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COMMISSION REGULATION (EC) No 1800/2004

of 15 October 2004

concerning the authorisation for 10 years of the additive Cycostat 66G in feedingstuffs, belonging to the group of coccidiostats and other medicinal substances

(Text with EEA relevance)

(OJ L 317, 16.10.2004, p. 37)

Amended by:

		Official Journal		
		No	page	date
►M1	Commission Regulation (EC) No 101/2009 of 3 February 2009	L 34	5	4.2.2009
►M2	Commission Regulation (EC) No 214/2009 of 18 March 2009	L 73	12	19.3.2009
►M3	Commission Implementing Regulation (EU) No 532/2011 of 31 May 2011	L 146	7	1.6.2011
►M4	amended by Commission Implementing Regulation (EU) No 118/2012 of 10 February 2012	L 38	36	11.2.2012
►M5	Commission Implementing Regulation (EU) No 118/2012 of 10 February 2012	L 38	36	11.2.2012

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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]), and in particular Article 9g(5)(b) thereof,

Whereas:

(1) In accordance with Directive 70/524/EEC, coccidiostats included in Annex I to that Directive before 1 January 1988 were provisionally authorised as from 1 April 1998 and transferred to Chapter I of Annex B with a view to their re-evaluation as additives linked to a person responsible for putting them into circulation. The robenidine product, Cycostat 66G, is an additive belonging to the group 'Coccidiostats and other medicinal substances' listed in Chapter I of Annex B of Directive 70/524/EEC.

(2) The person responsible for putting into circulation Cycostat 66G submitted an application for authorisation and a dossier, according to Article 9g(2) and (4) of that Directive.

(3) Article 9g(6) of Directive 70/524/EEC allows the automatic extension of the period of authorisation of the additives concerned until the Commission takes a decision in case of, for reasons beyond the control of the authorisation holder, no decision may be taken on the application before the expiry date of the authorisation. This provision is applicable to the authorisation of Cycostat 66G. The Commission requested the Scientific Committee for Animal Nutrition on 26 April 2001 a full risk evaluation and this request was consequently transferred to the European Food Safety Authority. Several requests for additional information were made during the re-evaluation process making it impossible to complete the re-evaluation within the time limits required by Article 9g.

(4) The Scientific Panel on Additives and Products or Substances used in Animal Feed attached to the European Food Safety Authority has delivered a favourable opinion with regard to the safety and to the efficacy of Cycostat 66G for chickens for fattening, rabbits for fattening and for turkeys.

([1]) OJ L 270, 14.12.1970, p. 1. Directive as last amended by Commission Regulation (EC) No 1464/2004 (OJ L 270, 18.8.2004, p. 8).

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(5) The re-evaluation of Cycostat 66G carried out by the Commission showed that the relevant conditions laid down in Directive 70/524/EEC are satisfied. Cycostat 66G should therefore be authorised for ten years as an additive linked to the person responsible for putting it into circulation and included in Chapter I of the list referred to Article 9t(b) of that Directive.

(6) As the authorisation for the additive is now linked to a person responsible for putting it into circulation, and replaces the previous authorisation which was not linked to any specific person, it is appropriate to delete the latter authorisation.

(7) Since there are no safety reasons for withdrawing the product robenidine from the market immediately, it is appropriate to allow a transitional period of six months for the disposal of existing stocks of the additive.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health.

HAS ADOPTED THIS REGULATION:

Article 1

In chapter I of Annex B to Directive 70/524/EEC the additive robenidine, belonging to the group 'Coccidiostats and other medical substances', shall be deleted.

Article 2

The additive Cycostat 66G belonging to the group 'Coccidiostats and other medical substances' as set out in the Annex to the present Regulation is authorised for use in animal nutrition under the conditions laid down in that Annex.

Article 3

A period of six months from the date of entry into force of this Regulation is permitted to use up the existing stocks of robenidine.

Article 4

This Regulation shall enter into force on the third 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.

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ANNEX

Registration number of the additive	Name and the registration number of the 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 period of authorisation	►M4 Maximum residue limits (MRLs) in the relevant foodstuffs of animal origin ◄
						mg of active substance/kg of complete feedingstuff				
Coccidiostats and other medicinal substances										
E 758	►M5 Pfizer Ltd ◄	Robenidine hydrochloride 66 g/kg ►M4 (Robenz 66 G) ◄	*Additive composition* Robenidine hydrochloride: 66 g/kg Lignosulfonate: 40 g/kg Calcium sulphate dihydrate: 894 g/kg *Active substance* Robenidine hydrochloride, $C_{15}H_{13}Cl_2N_5$. HCl, 1,3-bis [(p-chlorobenzylidene) amino]-guanidine hydrochloride CAS number: 25875-50-7, Related impurities: N,N',N''-Tris[(p-Cl-benzylidene)amino]guanidine (-TRIS): ≤ 0,5 % Bis-4[4-Cl-benzylidene]hydrazine (AZIN): ≤ 0,5 %	Chickens for fattening	—	30	36	Use is prohibited at least 5 days before slaughter.	29 October 2014	►M4 800 µg robenidine hydrochloride/kg of wet liver. 350 µg robenidine hydrochloride/kg of wet kidney. 200 µg robenidine hydrochloride/kg of wet muscle. 1 300 µg robenidine hydrochloride/kg of wet skin/fat. ◄
				Turkeys		30	36	Use is prohibited at least 5 days before slaughter.	29 October 2014	►M4 400 µg robenidine hydrochloride/kg of skin/fat. 400 µg robenidine hydrochloride/kg of wet liver. 200 µg robenidine hydrochloride/kg of wet kidney. 200 µg robenidine hydrochloride/kg of wet muscle. ◄