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EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the renewal of the authorisation of a preparation of diclazuril (Clinacox 0,5%) as a feed additive for chickens for fattening and chickens reared for laying (holder of authorisation: Elanco GmbH), and repealing Regulation (EU) No 1118/2010 and Implementing Regulation (EU) No 667/2013

(Text with EEA relevance)

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(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 and renewing such an authorisation.

(2) A preparation of diclazuril (Clinacox 0,5%) ('the preparation') was authorised for a period of 10 years as a feed additive for chickens for fattening by Commission Regulation (EU) No 1118/2010[2] and for chickens reared for laying by Implementing Regulation (EU) No 667/2013[3].

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of the preparation as a feed additive for chickens for fattening and chickens reared for laying. The application requested that additive to be classified in the category 'coccidiostats and histomonostats'. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 27 June 2024[4] and 28 January 2026[5] that the applicant has provided evidence that the preparation remains safe for the target species, as well as for the consumers and the

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1 OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj.

2 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 (OJ L 317, 3.12.2010, p. 5, ELI: http://data.europa.eu/eli/reg/2010/1118/oj).

3 Commission Implementing Regulation (EU) No 667/2013 of 12 July 2013 concerning the authorisation of diclazuril as a feed additive for chickens reared for laying (holder of authorisation Eli Lilly and Company Ltd) and repealing Regulation (EC) No 162/2003 (OJ L 192, 13.7.2013, p. 35, ELI: http://data.europa.eu/eli/reg_impl/2013/667/oj).

4 EFSA Journal. 2024;22:e8908. https://doi.org/10.2903/j.efsa.2024.8908.

5 EFSA Journal. 2026;24:e9930. https://doi.org/10.2903/j.efsa.2026.9930.

environment at a maximum use level of 1 mg diclazuril/kg complete feed. It also concluded that the preparation is irritant to skin, eyes and the respiratory tract but is not a skin sensitiser. The Authority further concluded that the preparation at a concentration of 1 mg diclazuril/kg complete feed has the potential to control coccidiosis in chickens for fattening and extended that conclusion to chickens reared for laying. It considered that there is a need for specific requirements of post-market monitoring, recommending that the development of resistance to diclazuril of field *Eimeria* spp. strains isolated from chickens be monitored.

(5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the assessment carried out regarding the method of analysis of the preparation as a feed additive in the context of the previous authorisation are valid and applicable for the current application. In accordance with Article 5(4), point (c), of Commission Regulation (EC) No 378/2005[6], an evaluation report of the Reference Laboratory is therefore not required.

(6) In view of the above, the Commission considers that the preparation satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.

(7) As a consequence of the renewal of the authorisation of the preparation as a feed additive, Regulation (EU) No 1118/2010 and Implementing Regulation (EU) No 667/2013 should be repealed.

(8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation.

(9) 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

Renewal of authorisation

The authorisation of the preparation specified in the Annex, belonging to the additive category ‘coccidiostats and histomonostats’ is renewed subject to the conditions laid down in that Annex.

Article 2

Repeal

Regulation (EU) No 1118/2010 and Implementing Regulation (EU) No 667/2013 are repealed.

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[6] 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, ELI: http://data.europa.eu/eli/reg/2005/378/oj).

Article 3

Transitional measures

1. The preparation, as authorised by Regulation (EU) No 1118/2010 and Implementing Regulation (EU) No 667/2013 and premixtures containing that additive, which are produced and labelled before [*6 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] may continue to be placed on the market and used until the stocks concerned are exhausted.

2. Compound feed and feed materials containing the feed additive referred to in paragraph 1, which are produced and labelled before [*12 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] may continue to be placed on the market and used until the stocks concerned are exhausted.

Article 4

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.*

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN