COMMISSION REGULATION (EU) No 169/2011

of 23 February 2011

concerning the authorisation of diclazuril as a feed additive for guinea fowls (holder of authorisation Janssen Pharmaceutica N.V.)

(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 diclazuril. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of a new use of diclazuril as a feed additive for guinea fowls, to be classified in the additive category 'coccidiostats and histomonostats'.

(4) The use of diclazuril was authorised for 10 years in accordance with Council Directive 70/524/EEC [2] as a feed additive for use in chickens reared for laying up to 16 weeks and turkeys up to 12 weeks by Commission Regulation (EC) No 2430/1999 [3]. The use for chickens for fattening was authorised for 10 years by Commission Regulation (EU) No 1118/2010 [4].

(5) New data were submitted in support of the application for the authorisation of diclazuril for guinea fowls. The European Food Safety Authority (the Authority) concluded in its opinion of 5 October 2010 [5] that, under the proposed conditions of use, diclazuril does not have an adverse effect on animal health, human health or the environment and that its use controls coccidiosis in guinea fowls. It considers that there is a need for specific requirements of post-market monitoring to control the possible development of bacterial and/or *Eimeria* spp resistances. The Authority also verified the report on the method of analysis of the feed additive in feed submitted by the Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of diclazuril 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.

(7) 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:

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

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.

Done at Brussels, 23 February 2011.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 268, 18.10.2003, p. 29.
[2] OJ L 270, 14.12.1970, p. 1.
[3] OJ L 296, 17.11.1999, p. 3.
[4] OJ L 317, 3.12.2010, p. 5.
[5] EFSA Journal 2010; 8(10):1866.

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										
5 1 771	Janssen Pharmaceutica N.V.	Diclazuril 0,5 g/100 g (Clinacox 0,5 %)	*Additive composition* 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 *Characterisation of the active substance* Diclazuril, $C_{17}H_9Cl_3N_4O_2$, (±)-4-chlorophenyl[2,6-dichloro4-(2,3,4,5-tetrahydro-3,5-dioxo-1,2,4-triazin-2-yl)phenyl]acetonitrile, CAS number: 101831-37-2 Related impurities: Degradation compound (R064318): ≤ 0,1 % Other related impurities (T001434, R066891, R068610, R070156, R070016): ≤ 0,5 % individually Total impurities: ≤ 1,5 % *Analytical method* [1] For determination of diclazuril in feed: reversed-phase high performance liquid chromatography (HPLC) using Ultraviolet detection at 280 nm (Regulation (EC) No 152/2009) For determination of diclazuril in poultry tissues: HPLC coupled to triple quadrupole mass spectrometer (MS/MS) using one precursor ion and two product ions	Guinea fowls	—	1	1	1. The additive shall be incorporated in compound feed in 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. The holder of the authorisation shall carry out a post-market monitoring programme on the resistance to bacteria and *Eimeria* spp.	16 March 2021	1 500 µg 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] Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/crl-feed-additives