

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3 OJ C

4 OJ C

5 OJ C

6 OJ L 270, 14.12.1970, p. 1. Directive as last amended by Commission Regulation (EC) No 1411/99 (OJ L 164,30.6.1999, p. 56).

7 OJ L 235, 17.9.1996, p. 39.

(4) Whereas the fact that a re-evaluation of the substances authorised before 1 January 1988 is regarded to be necessary, does not justify that their copies may continue to be put into circulation after October 1999, while copies of the other substances authorised after 1 January 1988 may not be put into circulation after 1 October 1999; whereas in many cases according to the existing provisions it may occur, that a copy product may still be put into circulation because a certain use of the substance was authorised before 1988, while the authorisation of the same substance authorised subsequently for a certain use would be linked to a person responsible for putting the additive into circulation; whereas it is necessary to establish coherent conditions in this respect for all additives belonging to the groups of antibiotics, coccidiostats and other medicinal substances, and growth promoters;

(5) Whereas the relevant provision in Directive 70/524/EEC should be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The paragraphs 4, 5 and 6 of Article 9g of Directive 70/524/EEC are replaced by the following:

"4. In accordance with the procedure laid down in Article 23, provisional authorisations of the additives referred to in paragraph 1 shall be replaced by provisional authorisations linked to the person responsible for putting them into circulation through the adoption of a regulation taking effect no later than 1 October 1999 and the additives shall be included in Chapter II of the list referred to in Article 9t (b).

5. Member States shall ensure that the person responsible for putting an additive referred to in paragraph 1 into circulation submits, as provided for in Article 4 and not later than 30 September 2000, the dossier referred to in Article 4 with a view to re-evaluation. Where he fails to do so, the provisional authorisation linked to the person responsible for putting the additive in question into circulation as referred to in paragraph 4 shall be withdrawn through the adoption of a regulation in accordance with Article 23.

6. The Commission shall take the necessary measures to ensure that the re-evaluation of the dossiers submitted in accordance with paragraph 5 is completed no later than three years after the dossier is submitted.

In accordance with the procedure laid down in Article 23, authorisations of the additives referred to in paragraph 1:

(a) shall be withdrawn through the adoption of a regulation, or

(b) shall be replaced by authorisations linked to the person responsible for putting them into circulation which shall be given for a period of 10 years, including the period of the provisional authorisation referred to in paragraph 4, through the adoption of a regulation taking effect no later than 1 October 2003 and included in Chapter I of the list referred to in Article 9t (b).

7. The provisions of Article 9b (3) shall apply *mutatis mutandis.*"

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 September 1999. They shall forthwith inform the Commission thereof. When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the Council
The President