

**COMMISSION IMPLEMENTING REGULATION (EU) 2023/54**  
**of 4 January 2023**  
**correcting Implementing Regulation (EU) 2022/652 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 <sup>(1)</sup>, and in particular Article 9(2) thereof,

Whereas:

- (1) The use of the bitter orange extract as a feed additive was authorised for certain animal species by Commission Implementing Regulation (EU) 2022/652 <sup>(2)</sup>.
- (2) Bitter orange extract is known to contain 10 to 20 % neohesperidin, as detailed in the column 'Composition, chemical formula, description, analytical method' in the Annex to Implementing Regulation (EU) 2022/652.
- (3) An incorrect presumption of a relationship between neohesperidin, identified with CAS number 13241-33-3, and neohesperidin dihydrochalcone, identified with CAS number 20702-77-6, which has a similar name, but is a distinct substance, resulted in point 3 of the column 'Other provisions' in the Annex to Implementing Regulation (EU) 2022/652, which mistakenly provides for the exclusion of the use of bitter orange extract in combination with neohesperidin dihydrochalcone.
- (4) The opinion of the European Food Safety Authority of 23 June 2021 on the safety of bitter orange extract <sup>(3)</sup> does not mention any risk as regards the use of bitter orange extract in combination with neohesperidin dihydrochalcone.
- (5) It is therefore necessary to correct the Annex to Implementing Regulation (EU) 2022/652 by deleting point 3 of the column 'Other provisions' in that Annex. For the sake of clarity, it is appropriate to replace the whole Annex to that Implementing Regulation.
- (6) In the interest of preventing disruptions to the placing of the feed additive in the market due to the error in Implementing Regulation (EU) 2022/652, this Regulation should enter into force as a matter of urgency.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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

<sup>(2)</sup> 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 (OJ L 119, 21.4.2022, p. 74).

<sup>(3)</sup> EFSA Journal 2021;19(7):6709.

HAS ADOPTED THIS REGULATION:

*Article 1*

The Annex to Implementing Regulation (EU) 2022/652 is replaced by the Annex to this Regulation.

*Article 2*

This Regulation shall enter into force on the 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, 4 January 2023.

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

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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 <sup>(1)</sup>.</p> <p>Flavonoids: 45-55 % of which — Naringin: 20-30 % — Neohesperidin: 10-20 %</p> <p>5- methoxypsoralen (also known as bergapten): ≤ 0,03 % (-)-Synephrine: ≤ 1 %</p> <p>CoE number: 136</p> <p><i>Analytical method</i> <sup>(2)</sup></p> <p>For the quantification of naringin (phytochemical marker) in the feed additive:</p> <p>— High performance liquid chromatography (HPLC) with spectrophotometric (UV) detection</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"> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</li> <li>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.'</li> </ol>	11 May 2032
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								<p>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.</p> <p>5. 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.</p> <p>6. 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.</p>
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<sup>(1)</sup> Natural sources of flavourings – Report No 2 (2007)

<sup>(2)</sup> 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><sup>1</sup>