Commission Implementing Regulation (EU) 2020/148 of 3 February 2020 concerning the authorisation of robenidine hydrochloride (Robenz 66G) as a feed additive for chickens for fattening and amending Regulation (EC) No 1800/2004 (holder of authorisation Zoetis SA) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/148

of 3 February 2020

concerning the authorisation of robenidine hydrochloride (Robenz 66G) as a feed additive for chickens for fattening and amending Regulation (EC) No 1800/2004 (holder of authorisation Zoetis SA)

(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(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC[(2)].

(2) The preparation of robenidine hydrochloride (Robenz 66G) was authorised, in accordance with Directive 70/524/EEC, as a feed additive for chickens for fattening by Commission Regulation (EC) No 1800/2004[(3)]. That preparation 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 thereof, an application was submitted for the re-evaluation of robenidine hydrochloride (Robenz 66G) as a feed additive for chickens for fattening. The applicant requested 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 24 January 2019[(4)] that, under the proposed conditions of use, robenidine hydrochloride (Robenz 66G) does not have an adverse effect on animal health, human health or the environment. The Authority considered that the additive has the potential to effectively control coccidiosis in chickens for fattening. The Authority considered that there is a need for a field post-market monitoring of *Eimeria* spp., preferably during the latter part

of the period of the authorisation. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of robenidine hydrochloride (Robenz 66G) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.

(6) As a consequence of this re-evaluation, Regulation (EC) No 1800/2004 should be amended accordingly.

(7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, 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

Regulation (EC) No 1800/2004 is amended as follows:

(1) Article 2 is deleted;

(2) the Annex is deleted.

Article 3

The preparation specified in the Annex and feed containing that preparation, which are produced and labelled before 25 August 2020 in accordance with the rules applicable before 25 February 2020 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 4

This Regulation shall enter into force on the twentieth 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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/148. (See end of Document for details)*

Done at Brussels, 3 February 2020.

For the Commission

The President

Ursula VON DER LEYEN

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/148. (See end of Document for details)*

ANNEX

Identification number of additive	Name of the holder of authorisation	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 with a moisture content of 12 %				
Additive category: Coccidiostats and histomonostats										
5a758	Zoetis SA	Robenidine hydrochloride (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 (97 %) CAS number: 25875-50-7, Related impurities: —	Chickens fattening	—	36	36	1. 2. 3. 4.	25 February 2030 Use of the additive prohibited at least five days before slaughter. The additive shall be incorporated in compound feed in the form of a premixture. The additive shall not be mixed with other coccidiostats. Post-market monitoring	800 µg robenidine hydrochloride/kg of wet liver. 350 µg robenidine hydrochloride/kg of wet kidney. 200 µg robenidine hydrochloride/kg of wet muscle. 1300 µg robenidine hydrochloride/kg of wet skin/fat.
				N,N’,N"-tris[(p-chlorobenzylidene) amino]guanidine (TRIS)						

a Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports