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)

(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.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of a preparation of diclazuril. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of diclazuril, CAS number 101831-37-2, as a feed additive for chickens for fattening, for turkeys for fattening and for guinea fowl for fattening and breeding, to be classified in the additive category 'coccidiostats and histomonostas'.

(4) The European Food Safety Authority (the Authority) concluded in its opinions of 21 May 2014 ([2]), 22 May 2014 ([3]) that, under the proposed conditions of use, diclazuril does not have an adverse effect on animal health, human health or the environment and it is effective in controlling coccidiosis in chickens for fattening, turkeys for fattening and guinea fowl for fattening and breeding. The Authority does not consider that there is a need for specific requirements of post-market monitoring. 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 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) 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

Diclazuril, CAS number 101831-37-2, belonging to the additive category 'coccidiostats and histomonostas', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal 2014*; 12(6):3728.
([3]) *EFSA Journal 2014*; 12(6):3729, *EFSA Journal 2014*; 12(6):3730.

Article 2

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.

Done at Brussels, 14 January 2015.

For the Commission

The President

Jean-Claude JUNCKER

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	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										
51775	Huvepharma NV.	Diclazuril 0,5 g/100 g (Coxiril)	*Additive composition* Diclazuril: 5 g/kg. Starch: 15 g/kg. Wheat meal: 700 g/kg. Calcium carbonate: 280 g/kg. *Characterisation of the active substance* Diclazuril, $C_{17}H_9Cl_3N_4O_2$, (±)-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. Impurity D [1]: ≤ 0,1 %. Any other single impurity: ≤ 0,5 %. Total impurities: ≤ 1,5 %. *Analytical method* [2] For determination of diclazuril in feed: reversed-phase high performance liquid chromatography (HPLC) using Ultraviolet detection at 280nm (Regulation (EC) No 152/2009) [3].	Chickens for fattening Turkeys for fattening Guinea fowl for fattening and for breeding	—	0,8	1,2	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. 4. A post-market monitoring programme concerning the resistance to bacteria and Eimeria spp. shall be carried out by the holder of authorisation.	4 February 2025	Regulation (EU) No 37/2010 [4] — 1 500µg diclazuril/kg of wet liver; — 1 000 µg diclazuril/kg of wet kidney; — 500 µg diclazuril/kg of wet muscle; — 500 µg diclazuril/kg of wet skin/fat.

[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://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports
[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 (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).