

COMMISSION IMPLEMENTING REGULATION (EU) 2022/652
of 20 April 2022
concerning the authorisation of bitter orange extract as a feed additive for certain animal species
(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 an authorisation. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) Bitter orange extract was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for all animal species. That additive was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003.
- (3) The applicant requested 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 7(3) of Regulation (EC) No 1831/2003.
- (4) 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 bitter orange extract for all animal species.
- (5) The applicant requested bitter orange extract to be authorised also for use in water for drinking. However, Regulation (EC) No 1831/2003 does not allow the authorisation of flavouring compounds for use in water for drinking. Therefore, the use of bitter orange extract in water for drinking should not be allowed.
- (6) The European Food Safety Authority ('the Authority') concluded in its opinion of 23 June 2021 ⁽³⁾ that, under the proposed conditions of use, bitter orange extract does not have adverse effects on animal health, consumer health or the environment. The Authority also concluded that bitter orange extract should be considered as an irritant to skin and eyes, and as a skin and respiratory sensitiser. Therefore, 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.
- (7) The Authority concluded, that bitter orange extract is recognised to flavour food and its function in feed would be essentially the same as that in food, therefore, no further demonstration of efficacy is considered necessary. It also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

⁽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 2021;19(7):6709.

- (8) The assessment of bitter orange extract 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 Annex to this Regulation.
- (9) Certain conditions should be provided for to allow better control. In particular, a recommended content should be indicated on the label of the feed additive. Where such content is exceeded, certain information should be indicated on the label of premixtures.
- (10) The fact that bitter orange extract is not authorised for use as a flavouring in water for drinking does not preclude its use in compound feed which is administered via water.
- (11) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the substance concerned, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (12) 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 specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Transitional measures

1. The substance specified in the Annex and premixtures containing this substance, which are produced and labelled before 11 November 2022 in accordance with the rules applicable before 11 May 2022 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 as specified in the Annex which are produced and labelled before 11 May 2023 in accordance with the rules applicable before 11 May 2022 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 as specified in the Annex which are produced and labelled before 11 May 2024 in accordance with the rules applicable before 11 May 2022 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 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*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 April 2022.

For the Commission
The President
Ursula VON DER LEYEN

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 active substance/kg of complete feed with a moisture content of 12 %			

Category: Sensory additives. Functional group: Flavouring compounds

2b136-ex	-	Bitter orange extract	<p><i>Additive composition:</i></p> <p>Bitter orange extract from the fruit of <i>Citrus x aurantium</i> L.</p> <p>Solid form</p> <p><i>Characterisation of the active substance:</i></p> <p>Bitter orange extract from the fruit of <i>Citrus x aurantium</i> L. as defined by the Council of Europe ⁽¹⁾.</p> <p>Flavonoids: 45-55 % of which — Naringin: 20-30 % — Neohesperidin: 10-20 %</p> <p>5- methoxypsoralen (also known as bergapten): ≤ 0,03 %</p> <p>(-)-Synephrine: ≤ 1 %</p> <p>CoE number: 136</p>	<p>Chickens for fattening</p> <p>Laying hens</p> <p>Turkeys for fattening</p> <p>Piglets</p> <p>Pigs for fattening</p> <p>Sows</p> <p>Dairy cows</p> <p>Calves</p> <p>Cattle for fattening</p> <p>Sheep/goats</p> <p>Horses</p> <p>Rabbits</p> <p>Salmonids</p> <p>Ornamental fish</p> <p>Dogs</p> <p>Cats</p>	-	-		<ol style="list-style-type: none"> The additive shall be incorporated into the feed in the form of a premixture. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. The additive shall be not used in combination with neohesperidine dihydrochalcone (2b959). 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 %: — Chickens for fattening: 102 mg. — Laying hens: 151 mg. — Turkeys for fattening: 136 mg. — Piglets: 182 mg. — Pigs for fattening: 217 mg. — Sows: 268 mg. — Dairy cows: 259 mg. — Calves (milk replacer), cattle for fattening, sheep/goats, horses, salmonids, dogs and ornamental fish: 400 mg. — Cats: 80 mg. — Rabbits: 161 mg.' 	11 May 2032
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		<p><i>Analytical method</i> ⁽²⁾</p> <p>For the quantification of naringin (phytochemical marker) in the feed additive: — High performance liquid chromatography (HPLC) with spectrophotometric (UV) detection</p>					<ol style="list-style-type: none"> 5. 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 4. 6. The mixture of bitter orange extract from the fruit of <i>Citrus x aurantium</i> L with other authorised additives obtained from <i>Citrus aurantium</i> L. shall not be allowed in feedingstuffs. 7. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. 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 skin, eye and breathing protection. 	
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⁽¹⁾ Natural sources of flavourings – Report No. 2 (2007).

⁽²⁾ 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>.