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COMMISSION

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

**of **XXX****

**concerning the authorisation of decoquinate (Deccox and Avi-Deccox 60G) as a feed additive for chickens for fattening, (holder of authorisation Zoetis Belgium SA) and repealing Regulation (EC) No 1289/2004**

(Text with EEA relevance)

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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 Articles 9(2) and 13(3) 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 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC<sup>2</sup>.
- (2) The use of decoquinate 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 1289/2004<sup>3</sup>. That additive was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, an application was submitted for the re-evaluation of the substance decoquinate as a feed additive for chickens for fattening. The applicant requested that 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.
- (4) In accordance with Article 13(3) of Regulation (EC) No 1831/2003, an application was submitted for the modification of the composition of the additive decoquinate (Deccox) as a feed additive for chickens for fattening, in particular replacing vegetable components with minerals. The applicant requested to maintain both compositions of the additive on the market. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

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

<sup>2</sup> Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).

<sup>3</sup> Commission Regulation (EC) No 1289/2004 of 14 July 2004 concerning the authorisation for 10 years of the additive Deccox® in feedingstuffs, belonging to the group of coccidiostats other medicinal substances (OJ L 243, 15.7.2004, p. 15).

- (5) The European Food Safety Authority ('the Authority') concluded in its opinions of 29 November 2018<sup>4</sup>, 28 January 2021<sup>5</sup> and 30 October 2014<sup>6</sup> that, under the proposed conditions of use, the substance decoquinate does not have an adverse effect on animal health, human health or the environment and it is efficacious in preventing coccidiosis. It was also concluded that no withdrawal period is required to ensure consumer safety and no Maximum Residue Limits (MRL) are considered necessary. The Authority also concluded that the requested change of carriers and physical form in Avi-Deccox 60G with respect of Deccox do not affect its safety and its capacity to control coccidiosis. Therefore, both forms of the additive are considered equivalent in terms of controlling coccidiosis. The Authority concluded that a post-market monitoring plan to monitor the *Eimeria* spp. resistance should be undertaken. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (6) The assessment of the substance decoquinate 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 substance should be authorised as specified in the Annexes to this Regulation.
- (7) For reasons of legal certainty, Regulation (EC) No 1289/2004 should be repealed.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (9) 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 substance decoquinate specified in the Annexes, belonging to the additive category 'coccidiostats and histomonostats', is authorised as an additive in animal nutrition, subject to the conditions laid down in those Annexes.

*Article 2*  
*Repeal*

Regulation (EC) No 1289/2004 is repealed.

*Article 3*  
*Transitional measures*

The substance specified in Annex I and feed containing that substance, which are produced and labelled before [6 months after the date of entry into force of this Regulation – Date to be inserted by the OP] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the OP] may continue to be placed on the market and used until the existing stocks are exhausted.

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<sup>4</sup> EFSA Journal 2019;17(1):5541.

<sup>5</sup> EFSA Journal 2021;19(3):6453.

<sup>6</sup> EFSA Journal 2014;12(11):3905.

*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,

*For the Commission*  
*The President*  
*Ursula VON DER LEYEN*