2023/2733

8.12.2023

COMMISSION IMPLEMENTING REGULATION (EU) 2023/2733

of 7 December 2023

concerning the authorisation of a preparation of diclazuril (Coxiril) as a feed additive for chickens reared for laying and pheasants (holder of authorisation: Huvepharma NV) and correcting Implementing Regulation (EU) 2015/46

(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 an authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, two applications were submitted for the authorisation of a preparation of diclazuril as a feed additive. Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) Those applications concern the authorisation of a preparation of diclazuril (Coxiril) as a feed additive for chickens reared for laying and pheasants respectively, requesting that additive to be classified in the category 'coccidiostats and histomonostats'.

(4) The preparation of diclazuril (Coxiril) is already authorised as a feed additive for chickens for fattening, turkeys for fattening, as well as guinea fowls for fattening and breeding by Commission Implementing Regulation (EU) 2015/46 ([2]).

(5) The European Food Safety Authority ('the Authority') concluded in its opinions of 20 February 2018 ([3]) and 23 March 2023 ([4]) that, under the proposed conditions of use, the preparation of diclazuril (Coxiril) is safe for chickens reared for laying and pheasants. It is safe for consumers provided that the maximum residue limits ('MRLs') established for poultry are not exceeded. As regards the environment, the Authority concluded that no risk is expected for the terrestrial compartment and for sediment (in both acidic and non-acidic soils), that no concern is expected for groundwater for both acidic and non-acidic soils, that no conclusions can be drawn for the aquatic compartment due to the lack of data and that the preparation of diclazuril (Coxiril) does not have the potential for bioaccumulation, therefore making a risk of secondary poisoning unlikely. It also concluded that the preparation of diclazuril (Coxiril) is considered as a non-irritant to eyes and skin, is not a potential skin sensitiser, and that user inhalation exposure is unlikely to cause respiratory or systemic toxicity. The Authority further concluded that the preparation of diclazuril (Coxiril) has the potential to control coccidiosis at the proposed conditions of use. It recommended undertaking field monitoring of *Eimeria* spp. resistance to diclazuril, preferably during the latter part of the period of authorisation. In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005 ([5]), the Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the previous assessment concerning the same additive are valid and applicable for the current application.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Commission Implementing Regulation (EU) 2015/46 of 14 January 2015 concerning the authorisation of diclazuril as a feed additive for chickens for fattening, for turkeys for fattening and for guinea fowl for fattening and breeding (holder of authorisation Huvepharma NV) (OJ L 9, 15.1.2015, p. 5).
([3]) *EFSA Journal* 2018;16(3):5195 and *EFSA Journal* 2018;16(3):5196.
([4]) *EFSA Journal* 2023;21(4):7963.
([5]) Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8).

(6) In view of the above, considering that chickens reared for laying and pheasants are exclusively kept in the terrestrial compartment, the Commission considers that the preparation of diclazuril (Coxiril) satisfies the conditions for authorisation provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised for chickens reared for laying and pheasants. It is appropriate to provide for post-market monitoring on the resistance of *Eimeria* spp. to diclazuril and to mention that, in accordance with article 9(7) of Regulation (EC) No 1831/2003, the maximum residue limits established in Commission Regulation (EU) No 37/2010 ([6]) for diclazuril in poultry apply in the relevant foodstuffs derived from the animals fed with that preparation.

(7) In the last column of the Annex to Implementing Regulation (EU) 2015/46, on maximum residue limits (MRLs) in the relevant foodstuffs of animal origin, reference is made to Regulation (EU) No 37/2010 and the MRLs are also detailed. However, in accordance with article 9(7) of Regulation (EC) No 1831/2003, where an MRL has already been established for a substance under Community rules, that MRL shall also apply to residues of the active substance or its metabolites originating from the use of the substance as a feed additive. The MRLs established in Regulation (EU) No 37/2010 for diclazuril in poultry therefore also apply under Implementing Regulation (EU) 2015/46 and a reference to Regulation (EU) No 37/2010 was sufficient without adding the details of the MRLs. Consequently, the Annex to Implementing Regulation (EU) 2015/46 should be corrected accordingly.

(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

Authorisation

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

Correction of Implementing Regulation (EU) 2015/46

In the Annex to Implementing Regulation (EU) 2015/46, the text in the column 'Maximum residue limits (MRLs) in the relevant foodstuffs of animal origin' is replaced by the following:

'Regulation (EU) No 37/2010 (*)

(*) Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).'.

Article 3

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

([6]) Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 7 December 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content (mg of active substance/kg of complete feedingstuff with a moisture content of 12 %)	Maximum content (mg of active substance/kg of complete feedingstuff with a moisture content of 12 %)	Other provisions	End of period of authorisation	Maximum residue limits (MRLs) in the relevant foodstuffs of animal origin
Category: coccidiostats and histomonostats										
51775	Huvepharma NV	Diclazuril 0,5 g/100 g (Coxiril)	*Additive composition:* Preparation of diclazuril: 5 g/kg. Starch: 15 g/kg. Wheat meal: 700 g/kg. Calcium carbonate: 280 g/kg. *Characterisation of the active substance:* Diclazuril: — $C_{17}H_9Cl_3N_4O_2$ — CAS number: 101831-37-2 — (±)-4-chlorophenyl[2,6-dichloro-4-(2,3,4,5-tetrahydro– 3,5-dioxo-1,2,4-triazin-2-yl)phenyl]acetonitrile — Produced by chemical synthesis. — Impurity D (1): ≤ 0,1 %. Any other single impurity: ≤ 0,5 %. Total impurities: ≤ 1,5 %. *Analytical method* (2): For determination of diclazuril in feed additive and premixtures: reversed-phase high performance liquid chromatography (HPLC) using Ultraviolet detection at 280 nm (Commission Regulation (EC) No 152/2009 (3)).	Chickens reared for laying	12 weeks	0,8	1,2	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. The additive shall be incorporated in compound feed in the form of a premixture. 3. Diclazuril shall not be mixed with other coccidiostats. 4. A post-market monitoring program on the resistance of *Eimeria* spp. to diclazuril shall be planned and executed by the holder of authorisation, in accordance with Commission Regulation (EC) No 429/2008 (4).	28 December 2033	Regulation (EU) No 37/2010
				Pheasants	—	1,0	1,2			

Identification number of the additive	Name of the holder of authorisation	Additive	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 %				
			For the determination of diclazuril in compound feed: — reversed-phase high performance liquid chromatography (HPLC) using Ultraviolet detection at 280 nm (Regulation (EC) No 152/2009), or — high performance liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS) – EN 17299.							

(1) European Pharmacopoeia monograph 1718 (Diclazuril for Veterinary use).

(2) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

(3) Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).

(4) Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 22.5.2008, p. 1).