



**COUNCIL OF
THE EUROPEAN UNION**

**Brussels, 13 February 2003
(OR. en)**

6120/03

**AGRILEG 30
OC 35**

LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject : Council Regulation on the authorisation of the additive avilamycin in
feedingstuffs
COMMON GUIDELINES
Time limit for consultation: 19.02.2003

COUNCIL REGULATION (EC) No /2003

of

on the authorisation of the additive avilamycin 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, and in particular Article 9 thereof,

¹ OJ L 270, 14.12.1970, p. 1. Directive as last amended by Council Regulation (EC) No 1756/2002 (OJ L 265, 3.10.2002, p. 1).

Whereas:

- (1) Article 2(aaa) of Directive 70/524/EEC requires authorisations for antibiotics to be linked to the person responsible for putting them into circulation.
- (2) Article 9 of the said Directive provides that a substance linked to the person responsible for putting it into circulation may be authorised for a period of ten years if all conditions laid down in Article 3a of the said Directive 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 of the said Directive are satisfied, and the product may therefore be entered in Chapter I of the list of the authorised additives in feedingstuffs pursuant to Article 9t(b) of the said Directive. 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 European Parliament and of the Council on additives for use in animal nutrition which provides for the phasing out of the use of antibiotics for growth promotion. The European Parliament during its first reading of the proposal supported a phasing out. The Council reached in December 2002 a political agreement in view of the adoption of a common position providing for the discontinuation of the use of antibiotics as growth promoters by 1 January 2006. The duration of the authorisation provided for in this Regulation is therefore likely to be substantially reduced as an effect of the adoption of the new Regulation governing the use of additives in animal nutrition.
- (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 the said Directive,

HAS ADOPTED THIS REGULATION:

Article 1

The additive avilamycin belonging to the group "Antibiotics" listed in the Annex shall be authorised for use as an additive in animal nutrition under the conditions laid down in the Annex.

Article 2

This Regulation shall enter into force on the day following that of its publication in the Official Journal of the European Union.

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

Done at Brussels,

For the Council
The President

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.	<p>Avilamycin: 200 g/kg (Maxus G200, Maxus 200)</p> <p>Avilamycin: 100 g/kg (Maxus G100, Maxus 100)</p> <p>Active substance: C₅₇₋₆₂H₈₂₋₉₀Cl₁₋₂ O₃₁₋₃₂, 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 <i>Streptomyces viridochromogenes</i>, (NRRL 2860) in granular form.</p> <p>Factor composition: Avilamycin A: ≥ 60%. Avilamycin B: ≤ 18% Avilamycin A+B: ≥ 70% Other single avilamycins ≤ 6%</p>	<p>Additive composition:</p> <p>Avilamycin: 200 g activity/kg Soyabean oil or mineral oil: 5 to 30 g/kg Soyabean hulls qs 1 kg</p> <p>Avilamycin: 100 g activity/kg Soyabean oil or mineral oil: 5 to 30 g/kg Soyabean hulls qs 1 kg</p> <p>Turkeys</p> <p>–</p> <p>5</p> <p>10</p> <p>–</p> <p>20.1.2013</p>						