COMMISSION REGULATION (EC) No 2562/1999

of 3 December 1999

linking the authorisation of certain additives belonging to the group of antibiotics in feedingstuffs to persons responsible for putting them into circulation

(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 Commission Regulation (EC) No 2439/1999 ([2]), and in particular Article 9h(3)(b) and Article 9i(3)(b), thereof,

Whereas:

(1) because of the risk for human and animal health posed by the circulation in the Community of poor copies of zootechnical additives, Directive 70/524/EEC, as amended by Council Directive 96/51/EC ([3]), provides for the linking of the authorisation of certain classes of additives to the person responsible for putting them into circulation;

(2) in particular Article 9h of Directive 70/524/EEC provides for the replacement of the provisional authorisations of additives included in Annex I after 31 December 1987 and belonging to the group of antibiotics and transferred to Chapter II of Annex B, by authorisations linked to the person responsible for putting them into circulation for a period of ten years;

(3) in particular Article 9i of Directive 70/524/EEC provides for the replacement of the provisional authorisations of additives included in Annex II before 1 April 1998 and belonging to the group of antibiotics and transferred to Chapter III of Annex B by provisional authorisations linked to the person responsable for putting them into circulation;

(4) the additives listed in the Annexes to this Regulation were the subject of new applications for authorisation by the person responsible for the dossier on the basis of which the former authorisations were given or by their successors. The applications relating to those additives were accompanied by the required monographs and identification notes;

(5) the linking of the authorisation to a person responsible for putting the additive into circulation is based on a purely administrative procedure and did not entail a fresh assessment of the additives. Although the authorisations under this Regulations are granted for a specified period, they may be withdrawn at any time in accordance with Article 9m and Article 11 of Directive 70/524/EEC. They may be withdrawn in particular in the light of the following: the Scientific Steering Committee has issued an opinion on antimicrobial resistance on 28 May 1999; a re-evaluation of the use of certain antibiotics as additives in feedingstuffs is currently being undertaken under Article 9g of Directive 70/524/EEC; the Kingdom of Sweden has prohibited the use on its territory of all antibiotics as additives in feedingstuffs on the basis of Article 11 of Directive 70/524/EEC. Moreover, the Commission is examining the data provided and the more general question of whether the use of antibiotics as additives in feedingstuffs meets the conditions set out in Article 3a of Directive 70/524/EEC for the authorisation of additives;

(6) the measures provided for in this Regulation are in accordance with the opinion of the Standing Committee for Feedingstuffs,

HAS ADOPTED THIS REGULATION:

Article 1

The provisional authorisations of the additives listed in the Annex I to this Regulation are replaced by authorisations granted to the person responsible for putting the additive in circulation, inserted in the second column of the Annex I.

Article 2

The provisional authorisations of the additives listed in Annex II to this Regulation are replaced by provisional authorisations granted to the person responsible for putting the additive into circulation, inserted in the second column of Annex II.

Article 3

This Regulation shall enter into force on the seventh day of its publication in the *Official Journal of the European Communities*.

([1]) OJ L 270, 14.12.1970, p. 1.
([2]) OJ L 297, 18.11.1999, p. 8.
([3]) OJ L 235, 17.9.1996, p. 39.

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

Done at Brussels, 3 December 1999.

For the Commission
David BYRNE
Member of the Commission

ANNEX I

Registration number of additive	Name and registration number 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	Period of authorisation
						mg of active substance/kg of complete feedingstuff			
E 712	Hoechst Roussel Vet GmbH	Flavophospholipol 80 g/kg (Flavomycin 80) Flavophospholipol 40 g/kg (Flavomycin 40)	**Additive composition:** Flavophospholipol: ≥80 g activity/kg Silicium dioxide: 50-150 g/kg Calcium carbonate: 0-400 g/kg Flavophospholipol: ≥40 g activit/kg Silicium dioxide: 20-120 g/kg Calcium carbonate: 200-750 g/kg **Active substance:** Flavophospholipol, CAS number: 11015-37-5, (moenomycin A: $C_{69}H_{108}N_5O_{34}P$), phosphoglycolipid produced by fermentation of *Streptomyces ghanaensis* (DSM 12218), composition of antibiotic factors: moenomycin A: 40-80 % moenomycin $A_{1/2}$: 0-20 % moenomycin C_1: 0-20 % moenomycin C_3: 5-25 % moenomycin C_4: 0-15 %	Rabbits	—	2	4	—	30.9.2009

Registration number of additive	Name and registration number 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	Period of authorisation
						mg of active substance/kg of complete feedingstuff			
E 716	Hoechst Roussel Vet GmbH	Salinomycin sodium 120 g/kg (Salocin 120 micro Granulate)	**Additive composition:** Salinomycin sodium: ≥120 g/kg Silicium dioxide: 10-100 g/kg Calcium carbonate: 350-700 g/kg **Active substance:** Salinomycin sodium, $C_{42}H_{69}O_{11}Na$, CAS number: 53003-10-4, sodium salt of polyether monocarboxylic acid produced by fermentation of *Streptomyces albus* (DSM 12217) Related impurities: < 42 mg elaiophylin/kg salinomycin sodium < 40 g 17-epi-20-desoxy-salinomycin/kg salinomycin solium	Piglests	4 months	30	60	Indicate in the instructions for use: 'Dangerous for equines' 'This feddingstuff contains an ionophore: simultaneous use with certain medicinal substances (e.g. tiamulin) can be contraindicated'	30.9.2009
				Pigs for fattening	6 months	15	30	Indicate in the instructions for use: 'Dangerous for equines' 'This feddingstuff contains an ionophore: simultaneous use with certain medicinal substances (e.g. tiamulin) can be contraindicated'	30.9.2009

Registration number of additive	Name and registration number 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	Period of authorisation
						mg of active substance/kg of complete feedingstuff			
E 717	Eli Lilly and Company Ltd	Avilamycin 200 g/kg (Maxus G200, Maxus 200) Avilamycin 100 g/kg (Maxus G100, Maxus 100)	**Additive composition:** Avilamycin: 200 g activity/kg Soyabean oil or mineral oil: 5-30 g/kg Soyabean hulls qs 1 kg Avilamycin: 100 g activity/kg Soyabean oil or mineral oil: 5-30 g/kg Soyabean hulls qs 1 kg **Active substance:** Avilamycin, $C_{57-62}H_{82-90}Cl_{1-2}O_{31-32}$ CAS number of avilamycin A: 69787-79-7, CAS number 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 % Avilamycins A + B: ≥ 70 % Other single avilamycins: ≤ 6 %	Piglets	4 months	20	40	—	30.9.2009
				Pigs for fattening	6 months	10	20	—	30.9.2009
				Chickens for fattening	—	2.5	10	—	30.9.2009

ANNEX II

Registration number of additive	Name and registration number 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	Period of authorisation
						mg of active substance/kg of complete feedingstuff			
33	Eli Lilly and Company Ltd	Avilamycin 200 g/kg (Maxus G200, Maxus 200) Avilamycin 100 g/kg (Maxus G100, Maxus 100)	**Additive composition:** Avilamycin: 200 g activity/kg Soyabean oil or mineral oil: 5-30 g/kg Soyabean hulls qs 1 kg Avilamycin: 100 g activity/kg Soyabean oil or mineral oil: 5-30 g/kg Soyabean hulls qs 1 kg **Active substance:** Avilamycin, $C_{57-62}H_{82-90}Cl_{1-2}O_{31-32}$, CAS number of avilamycin A: 69787-79-7, CAS number 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 % Avilamycins A + B: ≥ 70 % Other single avilamycins: ≤ 6 %	Turkeys	—	5	10	—	30.9.2000 (1)

(1) First authorisation: Commission Directive 97/72/EC (OJ L 351, 23.12.1997, p. 55).