Commission Regulation (EC) No 101/2009 of 3 February 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 101/2009

of 3 February 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 hydrocloride 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 (the Authority). Alpharma (Belgium) BVBA, holder of the authorisation of Cycostat 66G, has submitted an application with which it proposes changing the conditions of the authorisation for chickens for fattening and for turkeys by introducing a maximum residue limit (MRL) and by modifying the withdrawal period, as evaluated by the Authority. At the same time it provided data to support that request.

(3) In its opinion adopted on 16 September 2008[(4)], the Authority concluded that, based on safety considerations, there is no necessity for setting a withdrawal period for chickens for fattening and consequently for MRLs. It came to the same conclusions concerning turkeys. However, in case MRLs are required, it suggested values. It further proposed to maintain the five-day withdrawal period, to avoid off-flavours in edible tissues from poultry treated with Cycostat 66G.

(4) To ensure a high level of safety for the consumers and to improve the control of the correct use of Cycostat 66G, it is appropriate to establish MRLs as proposed by the Authority. To keep acceptable organoleptic properties of meat, the withdrawal period should be maintained at five days.

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

(6) 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 Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 20th 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.

Done at Brussels, 3 February 2009.

For the Commission

Androulla VASSILIOU

Member of the Commission

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EC) No 101/2009. (See end of Document for details)*

ANNEX

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	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 (Cycostat 66G)	Additive composition: Robenidine hydrochloride: 66 g/kg Lignosulfonate: 40 g/kg Calcium sulfate dihydrate: 894 g/kg Active substance: Robenidine hydrochloride, $C_{15}H_{13}Cl_2N_5 . HCl$, 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	400 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 prohibited at least five days before slaughter.	29.10.2014	400 µg robenidine hydrochloride/kg of skin/fat. 400 µg robenidine hydrochloride/kg of