

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 29.1.2003
COM(2003) 39 final

Proposal for a

COUNCIL REGULATION

Concerning the authorisation of an additive in feedingstuffs

(presented by the Commission)

EXPLANATORY MEMORANDUM

The purpose of this Regulation is to extend the provisional authorisation for use of avilamycin as a growth promoter in feed for turkeys. In application of Article 9 of Directive 70/524/EEC this extension of this period is limited to a period 10 years.

The assessment of the dossier submitted in respect of the antibiotic preparation described in the Annex to this Regulation, shows that the conditions referred to in Article 3a of Directive 70/524/EEC are satisfied, and the product may therefore be inscribed in Chapter I of the list of the authorised additives in feedingstuffs in application of Article 9t (b).

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 authorises avilamycin for a period of 10 years.

Owing to the fact that the Standing Committee on the Food Chain and Animal Health failed to deliver an opinion on 20 December 2002, 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

Concerning the authorisation of an additive in feedingstuffs

(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], as last amended by Council Regulation N°1756/2002[2] and in particular Article 9 thereof,

Whereas:

(1) Article 2 (aaa) requires authorisations for antibiotics to be linked to the person responsible for putting them into circulation.

(2) Article 9 provides that a substance linked to a responsible for putting it into circulation may be authorised for a period of ten years if all conditions laid down in Article 3a are met.

(3) The assessment of the dossier submitted in respect of the antibiotic preparation described in the Annex to this Regulation, shows that the conditions referred to in Article 3a are satisfied, and the product may therefore be inscribed in Chapter I of the list of the authorised additives in feedingstuffs in application of Article 9t (b). This list provides for additives authorised for a period of ten years.

(4) The Communication of the Commission of July 2001 on a Community strategy against antimicrobial resistance sets out the elements for an effective policy against antimicrobial resistance. One of these elements is the ban of the use of antibiotics in feedingstuffs as growth promoters from 1 January 2006.

(5) The Commission has submitted a proposal for a Regulation of the Parliament and of the Council on additives for use in animal nutrition (COM (2002) 153-final) which provides for the phasing out of the use of the last remaining antibiotics for growth promotion from 1 January 2006. The duration of the authorisation provided for in the present Regulation will therefore have to be kept under review to take account of steps taken in that regard.

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1 OJ L 270, 14.12.1970, p. 1.
2 OJ L 265, 3.10.2002, p. 1

(6) 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

The additive belonging to the group "Antibiotics" listed in the Annex to the present Regulation is authorised for use as additive in animal nutrition under the conditions laid down in that Annex.

Article 2

This Regulation shall enter into force on the day following that of 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
[…]

ANNEX

Registration number of additive	Name and registration No. of person responsible for putting additive into circulation	Additive (trade name)	Composition, chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of authorisation period
						mg/kg of complete feedingstuffs			
Antibiotics									
E717	Eli Lilly and Company Ltd.	Avilamycin: 200 g/kgx (Maxus G200, Maxus 200) Avilamycin: 100 g/kg (Maxus G100, Maxus 100)	**Additive composition:** Avilamycin: 200 g activity/kg Soyabean oil or mineral oil: 5 to 30 g/kg Soyabean hulls qs 1 kg Avilamycin: 100 g activity/kg Soyabean oil or mineral oil: 5 to 30 g/kg Soyabean hulls qs 1 kg **Active substance:** $C_{57-62}H_{82-90}Cl_{1-2}O_{31-32,}$ CAS No. of avilamycin A: 69787-79-7 CAS No. of avilamycin B: 73240-30-9 Mixture of oligosaccharides of the orthosomycin group produced by *Streptomyces viridochromogenes*,(NRRL 2860) in granular form. **Factor composition:** Avilamycin A: ≥ 60%. Avilamycin B: ≤ 18% Avilamycin A+B: ≥ 70% Other single avilamycins ≤ 6%	Turkeys	-	5	10	-	20.01.2013