

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1451**of 1 September 2022****concerning the authorisation of camphor white essential oil from *Cinnamomum camphora* (L.) J. Presl. and cinnamon tincture from *Cinnamomum verum* J. Presl. as feed additives for all 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) Camphor white essential oil and cinnamon tincture were authorised without a time limit in accordance with Directive 70/524/EEC as feed additives for all animal species. Those additives were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003.
- (3) 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 camphor white essential oil from *Cinnamomum camphora* (L.) J. Presl. and cinnamon tincture from *Cinnamomum verum* J. Presl. as feed additives for all animal species.
- (4) The applicant requested the additives to be classified in the additive category 'sensory additives' and in the functional group 'flavouring compounds'. The applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (5) The applicant requested those additives 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 camphor white oil and cinnamon tincture in water for drinking should not be allowed.

⁽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).

- (6) The European Food Safety Authority ('the Authority') concluded in its opinions of 10 November 2021 ⁽³⁾ ⁽⁴⁾ that, under the proposed conditions of use, camphor white essential oil from *Cinnamomum camphora* (L.) J. Presl. and cinnamon tincture from *Cinnamomum verum* J. Presl. do not have adverse effects on animal health, consumer health or the environment. The Authority also concluded that camphor white essential oil from *Cinnamomum camphora* (L.) J. Presl. and cinnamon tincture from *Cinnamomum verum* J. Presl. should be considered as irritants to skin and eyes, and as skin and respiratory sensitisers. 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 additives.
- (7) The Authority further concluded that camphor white essential oil from *Cinnamomum camphora* (L.) J. Presl. and cinnamon tincture from *Cinnamomum verum* J. Presl. are recognised to flavour food and since their function in feed would be essentially the same as that in food, 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.
- (8) The assessment of camphor white essential oil from *Cinnamomum camphora* (L.) J. Presl. and cinnamon tincture from *Cinnamomum verum* J. Presl. shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those additives 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 additives. Where such content is exceeded, certain information should be indicated on the label of premixtures.
- (10) The fact that camphor white essential oil from *Cinnamomum camphora* (L.) J. Presl. and cinnamon tincture from *Cinnamomum verum* J. Presl. are not authorised for use as a flavouring compound in water for drinking does not preclude their 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 substances 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 substances specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds', are authorised as additives in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Transitional measures

1. The substances specified in the Annex and premixtures containing these substances, which are produced and labelled before 22 March 2023, in accordance with the rules applicable before 22 September 2022, may continue to be placed on the market and used until the existing stocks are exhausted.

⁽³⁾ EFSA Journal 2022;20(1):6985.

⁽⁴⁾ EFSA Journal 2021;19(12):6986.

2. Compound feed and feed materials containing the substances as specified in the Annex, which are produced and labelled before 22 September 2023, in accordance with the rules applicable before 22 September 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 substances as specified in the Annex, which are produced and labelled before 22 September 2024, in accordance with the rules applicable before 22 September 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, 1 September 2022.

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 additive/kg of complete feed with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
2b130-eo	Camphor white essential oil	<p><i>Additive composition</i></p> <p>Camphor white essential oil obtained from the whole plant <i>Cinnamomum camphora</i> (L.) J. Presl.</p> <p>Camphor ≤ 0,1 % Safrole ≤ 0,0002 %</p> <p>Liquid form</p> <p><i>Characterisation of the active substance</i></p> <p>Camphor white essential oil obtained by steam distillation from the whole</p>	All animal species except cats	-	-	-	<p>1. The additive shall be incorporated into the feed in the form of a premixture.</p> <p>2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</p> <p>3. Mixture with other additives containing camphor and safrole is not permitted.</p> <p>4. On the label of the additive the following shall be indicated:</p>	22 September 2032
		<p>plant <i>Cinnamomum camphora</i> (L.) J. Presl as defined by the Council of Europe ⁽¹⁾.</p> <p>1,8-Cineole: 27–43 % d-Limonene (18–27 %) 1-Isopropyl-4-Methylbenzene (p-cymene): 6–15 % α-Pinene (pin-2(3)-ene): 4–10 %</p> <p>CAS number: 8008-51-3 Einecs number: 294-760-2 FEMA number: 2231 CoE number: 130</p>	Cats	-	-	22		

		<p><i>Analytical method</i> ⁽²⁾</p> <p>For the determination of <i>1,8-Cineole</i> (phytochemical marker) in the feed additive:</p> <p>— gas chromatography coupled with flame ionisation detection (GC-FID) (based on ISO 11024)</p>					<p>— Ruminants: 50 mg; — Other species except cats: 22 mg.”</p> <p>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.</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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⁽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://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

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 additive/kg of complete feed with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
2b2289-t	Cinnamon tincture	<p><i>Additive composition</i></p> <p>Cinnamon tincture obtained from the bark of <i>Cinnamomum verum</i> J. Presl.</p> <p>Methyleugenol ≤ 0,00001 % Safrole ≤ 0,00002 %</p> <p>Liquid form</p> <p><i>Characterisation of the active substance</i></p> <p>Cinnamon tincture obtained by extended extraction with water/ethanol mixture (3:1, v/v) from the bark of <i>Cinnamomum verum</i> J. Presl. as defined by the Council of Europe ⁽¹⁾. Cinnamaldehyde: ≤ 0,0012 %</p> <p>FEMA number cinnamon: 2289</p> <p><i>Analytical method</i> ⁽²⁾</p> <p>For the characterisation of the feed additive (cinnamon tincture):</p> <ul style="list-style-type: none"> — gravimetry for the determination of dry matter and ash content; — spectrophotometry for the determination of total polyphenols and total flavonoids content; 	All animal species	-	-	-	<ol style="list-style-type: none"> 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. Mixture with other additives containing methyleugenol and safrole is not permitted. 4. 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 %: — All animal species except horses: 50 mg; — Horses: 60 mg.” 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. 	22 September 2032

		— high performance thin-layer chromatography (HPTLC) for the determination of cinnamaldehyde content.					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.	
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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://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en