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COMMISSION REGULATION (EC) No 2380/2001

of 5 December 2001

concerning the 10 year authorisation of an additive in feedingstuffs

(Text with EEA relevance)

(OJ L 321, 6.12.2001, p. 18)

Amended by:

		Official Journal		
		No	page	date
►M1	Commission Regulation (EC) No 552/2008 of 17 June 2008	L 158	3	18.6.2008
►M2	Commission Implementing Regulation (EU) No 406/2011 of 27 April 2011	L 108	11	28.4.2011

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COMMISSION REGULATION (EC) No 2380/2001

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concerning the 10 year authorisation of an additive in feedingstuffs

(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 Directive 2001/46/EC of the European Parliament and of the Council [2], and in particular Article 4 thereof,

Whereas:

(1) Article 2(aaa) of Directive 70/524/EEC requires authorisations for coccidiostats to be linked to the person responsible for putting them into circulation.

(2) Article 9 of Directive 70/524/EEC provides that a substance may be authorised if all conditions laid down in Article 3a of that Directive are met.

(3) The assessment of the dossier submitted shows that the coccidiostat described in the Annex satisfies all the requirements of Article 3a of Directive 70/524/EEC, when used for the animal category and under the conditions described in the Annex to this Regulation: the substance should therefore be authorised under those conditions.

(4) Article 9b of Directive 70/524/EEC provides that the authorisations of such substances shall be given for a period of 10 years from the date on which the final authorisation takes effect.

(5) The assessment of the dossier shows that certain procedures may be required to protect workers from exposure to the additives. Such protection should however be assured by the application of Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work [3].

(6) The Scientific Committee for Animal Nutrition has delivered a favourable opinion with regard to the safety and with regard to the favourable effect on animal production of the coccidiostat under the conditions described in the said Annex.

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

HAS ADOPTED THIS REGULATION:

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[1] OJ L 270, 14.12.1970, p. 1.
[2] OJ L 234, 1.9.2001, p. 55.
[3] OJ L 183, 29.6.1989, p. 1.

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Article 1

The additive belonging to the 'Coccidiostats and other medicinal substances' 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 third day following that of its publication in the *Official Journal of the European Communities*.

It shall apply from 15 December 2001.

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

▼M2

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive (Trade name)	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Coccidiostats and other medicinal substances									
E 770	Alpharma Belgium BVBA	Maduramicin ammonium alpha 1 g/100 g (Cygro 1 %)	Additive composition Maduramicin ammonium alpha: 1 g/100 g Carboxymethylcellulose sodium: 2 g/100 g Calcium sulphate dihydrate: 97 g/100 g Active substance Maduramicin ammonium α $C_{47}H_{83}O_{17}N$ CAS number: 84878-61-5, ammonium salt of a polyether monocarboxylic acid produced by a fermentation process by the strain *Actinomadura yumaensis* (ATCC 31585) (NRRL 12515) Related impurities: Maduramicin ammonium β: < 10 %	Turkeys	16 weeks	5	5	1. Use prohibited at least 5 days before slaughter. 2. 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 contraindicated'.	15.12.2011