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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

concerning the authorisation of a preparation of monensin sodium (Elancoban G200) as a feed additive for chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for reproduction (holder of authorisation: Elanco GmbH), the withdrawal from the market of monensin sodium (Elancoban G100, Elancoban 100, Elancogran 100 and Elancoban 200) as a feed additive for chickens for fattening, chickens reared for laying and turkeys and repealing Regulation (EC) No 1356/2004

(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 nutrition¹, and in particular Article 9(2) and Article 10(5) 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 authorisation. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC².
- (2) Monensin sodium (Elancoban G100, Elancoban 100, Elancogran 100, Elancoban G200 and Elancoban 200) was authorised for 10 years in accordance with Directive 70/524/EEC as a feed additive for chickens for fattening, chickens reared for laying up to a maximum of 16 weeks of age and for turkeys up to a maximum of 16 weeks of age, by Commission Regulation (EC) No 1356/2004³. The feed additive 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 monensin sodium (Elancoban G200) as a feed additive for chickens for fattening, chickens reared for laying up to a maximum of 16 weeks of age, turkeys for fattening and turkeys reared for reproduction up to a maximum of 16 weeks of age, requesting the additive to be classified in the additive category ‘coccidiostats and histomonostats’. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

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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 1356/2004 of 26 July 2004 concerning the authorisation for 10 years of the additive «Elancoban» in feedingstuffs, belonging to the group of coccidiostats and other medicinal substances (OJ L 251, 27.7.2004, p. 6, ELI: <http://data.europa.eu/eli/reg/2004/1356/oj>).

- (4) However, no application was submitted in accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof for the authorisation of monensin sodium (Elancoban G100, Elancoban 100, Elancogran 100 and Elancoban 200) as a feed additive.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinions of 13 November 2019⁴, 11 May 2023⁵ and 5 May 2026⁶, that monensin sodium (Elancoban G200) is safe at a maximum concentration of 100 mg monensin sodium/kg complete feed for chickens for fattening, chickens reared for laying and turkeys up to 16 weeks of age, as well as for consumers provided that the existing maximum residue limits (MRLs) and the withdrawal period of 1 day are respected. It considered the additive safe for the environment. The Authority highlighted that monensin sodium is toxic to horses at doses proposed for feed supplementation in poultry and that the simultaneous use of monensin sodium (Elancoban G200) and certain antibiotic drugs (e.g. tiamulin) is contraindicated. The Authority also concluded that the additive is very irritant to the eye but is not a skin irritant, and that it should be regarded as a potential skin and respiratory sensitiser, inhalation exposure being considered a risk to persons handling the additive. The Authority further concluded that the use of monensin sodium (Elancoban G200) has the potential to effectively control coccidiosis at the minimum concentration of 100 mg monensin sodium/kg complete feed in chickens for fattening and chickens reared for laying and at the minimum concentration of 60 mg monensin sodium/kg complete feed in turkeys up to 16 weeks of age. It considered that there is a need for specific requirements of post-market monitoring, recommending that field monitoring of *Eimeria* spp. resistance to monensin sodium is 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.
- (6) In view of the above, the Commission considers that monensin sodium (Elancoban G200) is a preparation which 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, chickens reared for laying, turkeys for fattening and turkeys reared for reproduction, including maintaining the existing maximum residue limits (MRLs) and the withdrawal period of 1 day. It is appropriate to provide for post-market monitoring of the resistance of *Eimeria* spp. to monensin sodium. Furthermore, it is appropriate to indicate 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.
- (7) According to Article 10(5) of Regulation (EC) No 1831/2003, the Commission is to adopt a Regulation requiring the withdrawal from the market of feed additives for which no applications were submitted before the deadline laid down in Article 10(2) of that Regulation. Therefore, monensin sodium (Elancoban G100, Elancoban 100, Elancogran 100 and Elancoban 200) should be withdrawn from the market.

⁴ EFSA Journal 2019;17(12):5891. <https://doi.org/10.2903/j.efsa.2019.5891>.

⁵ EFSA Journal 2023;21(6):8044. <https://doi.org/10.2903/j.efsa.2023.8044>.

⁶ EFSA Journal. 2026;24:e10123. <https://doi.org/10.2903/j.efsa.2026.10123>.

- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation of monensin sodium (Elancoban G200), it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (9) In addition, in so far as feed additives are withdrawn from the market, it is also appropriate to allow for a transitional period within which existing stocks of the additives, premixtures, feed materials and compound feed which have been produced with these additives, may be used up, so that the interested parties can adapt to the obligation to withdraw those products from the market.
- (10) As a consequence of the authorisation of the preparation of monensin sodium (Elancoban G200) as a feed additive for chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for reproduction, and of the withdrawal from the market of monensin sodium (Elancoban G100, Elancoban 100, Elancogran 100 and Elancoban 200), Regulation (EC) No 1356/2004 should be repealed.
- (11) 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, chickens reared for laying, turkeys for fattening and turkeys reared for reproduction, subject to the conditions laid down in that Annex.

Article 2
Withdrawal from the market

Monensin sodium (Elancoban G100, Elancoban 100, Elancogran 100 and Elancoban 200), as authorised by Regulation (EC) No 1356/2004 pursuant to Directive 70/524/EEC, shall be withdrawn from the market.

Article 3
Repeal

Regulation (EC) No 1356/2004 is repealed.

Article 4
Transitional measures related to the authorisation

1. Monensin sodium (Elancoban G200), as authorised by Regulation (EC) No 1356/2004 pursuant to Directive 70/524/EEC, 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 5

Transitional measures related to the withdrawal from the market

1. Existing stocks of monensin sodium (Elancoban G100, Elancoban 100, Elancogran 100 and Elancoban 200) may continue to be placed on the market and used until *[12 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]*.
2. Premixtures produced with the feed additive referred to in paragraph 1 may continue to be placed on the market and used until *[15 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]*.
3. Compound feed and feed materials produced with the feed additive referred to in paragraph 1 or with the premixtures referred to in paragraph 2 may continue to be placed on the market and used until *[24 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]*.

Article 6

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