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

(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 authorisation. Article 10 provides for the re-evaluation of a feed additive pursuant to Council Directive 70/524/EEC ([2]).

(2) Neohesperidine dihydrochalcone was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for piglets, dogs, calves and ovines. This substance was subsequently entered in the Register of feed additives established in Article 17 of Regulation (EC) No 1831/2003 as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003. In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of neohesperidine dihydrochalcone as a feed additive for piglets suckling and weaned, pigs for fattening, calves for rearing, calves for fattening, sheep and dogs. An application was also submitted in accordance with Article 7 of that Regulation for a new use via water for drinking for those species and categories of animals and for a new use for fish. The applicant requested this additive to be classified in the category 'sensory additives'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The European Food Safety Authority ('the Authority') concluded in its opinion of 15 November 2011 ([3]) that, under the proposed conditions of use in feed for all species concerned except fish, neohesperidine dihydrochalcone does not have an adverse effect on animal health, human health or the environment. The Authority further concluded in the subsequent opinion of 9 April 2014 ([4]) that the use of neohesperidine dihydrochalcone as a feed additive for fish does not have an adverse effect on animal health, human health or the environment. The Authority considered that no further demonstration of efficacy is necessary since its function in feed is essentially the same as that in food. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(4) The assessment shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this substance should be authorised as specified in the Annex to this Regulation.

(5) 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.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).
([3]) *EFSA Journal* 2011;9(12):2444.
([4]) *EFSA Journal* 2014;12(5):3669.

HAS ADOPTED THIS REGULATION:

Article 1

The substance specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'Flavourings compounds', is authorised as additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

The substance specified in the Annex and premixtures containing that substance, which are produced and labelled before 11 September 2015 in accordance with the rules applicable before 11 March 2015 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for pigs, calves sheep and dogs.

Compound feed, feed materials containing that substance which are produced and labelled before 11 September 2015 in accordance with the rules applicable before 11 March 2015 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for pigs, calves and sheep.

Compound feed and feed materials containing that substance which are produced and labelled before 11 March 2017 in accordance with the rules applicable before 11 March 2015 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for dogs.

Article 3

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, 18 February 2015.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg/kg of complete feedingstuff with a moisture content of 12 %.			
Category: Sensory additives. Functional group: Flavouring compounds									
2b959	—	Neohesperidine dihydrochalcone	*Additive composition* Neohesperidine dihydrochalcone Ethanol ≤ 5 000 mg/kg *Characterisation of the active substance* Neohesperidine dihydrochalcone $C_{28}H_{36}O_{15}$ CAS No: 20702-77-6 Neohesperidine dihydrochalcone, solid form, produced by chemical synthesis Purity: min. 96 % (dried basis) *Method of analysis* (1) For the determination of neohesperidine dihydrochalcone in the feed additive: Thin Layer Chromatography (TLC), European Pharmacopoeia 6,0, method 01/2008:1547. For the determination of neohesperidine dihydrochalcone in premixtures and feedingstuffs: High-Performance Liquid Chromatography with Diode-Array Detection (HPLC-DAD).	Piglets and pigs for fattening.	—	—	35	1. In the directions for use of the additive and premixture, indicate the storage conditions. 2. For safety: breathing protection, safety glasses and gloves should be worn during handling.	11 March 2025
				Calves	—	—	35		
				Sheep	—	—	35		
				Fish	—	—	35		
				Dogs	—	—	35		

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports