



2026/1860

30.7.2026

COMMISSION IMPLEMENTING REGULATION (EU) 2026/1860

of 29 July 2026

concerning the authorisation of a preparation of narasin (Monteban G100) as a feed additive for chickens for fattening (holder of authorisation: Elanco GmbH) and repealing Regulation (EC) No 1464/2004

(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. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) A preparation of narasin (Monteban G100) ('the preparation') was authorised for 10 years in accordance with Directive 70/524/EEC as a feed additive for chickens for fattening by Commission Regulation (EC) No 1464/2004 ⁽³⁾. That preparation was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1), point (b), of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the authorisation of the preparation as a feed additive for chickens for fattening. The applicant requested the 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 opinions of 3 October 2018 ⁽⁴⁾, 30 January 2024 ⁽⁵⁾ and 28 January 2026 ⁽⁶⁾ that the preparation is safe for the target species, as well as for consumers and the environment, when used in chickens for fattening at 70 mg/kg feed. It highlighted that narasin is toxic to horses, turkeys and rabbits at levels below those used in the prevention of coccidiosis in chickens and that the simultaneous use of the preparation and certain antibiotic drugs (e.g. tiamulin) is contraindicated. The Authority also concluded that the preparation is irritant to the eyes but no to the skin, has the potential to induce skin sensitisation and that inhalation exposure would pose a risk to persons handling the additive. The Authority further concluded that the use of the preparation at 60 mg/kg feed is efficacious in controlling coccidiosis in chickens for fattening. It considered that there is a need for specific requirements of post-market monitoring, recommending that field monitoring of *Eimeria* spp. resistance to narasin be undertaken, preferably during the latter part of the period of authorisation. The Authority also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

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

⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1, ELI: <http://data.europa.eu/eli/dir/1970/524/oj>).

⁽³⁾ Commission Regulation (EC) No 1464/2004 of 17 August 2004 concerning the authorisation for 10 years of the additive 'Monteban' in feedingstuffs, belonging to the group of coccidiostats and other medicinal substances (OJ L 270, 18.8.2004, p. 8, ELI: <http://data.europa.eu/eli/reg/2004/1464/oj>).

⁽⁴⁾ EFSA Journal 2018;16(11):5460, <https://doi.org/10.2903/j.efsa.2018.5460>.

⁽⁵⁾ EFSA Journal 2024;00:e8613, <https://doi.org/10.2903/j.efsa.2024.8613>.

⁽⁶⁾ EFSA Journal 2026;24:e9931, <https://doi.org/10.2903/j.efsa.2026.9931>.

- (5) 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 use of that preparation should be authorised for chickens for fattening. It is appropriate to provide for post-market monitoring of the resistance of *Eimeria* spp. to narasin. It is appropriate to provide for indicating in the directions for use that the additive is dangerous for certain species and that its simultaneous use with certain medicinal substances can be contraindicated. 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.
- (6) 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 the interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (7) As a consequence of the authorisation of the preparation as a feed additive for chickens for fattening, Regulation (EC) No 1464/2004 should be repealed.
- (8) 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

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 for fattening, subject to the conditions laid down in that Annex.

Article 2

Repeal

Regulation (EC) No 1464/2004 is repealed.

Article 3

Transitional measures

1. The additive, as authorised by Regulation (EC) No 1464/2004 and premixtures containing that additive, which are produced and labelled before 19 February 2027 in accordance with the rules applicable before 19 August 2026 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the feed additive referred to in paragraph 1, which are produced and labelled before 19 August 2027 in accordance with the rules applicable before 19 August 2026 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, 29 July 2026.

For the Commission
The President
Ursula VON DER LEYEN

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										
51765	Elanco GmbH	Narasin 100 g/kg (Monteban G100)	<i>Additive composition</i> Preparation of — narasin: 95,0-107,5 g/kg — food grade mineral oil: 10-25 g/kg — rice hulls qs 1 kg. Solid form. <i>Characterisation of the active substance</i> Narasin granulated containing: — Narasin: ≥ 100 g/kg, including: — narasin A: (2R)-2-((2R,3S,5S,6R)-6-[(2S,3S,4S,6R)-6-((-2S,5S,7R,9S,10S,12R,15R)-2-[(2R,5R,6S)-5-ethyl-5-hydroxy-6-methyltetrahydro-2H-pyran-2-yl]-15-hydroxy-2,10,12-trimethyl-1,6,8-trioxadispiro[4.1.5 ^{7.3}]pentadec-13-en-9-yl]-3-hydroxy-4-methyl-5-oxooctan-2-yl]-3,5-dimethyltetrahydro-2H-pyran-2-yl]butanoic	Chickens for fattening	—	60	70	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. Indicate in the directions for use of the additive, premixtures and related feed: 'Dangerous for equines, turkeys and rabbits. This	19 August 2036	50 µg narasin/kg of all wet tissues

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 %				
			acid; C₄₃H₇₂O₁₁; CAS number: 55134-13-9: ≥ 90 %, — narasin B, D and I, — Fermentation mass: 28 %, — Dipotassium hydrogen phosphate: 6 %, — Montmorillonite clay: 53 %. Produced by fermentation with <i>Streptomyces</i> spp. NRRL B-67771. <i>Analytical methods</i> ⁽¹⁾ For the determination of narasin in the feed additive: High Performance Liquid Chromatography using post-column derivatisation coupled with photometric detection (HPLC-PCD-UV-Vis). For the determination of narasin in the premixtures: High Performance Liquid Chromatography using post-column derivatisation coupled with photometric detection (HPLC-PCD-UV-Vis) – EN ISO 14183. For the determination of narasin in compound feed: — High Performance Liquid Chromatography using post-column derivatisation coupled with photometric detection (HPLC-PCD-UV-Vis) – EN ISO 14183, or					feed contains an ionophore: simultaneous use with certain medicinal substances, including tiamulin, is contra-indicated.' 5. A post-market monitoring programme on the resistance of <i>Eimeria</i> spp. to narasin shall be planned and executed by the holder of authorisation, in accordance with Commission Regulation (EC) No-429/2008 ⁽²⁾. 6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to		

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						mg of active substance/kg of complete feed with a moisture content of 12 %				
			— High Performance Liquid Chromatography coupled with tandem mass spectrometry (LC-MS/MS) – EN 17299. For the determination of narasin in tissues: High Performance Liquid Chromatography coupled with tandem mass spectrometry (LC-MS/MS).					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) 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.

(²) 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>).