COMMISSION IMPLEMENTING REGULATION (EU) No 888/2011

of 5 September 2011

concerning the authorisation of diclazuril as a feed additive for turkeys for fattening (holder of authorisation Janssen Pharmaceutica N.V.) and amending Regulation (EC) No 2430/1999

(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 for fattening, chickens reared for laying up to 16 weeks and turkeys up to 12 weeks by Commission Regulation (EC) No 2430/1999 ([3]). The additive was subsequently entered in the Community Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003. Its use has further been authorised for 10 years for chickens for fattening by Commission Regulation (EU) No 1118/2010 ([4]), for guinea fowls by Commission Regulation (EU) No 169/2011 ([5]) and for rabbits by Commission Regulation (EC) No 971/2008 ([6]).

(3) In accordance with Article 10(2) in conjunction with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the re-evaluation of diclazuril as a feed additive for turkeys for fattening, requesting that additive 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 16 March 2011 ([7]) that, under the proposed conditions of use, diclazuril does not have an adverse effect on animal health, consumer health or the environment, and that it is effective in controlling coccidiosis in turkeys for fattening. It concluded that no safety concerns would arise for users provided that appropriate protective measures are taken. It 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.

(5) 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 that preparation should be authorised as specified in the Annex to this Regulation.

(6) As a consequence of a new authorisation being granted by this Regulation, the entry in Regulation (EC) No 2430/1999 concerning diclazuril should be deleted.

(7) Since the modifications to the conditions of authorisation are not related to safety reasons, it is appropriate to allow a transitional period for the disposal of existing stocks of premixtures and compound feed containing this preparation, as authorised by Regulation (EC) No 2430/1999 for use on turkeys up to 12 weeks.

(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,

([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]) OJ L 49, 24.2.2011, p. 6.
([6]) OJ L 265, 4.10.2008, p. 3.
([7]) *EFSA Journal 2011*; 9(4):2115.

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in 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

The entry in Annex II to Regulation (EC) No 2430/1999 concerning the diclazuril for turkeys, identified with registration number 27, is deleted.

Article 3

Premixtures and compound feed labelled in accordance with Directive 70/524/EEC and containing diclazuril, as authorised by Regulation (EC) No 2430/1999 for use on turkeys up to 12 weeks, 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 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, 5 September 2011.

For the Commission
The President
José Manuel BARROSO

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-dichloro-4-(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.	Turkeys for fattening	—	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. 4. A post-market monitoring program on the resistance to bacteria and *Eimeria* spp. shall be planned and executed by the holder of authorisation.	26 September 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: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx