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EUROPEAN
COMMISSION

Brussels, XXX
SANTE/2362048/2026
[…](2026) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of a preparation of narasin and diclazuril (Interban) as a feed additive for chickens for fattening and chickens reared for laying (holder of authorisation: Elanco GmbH)

(Text with EEA relevance)

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concerning the authorisation of a preparation of narasin and diclazuril (Interban) as a feed additive for chickens for fattening and chickens reared for laying (holder of authorisation: Elanco GmbH)

(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) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of narasin and diclazuril (Interban). That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of a preparation of narasin and diclazuril as a feed additive for chickens for fattening and chickens reared for laying, requesting that additive to be classified in the category ‘coccidiostats and histomonostats’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 6 February 2026[2] that the preparation of narasin and diclazuril is safe for the target species, as well as for consumers and the environment, when used at the proposed level of 50 mg narasin and 1 mg diclazuril/kg complete feed. It also concluded that the maximum residue limits currently in force for narasin and diclazuril are protective for the consumer at 0-day withdrawal. The Authority concluded that the preparation of narasin and diclazuril is not irritant to the skin, but should be considered a skin and respiratory sensitiser, inhalation and dermal exposure being considered a risk for the user, while it could not conclude on the eye irritation potential due to the lack of data. The Authority further concluded that the preparation of narasin and diclazuril is efficacious controlling coccidiosis in chickens for fattening when used at the proposed used level of 50 mg narasin and 1 mg diclazuril/kg complete feed and extended that conclusion to chickens reared for laying. It 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 additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003. In addition, the Authority highlighted the

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

[2] *EFSA Journal.* 2026;24:e9963, https://doi.org/10.2903/j.efsa.2026.9963.

danger of the additive for equine species, turkeys and rabbits, as well as the fact that simultaneous use with certain medicinal substances can be contraindicated.

(5) In view of the above, the Commission considers that the preparation of narasin and diclazuril satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised. It is appropriate to provide for post-market monitoring of the resistance of *Eimeria* spp. to narasin and diclazuril. 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) 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, subject to the conditions laid down in that Annex.

Article 2
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