Commission Implementing Regulation (EU) No 532/2011 of 31 May 2011 concerning the authorisation of robenidine hydrochloride as a feed additive for rabbits for breeding and rabbits for fattening (holder of authorisation Zoetis Belgium SA) and amending Regulations (EC) No 2430/1999 and (EC) No 1800/2004 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 532/2011

of 31 May 2011

concerning the authorisation of robenidine hydrochloride as a feed additive for rabbits for breeding and rabbits for fattening (holder of authorisation ⌈[F1]Zoetis Belgium SA⌋) and amending Regulations (EC) No 2430/1999 and (EC) No 1800/2004

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC[(2)].

(2) Robenidine hydrochloride, CAS number 25875-50-7, was authorised for 10 years in accordance with Directive 70/524/EEC as a coccidiostat for use on rabbits for breeding by Commission Regulation (EC) No 2430/1999[(3)] and for use on turkeys, chickens for fattening and rabbits for fattening by Commission Regulation (EC) No 1800/2004[(4)]. The additive was subsequently entered in the Register of Feed Additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, an application was submitted for the re-evaluation of robenidine hydrochloride as a feed additive for rabbits for breeding and rabbits for fattening, requesting that additive to be classified in the additive category ‘coccidiostats and histomonostats’. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority (the Authority) concluded in its opinion of 7 March 2011 that, under the proposed conditions of use, robenidine hydrochloride does not have an adverse effect on animal health, human health or the environment, and that the additive is effective in controlling coccidiosis in rabbits for fattening and for

breeding[5]. It also verified the report on the method of analysis of the feed additive in feed submitted by the European Union Reference Laboratory for Feed Additives set up by Regulation (EC) No 1831/2003.

(5) The assessment of robenidine hydrochloride shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this preparation should be authorised as specified in the Annex to this Regulation.

(6) As a consequence of a new authorisation being granted by this Regulation, the entry in Regulation (EC) No 2430/1999 concerning robenidine hydrochloride for rabbits for breeding purposes is deleted.

(7) As a further consequence of this new authorisation, the entry for robenidine hydrochloride in the Annex to Regulation (EC) No 1800/2004 should be amended.

(8) Since the modifications to the conditions of authorisation are not related to safety reasons, it is appropriate to allow a transitional period for the disposal of existing stocks of pre-mixtures and compound feed containing this preparation, as authorised by Regulation (EC) No 2430/1999 for use on rabbits for breeding purposes and by Regulation (EC) No 1800/2004 for use on rabbits for fattening.

(9) 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:

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) No 1014/2013 of 22 October 2013 amending Regulations (EC) No 2380/2001, (EC) No 1289/2004, (EC) No 1455/2004, (EC) No 1800/2004, (EC) No 600/2005, (EU) No 874/2010, Implementing Regulations (EU) No 388/2011, (EU) No 532/2011 and (EU) No 900/2011 as regards the name of the holder of the authorisation of certain additives in animal feed (Text with EEA relevance).

Article 1

The preparation specified in the Annex I, belonging to the additive category ‘coccidiostats and histomonostats’ is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

In Annex I to Regulation (EC) No 2430/1999, the entry under registration number of additive E 758 concerning robenidine hydrochloride for rabbits for breeding purposes is deleted.

Article 3

The Annex to Regulation (EC) No 1800/2004 is amended in accordance with Annex II to this Regulation.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 532/2011. (See end of Document for details)*

Article 4

Premixtures and compound feed labelled in accordance with Directive 70/524/EEC and containing robenidine hydrochloride, as authorised by Regulation (EC) No 2430/1999 for use on rabbits for breeding purposes and by Regulation (EC) No 1800/2004 for use on rabbits for fattening, may continue to be placed on the market and used until the existing stocks are exhausted.

Article 5

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.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 532/2011. (See end of Document for details)*

ANNEX I

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	Maximum Residue Limits (MRLs) in the relevant foodstuffs of animal origin
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %				
Coccidiostats and histomonostats										
5 1 758	[F1Zoetis Belgium SA]	Robenidine hydrochloride 66g/kg (Cycostat 66G)	*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, CAS number: 25875-50-7, 1,3-bis [(p-chlorobenzylidene) amino]-guanidine hydrochloride: > 97 % Related impurities:	Rabbits for breeding Rabbits for fattening		50 50	66 66	1. The additive shall be incorporated in compound feed in the form of a pre-mixture. 2. Robenidine hydrochloride shall not be mixed with other coccidiostats. 3. For safety: breathing protection, glasses and gloves shall be used during handling.	21 June 2021	200 µg/kg wet weight for liver and kidney 100 µg / kg wet weight for all other tissues

a Details of the analytical methods are available at the following address of the European Union Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx

b OJ L 54, 26.2.2009, p. 1.