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COMMISSION IMPLEMENTING REGULATION (EU) 2026/532

of 11 March 2026

concerning the renewal of the authorisation and the authorisation of new uses of a preparation of monensin sodium (Coxidin) as a feed additive for chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for reproduction (holder of authorisation: Huvepharma N.V.) and repealing Regulation (EC) No 109/2007 and Implementing Regulation (EU) No 140/2012

(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 an authorisation.

(2) Two forms of a preparation of monensin sodium (Coxidin) ('the preparation'), with wheat bran or with calcium carbonate, were authorised for 10 years as a feed additive for use in chickens for fattening and turkeys up to 16 weeks of age by Commission Regulation (EC) No 109/2007 ([2]). The form of the preparation with calcium carbonate was authorised also for use in chickens reared for laying by Commission Implementing Regulation (EU) No 140/2012 ([3]).

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, two applications were submitted for the renewal of the authorisation of the preparation as a feed additive for chickens for fattening and turkeys for fattening (both forms) and for chickens reared for laying (form with calcium carbonate), requesting the additive to be classified in the additive category coccidiostats and histomonostats. Those applications were accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.

(4) In parallel, two applications were submitted in accordance with Article 7 of Regulation (EC) No 1831/2003 for the authorisation of new uses of the preparation. Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(5) The applications submitted in accordance with Article 7 of Regulation (EC) No 1831/2003 concern the authorisation of the preparation as a feed additive for chickens reared for laying (form with wheat bran) and turkeys reared for reproduction (both forms), requesting that additive to be classified in the category coccidiostats and histomonostats.

(6) The European Food Safety Authority ('the Authority') concluded in its opinions of 31 January 2024 ([4]) and 24 June 2025 ([5]) that the applicant had provided evidence that the preparation remains safe for turkeys for fattening (up to 16 weeks) at the current maximum authorised level of 100 mg monensin sodium/kg complete feed and extended this conclusion to turkeys reared for reproduction (up to 16 weeks). It further concluded that the use of the preparation is safe up to the newly proposed maximum recommended level of 120 mg monensin sodium/kg complete feed for chickens for fattening and chickens reared for laying. Additionally, the Authority concluded that

([1]) OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj.
([2]) Commission Regulation (EC) No 109/2007 of 5 February 2007 concerning the authorisation of monensin sodium (Coxidin) as a feed additive (OJ L 31, 6.2.2007, p. 6, ELI: http://data.europa.eu/eli/reg/2007/109/oj).
([3]) Commission Implementing Regulation (EU) No 140/2012 of 17 February 2012 concerning the authorisation of monensin sodium as a feed additive for chickens reared for laying (holder of authorisation Huvepharma NV Belgium) (OJ L 47, 18.2.2012, p. 18, ELI: http://data.europa.eu/eli/reg_impl/2012/140/oj).
([4]) *EFSA Journal* 2024;22:e8628, https://doi.org/10.2903/j.efsa.2024.8628.
([5]) *EFSA Journal* 2025;23:e9541, https://doi.org/10.2903/j.efsa.2025.9541.

the use of the preparation remains safe for consumers – the existing maximum residue levels (MRLs) for poultry tissues ensuring consumer safety with no withdrawal time being necessary – and the environment. It also concluded that both formulations of the preparation pose a risk by inhalation and are not irritant to the skin. The Authority specified further that the formulation with wheat bran is not a skin sensitiser but is irritant to the eyes, and the formulation with calcium carbonate is to be considered as a skin and respiratory sensitiser, while no conclusions can be reached on its eye irritation potential. The Authority further concluded that the preparation is efficacious in controlling coccidiosis at a level of 100 mg monensin sodium/kg complete feed for chickens for fattening and at 60 mg monensin sodium/kg complete feed for turkeys for fattening. These conclusions were extended by the Authority to chickens reared for laying and turkeys reared for reproduction. It noted that there are signs of development of resistance of *Eimeria* spp. to monensin sodium and considered that there is a need for specific requirements of post-market monitoring. The Authority also verified the report on the methods of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003, resulting from the amendment/supplementation of the conditions of the previous authorisation.

(7) 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 both forms of that preparation for use in chickens for fattening and turkeys for fattening, and of the form with calcium carbonate for use in chickens reared for laying, should be renewed. In addition, that preparation should be authorised for the new uses applied for, namely for chickens reared for laying (form with wheat bran) and turkeys reared for reproduction (both forms). It is appropriate to provide for a post-market monitoring programme, starting five years after the entry into force of this Implementing Regulation, in order to trace and document any sign of resistance to monensin sodium resulting from the use of the preparation. Finally, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.

(8) As a consequence of the renewal of the authorisation of both forms of the preparation for use in chickens for fattening and turkeys for fattening, and of the form with calcium carbonate for use in chickens reared for laying, Regulation (EC) No 109/2007 and Implementing Regulation (EU) No 140/2012 should be repealed.

(9) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of both forms of the preparation for use in chickens for fattening and turkeys for fattening, and of the form with calcium carbonate for use in chickens reared for laying, it is appropriate to provide for a transitional period for the interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(10) 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 of monensin sodium (Coxidin) in both forms with wheat bran or with calcium carbonate, as specified in the Annex, belonging to the additive category coccidiostats and histomonostats, for use in chickens for fattening and turkeys for fattening, as well as authorisation of the preparation of monensin sodium (Coxidin) in the form with calcium carbonate, for use in chickens reared for laying, is renewed subject to the conditions laid down in that Annex.

Article 2

Authorisation

The preparation specified in the Annex, belonging to the additive category coccidiostats and histomonostats, is authorised as an additive in animal nutrition for chickens reared for laying (form with wheat bran) and turkeys reared for reproduction (forms with wheat bran or with calcium carbonate), subject to the conditions laid down in that Annex.

Article 3

Repeals

Regulation (EC) No 109/2007 and Implementing Regulation (EU) No 140/2012 are repealed.

Article 4

Transitional measures

1. The feed additive monensin sodium (Coxidin) (forms with wheat bran or with calcium carbonate), as authorised by Regulation (EC) No 109/2007, and premixtures containing that additive, which are intended for chickens for fattening and turkeys for fattening, as well as the feed additive monensin sodium (form with calcium carbonate), authorised by Implementing Regulation (EU) No 140/2012, and premixtures containing that additive, which are intended for chickens reared for laying, and which are produced and labelled before 1 October 2026 in accordance with the rules applicable before 1 April 2026 may continue to be placed on the market and used until the existing stocks concerned are exhausted.

2. Compound feed and feed materials containing the feed additive referred to in paragraph 1, which are intended for chickens for fattening and turkeys for fattening (forms with wheat bran or with calcium carbonate), as well as for chickens reared for laying (form with calcium carbonate), and which are produced and labelled before 1 April 2027 in accordance with the rules applicable before 1 April 2026 may continue to be placed on the market and used until the existing stocks concerned are exhausted.

Article 5

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, 11 March 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										
51701	Huvepharma N.V.	Monensin sodium (Coxidin)	*Additive composition* Preparation of monensin sodium equivalent to monensin activity ([1]): 23,7-26,2 % Forms with: — Wheat bran: q.s. or — Calcium carbonate q.s. Solid forms. *Characterisation of the active substance* Monensin sodium (sodium salt of polyether monocarboxylic acid), consisting of: — Monensin A sodium: sodium (2-[5-ethyltetrahydro-5-[tetrahydro-3-methyl-5-[tetrahydro-6-hydroxy-6-(hydroxymethyl)-3,5-dimethyl- 2H-pyran-2-yl]-2-furyl]-2- furyl]-9-hydroxy-β-methoxy- α, γ,2,8-tetramethyl-1,6-dioxaspiro-[4.5]decane-7-butyric acid; $C_{36}H_{61}NaO_{11}$;	Chickens for fattening	—	100	120	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. Monensin sodium shall not be mixed with other coccidiostats. 4. Indicate in the directions for use: 'Dangerous for equines. This feedingstuff contains an ionophore: avoid simultaneous administration with tiamulin and monitor for possible adverse reactions,	1 April 2036	25 µg monensin sodium/kg of wet skin + fat 8 µg monensin sodium/kg of wet liver, wet kidney and wet muscle
				Chickens reared for laying	16 weeks	100	120			
				Turkeys for fattening Turkeys reared for reproduction	16 weeks	60	100			

ELI: http://data.europa.eu/eli/reg_impl/2026/532/oj

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						mg of active substance/ kg of complete feed with a moisture content of 12 %				
			— Monensin B sodium: sodium 4-(9-hydroxy-2-(5'-(6-hydroxy-6-(hydroxymethyl)-3,5-dimethyltetrahydro-2H-pyran- 2-yl)-2,3'-dimethyloctahydro-[2,2'-bifuran]-5-yl)-2,8-dimethyl-1,6-dioxaspiro [4.5]decan-7-yl)-3-methoxy-2-methylpentanoate; $C_{35}H_{59}NaO_{11}$; — Monensin C sodium: sodium 2-ethyl-4-(2-(2-ethyl-5'-(6-hydroxy-6-(hydroxymethyl)-3,5-dimethyltetrahydro-2H- pyran-2-yl)-3'-methyloctahydro-[2,2'-bifuran]-5-yl)-9-hydroxy-2,8-dimethyl-1,6-dioxaspiro[4.5]decan-7- yl)-3-methoxypentanoate; $C_{37}H_{63}NaO_{11}$. From 'monensin sodium technical substance', composed of: — Monensin sodium equivalent to monensin activity: 32-42 %;					when used concurrently with other medicinal substances'. 5. A post-market monitoring program on the resistance of *Eimeria* spp. to monensin sodium shall be planned and executed by the holder of authorisation, in accordance with Commission Regulation (EC) No 429/2008 ([3]). That post-market monitoring program shall include, as of 1 April 2031, EU wide field monitoring of resistance of *Eimeria* to monensin sodium and in-vitro screenings or anticoccidial sensitivity tests for single *Eimeria* strains collected from different chicken		

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 %				
			— Perlite: 15-20 %; — Dried exhausted fermentation substrate: 38-53 %; CAS number: 22373-78-0; Produced by fermentation with *Streptomyces* sp. LMG S-19095. Factor composition: — Monensin A: ≥ 90 % — Monensin A + B: ≥ 95 % — Monensin C: 0,2-0,3 % *Analytical method* (2) For the determination of monensin sodium in the feed additive: high performance liquid chromatography using post-column derivatisation coupled with photometric detection (HPLC-PCD-UV-Vis). For the determination of monensin sodium in premixtures: high performance liquid chromatography using post-column derivatisation coupled with photometric detection (HPLC-PCD-UV-Vis) – EN ISO 14183.					farms across the EU for which an indication of resistance is identified. It shall also include, as of 1 April 2033 at the latest, anticoccidial sensitivity tests (mixed infection) in chickens and turkeys covering a broad range of *Eimeria* strains originating from EU locations in which indications of resistance have been identified and implemented consistently across the EU. 6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational		

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						mg of active substance/kg of complete feed with a moisture content of 12 %				
			For the determination of monensin sodium in compound feed: — High performance liquid chromatography using post-column derivatisation coupled with photometric detection (HPLC-PCD-UV-Vis) – EN ISO 14183 or — High performance liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS) – EN 17299. For the determination of monensin sodium in tissues: high performance liquid chromatography coupled with tandem mass spectrometry (HPLC-MS/MS).					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 and eye protective equipment, and also with skin protective equipment for the form with calcium carbonate.		

(1) The concentration of monensin sodium is expressed as monensin activity which includes the relative biopotency in terms of 'monensin activity' of the different monensin variants.

(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 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).