EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the renewal of the authorisation of neohesperidine dihydrochalcone as a feed additive for piglets, pigs for fattening, calves, sheep, food-producing finfish, ornamental finfish and dogs and repealing Implementing Regulation (EU) 2015/264

(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 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 and renewing such an authorisation.

(2) Neohesperidine dihydrochalcone was authorised for 10 years as a feed additive for piglets, pigs for fattening, calves, sheep, fish and dogs by Commission Implementing Regulation (EU) 2015/264[2].

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, two applications were submitted for the renewal of the authorisation of neohesperidine dihydrochalcone for piglets, pigs for fattening, calves, sheep, food-producing fish, ornamental finfish and dogs, requesting the additive to be classified in the additive category ‘sensory additives’ and in the functional group ‘flavouring compounds’. Those applications were accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinions of 19 March 2025[3] and 16 September 2025[4] that the applicants have provided evidence that neohesperidine dihydrochalcone remains safe for the target species as well as for the consumers and the environment under the conditions currently authorised. The Authority further stated that neohesperidine dihydrochalcone is not irritant to the eyes and the skin, it is not a skin sensitiser but the exposure through inhalation is likely.

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1 Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj).

2 Commission Implementing Regulation (EU) 2015/264 of 18 February 2015 concerning the authorisation of neohesperidine dihydrochalcone as a feed additive for sheep, fish, dogs, calves and certain categories of pigs (OJ L 45, 19.2.2015, p. 10, ELI: http://data.europa.eu/eli/reg_impl/2015/264/oj).

3 EFSA Journal. 2025;23:e9358. https://doi.org/10.2903/j.efsa.2025.9358.

4 EFSA Journal. 2025;23:e9681. https://doi.org/10.2903/j.efsa.2025.9681

The Authority stated that the application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of the additive. Therefore, it concluded that there is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation. The Authority considered that there is no need for specific requirements of post-market monitoring.

(5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the assessment carried out regarding the method of analysis of neohesperidine dihydrochalcone as a feed additive in the context of the previous authorisation are valid and applicable for the current application. In accordance with Article 5(4), point (c), of Commission Regulation (EC) No 378/2005[5], evaluation reports of the Reference Laboratory are therefore not required.

(6) In view of the above, the Commission considers that neohesperidine dihydrochalcone satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed. 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. Those protective measures should be without prejudice to other workers' safety requirements under Union law.

(7) As a consequence of the renewal of the authorisation of neohesperidine dihydrochalcone, Implementing Regulation (EU) 2015/264 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
Renewal of the authorisation

The authorisation of the substance specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds', is renewed subject to the conditions laid down in that Annex.

Article 2
Repeal

Implementing Regulation (EU) 2015/264 is repealed.

Article 3
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.

[5] Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additive (OJ L 59, 5.3.2005, p. 8, ELI: http://data.europa.eu/eli/reg/2005/378/oj).

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