Commission Implementing Regulation (EU) No 667/2013 of 12 July 2013 concerning the authorisation of diclazuril as a feed additive for chickens reared for laying (holder of authorisation Elanco GmbH) and repealing Regulation (EC) No 162/2003 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 667/2013

of 12 July 2013

concerning the authorisation of diclazuril as a feed additive for chickens reared for laying (holder of authorisation **[**F1Elanco GmbH**]**) and repealing Regulation (EC) No 162/2003

(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) Diclazuril, CAS number 101831-37-2, was authorised for 10 years in accordance with Directive 70/524/EEC as a feed additive for use on chickens reared for laying by Commission Regulation (EC) No 162/2003(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 diclazuril, as a feed additive for chickens reared for laying, 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 31 January 2013(4) that, under the proposed conditions of use in feed, diclazuril does not have an adverse effect on animal, human health or the environment and it is effective in controlling coccidiosis in chickens reared for laying. 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.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 667/2013. (See end of Document for details)*

(5) The assessment of diclazuril, CAS number 101831-37-2, 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 the granting of a new authorisation under Regulation (EC) No 1831/2003, Regulation (EC) No 162/2003 should be repealed.

(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 the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) 2019/138 of 29 January 2019 amending Regulations (EC) No 1356/2004, (EC) No 1464/2004, (EC) No 786/2007, (EC) No 971/2008, (EU) No 1118/2010, (EU) No 169/2011 and Implementing Regulations (EU) No 888/2011 and (EU) No 667/2013 as regards the name of the holder of the authorisation for feed additives (Text with EEA relevance).

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 162/2003 is repealed.

Article 3

The preparation specified in the Annex and feed containing that preparation, which are produced and labelled before 2 February 2014 in accordance with the rules applicable before 2 August 2013 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) No 667/2013. (See end of Document for details)*

ANNEX

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										
51771	[F1Elanco GmbH]	Diclazuril 0,5 g/100 g (Clinacox 0,5 %)	*Chicken reared for laying* *Characterisation of the active substance* Diclazuril, $C_{17}H_9Cl_3N_4O_2$, (±)-4-chlorophenyl[2,6-dichloro-4-(2,3,4,5-tetrahydro-3,5-dioxo-1,2,4-triazin-2-yl)phenyl]acetonitrile, CAS number: 101831-37-2	*Chicken reared for laying* Premixture Diclazuril: 0,50 g/100 g Protein-poor soybean meal: 99,25 g/100 g Polyvidone K 30: 0,20 g/100 g Sodium hydroxide: 0,05 g/100 g	16 weeks	1	1	1. The additive shall be incorporated in compound feed in the form of a premixture. 2. Diclazuril shall not be mixed with other coccidiostats. 3. For safety: breathing protection, glasses and gloves shall be used during handling.	2 Aug 2023	Commission Regulation (EU) No 37/2010[c]

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

b OJ L 54, 26.2.2009, p. 1.

c OJ L 15, 20.1.2010, p. 1.