COMMISSION IMPLEMENTING REGULATION (EU) 2023/255

of 6 February 2023

concerning the renewal of the authorisation of naringin as a feed additive for all animal species and repealing Implementing Regulation (EU) No 870/2012

(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 authorisation.

(2) Naringin was authorised for a period of 10 years as a feed additive for all animal species by Commission Implementing Regulation (EU) No 870/2012 ([2]).

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of naringin as a feed additive for all animal species, requesting the additive to be classified in the additive category 'sensory additives' and in the functional group 'flavouring compounds'. That application was accompanied by the particulars and documents required under Article 14(2) of that Regulation.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 24 March 2022 ([3]) that the applicant has provided evidence that the additive remains safe for all animal species, the consumers and the environment under the conditions of use currently authorised. It also concluded that naringin does not cause severe irritation or corrosion to eyes, is not irritant to skin and is not classified as a dermal sensitiser, but in the absence of data it could not conclude on the possible respiratory sensitisation of the additive.

(5) In accordance with Article 5(4), point (c), of Commission Regulation (EC) No 378/2005 ([4]), the Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the previous assessment are applicable for the current application.

(6) The assessment of naringin shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed.

(7) The Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. Those protective measures should comply with Union legislation on worker safety requirements.

([1]) OJ L 268, 18.10.2003, p. 29.

([2]) Commission Implementing Regulation (EU) No 870/2012 of 24 September 2012 concerning the authorisation of naringin as a feed additive for all animal species (OJ L 257, 25.9.2012, p. 10).

([3]) EFSA Journal 2022;20(4):7267.

([4]) 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 additives (OJ L 59, 5.3.2005, p. 8).

(8) Certain conditions should be provided for to allow better control. In particular, a recommended maximum content should be indicated on the label of the additive. Where such content is exceeded, certain information should be indicated on the label of premixtures.

(9) As a consequence of the renewal of the authorisation of naringin as a feed additive, Implementing Regulation (EU) No 870/2012 should be repealed.

(10) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of naringin, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation.

(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

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) No 870/2012 is repealed.

Article 3

Transitional measures

1. The substance specified in the Annex and premixtures containing that substance, which are produced and labelled before 27 August 2023 in accordance with the rules applicable before 27 February 2023 may continue to be placed on the market and used until the existing stocks are exhausted.

2. Compound feed and feed materials containing the substance specified in the Annex, which are produced and labelled before 27 February 2024 in accordance with the rules applicable before 27 February 2023 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

3. Compound feed and feed materials containing the substance specified in the Annex, which are produced and labelled before 27 February 2025 in accordance with the rules applicable before 27 February 2023 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food producing animals.

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, 6 February 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	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 of active substance /kg of complete feed with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
2b16058	Naringin	*Additive composition* Naringin *Characterisation of the active substance* Naringin Extracted from citrus fruits Purity: ≥ 90 % (2S)-4H-1-Benzopyran-4-one,7-((2-O-(6- deoxy-alpha-L-mannopyranosyl)-beta-D- glucopyranosyl) oxy)-2,3-dihydro-5- hydroxy-2-(4-hydroxyphenyl) Chemical formula: $C_{27}H_{32}O_{14}$ CAS number: 10236-47-2 FLAVIS number: 16.058 *Analytical method* (1) For the determination of naringin in the feed additive: — high performance liquid chromatography (HPLC) method coupled to an UV detector (European Pharmacopeia monograph 2.2.29).	All animal species	-	-	-	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 3. On the label of the additive, the following shall be indicated: "Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %: 5 mg." 4. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the level referred to in point 3. 5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.	27 February 2033

(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