# COMMISSION REGULATION (EU) No 1118/2010

## of 2 December 2010

## concerning the authorisation of diclazuril as a feed additive for chickens for fattening (holder of authorisation Janssen Pharmaceutica NV) 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 No 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]). That 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.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, an application was submitted for the re-evaluation of diclazuril as a feed additive for chickens for fattening, requesting that additive to be classified in the additive category 'coccidiostats and histomonostats'. The 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 23 June 2010 that, under the proposed conditions of use, diclazuril does not have an adverse effect on animal health, consumer health or the environment, and that that additive is effective in controlling coccidiosis in chickens for fattening ([4]). It concluded that no safety concerns would arise 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 the granting of a new authorisation under Regulation (EC) No 1831/2003, the provisions on diclazuril for chickens for fattening in Regulation (EC) No 2430/1999 should be deleted.

(7) Since the modifications on the conditions of the authorisation are not related to safety reasons, it is appropriate to allow a transitional period for the disposal of existing stocks of the premixtures and compound feed.

(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:

*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*

In Annex I to Regulation (EC) No 2430/1999, the entry under the registration number of additive E 771, concerning diclazuril for chickens for fattening, is deleted.

([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]) EFSA Journal 2010; 8(7):1663.

*Article 3*

Premixtures and compound feed containing diclazuril labelled in accordance with Directive 70/524/EEC may continue to be placed on the market and used until 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, 2 December 2010.

*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 NV | Diclazuril 0,5 g/ 100 g<br><br>(Clinacox 0,5 %) | *Additive composition*<br><br>Diclazuril: 0,50 g/100 g.<br><br>Protein-poor soybean meal: 99,25 g/100 g<br><br>Polyvidone K 30: 0,20 g/ 100 g<br><br>Sodium hydroxide: 0,05 g/ 100 g<br><br>*Characterisation of the active substance*<br><br>Diclazuril, $C_{17}H_9Cl_3N_4O_2$,<br><br>(±)-4-chlorophenyl[2,6-dichloro4-<br><br>(2,3,4,5-tetrahydro-3,5-dioxo-1,2,4-triazin-2-yl)phenyl]acetonitrile,<br><br>CAS number: 101831-37-2<br><br>Related impurities:<br><br>Degradation compound (R064318): ≤ 0,1 %<br><br>Other related impurities (T001434, R066891, R068610, R070156, R070016):<br><br>≤ 0,5 % individually<br><br>Total impurities: ≤ 1,5 % | Chickens for fattening | — | 1 | 1 | 1. The additive shall be incorporated in compound feed in form of a premixture.<br><br>2. Diclazuril shall not be mixed with other coccidiostats.<br><br>3. For safety: breathing protection, glasses and gloves shall be used during handling.<br><br>4. A post-market monitoring program on the resistance to bacteria and *Eimeria* spp. shall be planned and executed by the holder of authorisation. | 23 December 2020 | 1 500 µg diclazuril/kg of wet liver<br><br>1 000 µg diclazuril/kg of wet kidney<br><br>500 µg diclazuril/kg of wet muscle<br><br>500 µg diclazuril/kg of wet skin/fat |

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|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | mg of active substance/kg of complete feedingstuff with a moisture content of 12 % | | | | |
| | | | *Analytical method* (1)<br><br>For determination of diclazuril in feed: reversed-phase high performance liquid chromatography (HPLC) using Ultraviolet detection at 280nm (Regulation (EC) No 152/2009)<br><br>For determination of diclazuril in poultry tissues: HPLC coupled to triple quadrupole mass spectrometer (MS/MS) using one precursor ion and two product ions. | | | | | | | |

(1) Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/crl-feed-additives