



2026/2086

21.9.2026

COMMISSION IMPLEMENTING REGULATION (EU) 2026/2086

of 18 September 2026

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)

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 Commission 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 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.

⁽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>.

- (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.

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 11 April 2027 in accordance with the rules applicable before 11 October 2026 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 11 October 2027 in accordance with the rules applicable before 11 October 2026 may continue to be placed on the market and used until the stocks concerned are exhausted.

⁽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 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, 18 September 2026.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the holder of authorisation	Name of the 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 feed with a moisture content of 12 %				
Category: coccidiostats and histomonostats										
51771	Elanco GmbH	Diclazuril 0,5 g/100 g (Clinacox 0,5 %)	<i>Additive composition</i> Preparation of — Diclazuril: 5 g/kg — Polyvidone K30: 2 g/kg — Sodium hydroxide: 0,5 g/kg — Soybean meal q.s. Solid form. <i>Characterisation of the active substance</i> Diclazuril: (±)- 2,6-dichloro- α -(4-chlorophenyl)-4-(4,5-dihydro-3,5-dioxo-1,2,4-triazin-11-2(3H)-yl) benzeneacetonitrile; C ₁₇ H ₉ Cl ₃ N ₄ O ₂ . CAS number: 101831-37-2. Related impurities: Impurities D and H: ≤ 0,1 % individually; Impurities A, C, E and F: ≤ 0,5 % individually; Total impurities A to I ⁽¹⁾ : ≤ 1,5 %. Produced by chemical synthesis.	Chickens for fattening	—	1	1	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. The additive shall be incorporated in compound feed in the form of a premixture. 3. The additive shall not be used simultaneously with other coccidiostats. 4. A post-market monitoring programme on the resistance of <i>Eimeria</i> spp. to diclazuril shall be planned and executed by the holder of authorisation, in accordance with Commission Regulation (EC) No 429/2008 ⁽⁴⁾ .	11 October 2036	Commission Regulation (EU) No 37/2010 ⁽⁵⁾
				Chickens reared for laying	16 weeks	1	1			

Identification number of the additive	Name of the holder of authorisation	Name of the 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 feed with a moisture content of 12 %				
			<i>Analytical methods</i> ⁽²⁾ For the determination of diclazuril in the feed additive: High Performance Liquid Chromatography coupled with photometric detection (HPLC-UV). For the determination of diclazuril in premixtures: — High Performance Liquid Chromatography coupled with photometric detection (HPLC-UV) – Regulation (EC) No 152/2009 ⁽³⁾. For the determination of diclazuril in compound feed: — High Performance Liquid Chromatography coupled with photometric detection (HPLC-UV) – Regulation (EC) No 152/2009 or — High Performance Liquid Chromatography coupled with tandem mass spectrometry (LC-MS/MS) – EN 17299.					5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.		

⁽¹⁾ As listed in the European Pharmacopoeia (Ph. Eur. 11.1.2023).

⁽²⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

⁽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, ELI: <http://data.europa.eu/eli/reg/2009/152/oj>).

⁽⁴⁾ Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 22.5.2008, p. 1, ELI: <http://data.europa.eu/eli/reg/2008/429/oj>).

⁽⁵⁾ Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1, ELI: [http://data.europa.eu/eli/reg/2010/37\(1\)/oj](http://data.europa.eu/eli/reg/2010/37(1)/oj)).