COMMISSION REGULATION (EC) No 2786/98

of 22 December 1998

concerning the modification of the period of authorisations of additives referred to in Article 9i(1) of Council Directive 70/524/EEC

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 2785/98 [2], and in particular Articles 9j and 3 thereof,

Whereas Directive 70/524/EEC provides that new additives or uses of additives may be authorised, taking account of advances in scientific and technical knowledge;

Whereas a provisional authorisation of new additives or uses of additives may be given for a period of five years, if, at the level permitted in feedingstuffs, it does not adversely affect human or animal health or the environment, nor harm the consumer by altering the characteristics of livestock product, if its presence in feedingstuffs can be controlled, and it is reasonable to assume, in view of the available results, that it has a favourable effect on the characteristics of those feedingstuffs or on livestock production when incorporated in such feedingstuffs;

Whereas research into various additives referred to in Article 9i(1) of Directive 70/524/EEC and transferred to Chapter III of Annex B to this Directive which can accordingly be authorised provisionally at national level until 30 November 1998 has not yet been completed; whereas, therefore, the period of authorisation of these substances should be extended for a determined period;

Whereas the Commission has consulted the Scientific Committee for animal nutrition concerning the authorisation of the antibiotics and the coccidiostats included in the Annex to the present Regulation; whereas this Committee delivered an opinion with regard to the efficacy, the safety and the controllability of these substances;

Whereas the measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Feedingstuffs,

HAS ADOPTED THIS REGULATION:

Article 1

Chapter III of Annex B to Directive 70/524/EEC is amended in accordance with the Annex to this Regulation.

Article 2

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

It shall apply with effect from 1 December 1998.

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

Done at Brussels, 22 December 1998.

For the Commission
Franz FISCHLER
Member of the Commission

[1] OJ L 270, 14. 12. 1970, p. 1.
[2] See page 21 of this Official Journal.

ANNEX

Chapter III of Annex B to Directive 70/524/EEC is amended as follows:

Additives linked to a person responsible for marketing, inserted in Annex II before 1 April 1998

A. Antibiotics

Registration number	Name and registration number of person responsible for marketing (1)	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	Duration of authorisation
						mg/kg complete feedingstuff			
'31		Bacitracin zinc	$C_{66}H_{103}O_{16}N_{17}SZn$ (polypeptide containing 12 to 20 % zinc)	Chickens for fattening	—	5	50	—	17. 7. 1999 (2)
				Pigs	6 months	5	50	—	17. 7. 1999 (2)
33		Avilamycin	$C_{57.62}H_{82.90}Cl_{1.2}O_{31.32}$ (mixture of oligosaccharides of the orthosomycin group produced by *Streptomyces viridochromogenes,* NRRL 2860) Factor composition: — Avilamycin A: not less than 60 % — Avilamycin B: not more than 18 % — Avilamycins A + B: not less than 70 % — Other single avilamycins: not more than 6 %	Turkeys	—	5	10	—	30. 9. 1999 (3)'

B. Cooccidiostats and other medicinal substances

Registration number	Name and registration number of person responsible for marketing (1)	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	Duration of authorisation
						mg/kg complete feedingstuff			
'26		Salinomycin sodium	$C_{42}H_{69}O_{11}Na$ (sodium salt of a polyether monocarboxylic acid produced by *Streptomyces albus*) Elaiophylin content: less than 42 mg per kg of salinomycin sodium 17-epi-20-desoxysalinomycin content: less than 40 g per kg of salinomycin sodium	Rabbits for fattening	—	20	25	Use prohibited at least five days before slaughter. Indicate in the instructions for use: — "Dangerous for equines" — "This feedingstuff contains an ionophore; simultaneous use with certain medicinal substances (e.g. tiamulin) can be contra indicated"	30. 9. 1999 (4)
				Chickens reared for laying	12 weeks	30	50	Indicate in the instructions for use: — "Dangerous for equines" — "This feedingstuff contains an ionophore; simultaneous use with certain medicinal substances (e.g. tiamulin) can be contra indicated"	30. 9. 1999 (5)

Registration number	Name and registration number of person responsible for marketing (1)	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	Duration of authorisation
						mg/kg complete feedingstuff			
27		Diclazuril	(±)-4-chlorphenyl(2,6-dicloro-4-(2,3,4,5-tetrahydro-3,5-dioxo-1,2,4-triazin-2yl-phenyl)acetonitrile	Turkeys	12 weeks	1	1	Use prohibited at least five days before slaughter.	30. 9. 1999 (4)
				Chickens reared for laying	16 weeks	1	1	—	30. 9. 1999 (3)
28		Maduramycin ammonium	$C_{47}H_{83}O_{17}N$ (ammonium salt of a polyether monocarboxylic acid produced by *Actinomadura yumaensis*)	Turkeys	16 weeks	5	5	Use prohibited at least five days before slaughter. Indicate in the instructions for use: — "Dangerous for equines" — "This feedingstuff contains an ionophore; simultaneous use with certain medicinal substances (e.g. tiamulin) can be contra indicated"	30. 9. 1999 (5)'

C. Growth promoters

Registration number	Name and registration number of person responsible for marketing (1)	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	Duration of authorisation
						mg/kg complete feedingstuff			
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(1) Authorisation linked to the person responsible with effect from 1 October 1999.
(2) First authorisation 18 July 1994, Commission Directive 94/41/EC (OJ L 209, 12. 8. 1994, p. 18).
(3) First authorisation 15 December 1997, Commission Directive 97/72/EC (OJ L 351, 23. 12. 1997, p. 55).
(4) First authorisation 21 February 1996, Commission Directive 96/7/EC (OJ L 51, 1. 3. 1996, p. 45).
(5) First authorisation 14 October 1996, Commission Directive 96/66/EC (OJ L 272, 25. 10. 1996, p. 32).