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**[...]**(2020) **XXX** draft

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

**of **XXX****

**concerning the authorisation of monensin and nicarbazin (Monimax) a feed additive for  
turkeys for fattening, chickens for fattening and chickens reared for laying (holder of  
authorisation Huvepharma NV)**

(Text with EEA relevance)

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

of **XXX**

**concerning the authorisation of monensin and nicarbazin (Monimax) a feed additive for turkeys for fattening, chickens for fattening and chickens reared for laying (holder of authorisation Huvepharma NV)**

(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<sup>1</sup>, 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 authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of monensin and nicarbazin (Monimax). That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) That application concerns the authorisation of monensin and nicarbazin (Monimax) as a feed additive for turkeys for fattening, chickens for fattening and chickens reared for laying to be classified in the additive category 'coccidiostats and histomonostats'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 29 November 2017<sup>2</sup>, 2 October 2018<sup>3</sup> and 7 October 2019<sup>4</sup> that, under the proposed conditions of use, monensin and nicarbazin (Monimax) does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the additive presents a hazard by inhalation, and may act as dermal toxicant. No data are available for the eye irritation potential. Therefore, appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority concluded that the additive is considered efficacious to control coccidiosis in turkeys and chickens for fattening and chickens reared for laying. It also concluded that a post-market monitoring plan to monitor the *Eimeria* spp. resistance should be undertaken. The Authority also verified the report

<sup>1</sup> OJ L 268, 18.10.2003, p. 29.

<sup>2</sup> EFSA Journal 2017;15(12):5094.

<sup>3</sup> EFSA Journal 2018;16(11):5459.

<sup>4</sup> EFSA Journal 2019;17(11):5888.

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on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (5) The assessment of monensin and nicarbazin (Monimax) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that additive should be authorised as specified in the Annex to this Regulation.
- (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*

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*

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*

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