Commission Regulation (EC) No 214/2009 of 18 March 2009 amending Regulation (EC) No 1800/2004 as regards the terms of the authorisation of the feed additive Cycostat 66G (Text with EEA relevance)

COMMISSION REGULATION (EC) No 214/2009

of 18 March 2009

amending Regulation (EC) No 1800/2004 as regards the terms of the authorisation of the feed additive Cycostat 66G

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[(1)], and in particular Article 13(3) thereof,

Whereas:

(1) The additive robenidine hydrochloride 66 g/kg (Cycostat 66G), hereinafter referred to as Cycostat 66G, linked to the holder of authorisation, Alpharma (Belgium) BVBA, belonging to the group of coccidiostats and other medicinal substances, was authorised under certain conditions in accordance with Council Directive 70/524/EEC[(2)]. Commission Regulation (EC) No 1800/2004[(3)] authorised that additive for 10 years for use for chickens for fattening, turkeys and rabbits for fattening. That additive was notified as an existing product in accordance with Article 10 of Regulation (EC) No 1831/2003. Since all the information required under that provision was submitted, that additive was entered into the Community Register of Feed Additives.

(2) Regulation (EC) No 1831/2003 provides for the possibility of modifying the authorisation of an additive further to a request from the holder of the authorisation and an opinion of the European Food Safety Authority. Alpharma (Belgium) BVBA, holder of the authorisation of Cycostat 66G, has submitted an application with which it requests changing the conditions of the authorisation as regards chickens for fattening and turkeys by modifying the trade name from Cycostat 66G to Robenz 66G, leaving the trade name Cycostat 66G unchanged with respect to rabbits for fattening.

(3) The proposed change of the terms of the authorisation is purely administrative in nature and does not entail a fresh assessment of the additives concerned. The European Food Safety Authority was informed of the application.

(4) To allow the applicant to exploit its marketing rights under the new trade name of ‘Robenz 66G’, it is necessary to change the terms of the authorisation as regards chickens for fattening and turkeys.

(5) Regulation (EC) No 1800/2004 should therefore be amended accordingly.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EC) No 214/2009. (See end of Document for details)*

(6) It is appropriate to provide for a transitional period during which existing stocks may be used up.

(7) 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

The Annex to Regulation (EC) No 1800/2004 is replaced by the text in the Annex to this Regulation.

Article 2

Existing stocks which are in conformity with the provisions applicable before the entry into force of this Regulation may continue to be placed on the market and used until 30 June 2010.

Article 3

This Regulation shall enter into force on the 20th day following 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, 18 March 2009.

For the Commission

Androulla VASSILIOU

Member of the Commission

ANNEX

Registration number of additive	Name and registration number of person responsible for putting additives 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	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	Alpharma (Belgium) BVBA	Robenidine hydrochloride 66 g/kg (Robenz 66G)	Additive composition: Robenidine hydrochloride: 66 g/kg Lignosulfonate: 40 g/kg Calcium sulfate dihydrate: 894 g/kg Active substance: Robenidine hydrochloride, $C_{15}H_{13}Cl_2N_5 \cdot HCl$, 1,3-bis [(p-chlorobenzylidene) amino]-guanidine hydrochloride, CAS number: 25875-50-7, Related impurities: N,N′,N″-Tris[(p-Cl-	Chickens for fattening	—	30	36	Use prohibited at least five days before slaughter	29.10.2014	40 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