



COMMISSION IMPLEMENTING REGULATION (EU) 2025/276

of 12 February 2025

concerning the authorisation of clove tincture from *Syzygium aromaticum* (L.) Merr. & L.M. Perry as a feed additive 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) The substance clove tincture from *Syzygium aromaticum* (L.) Merr. & L.M. Perry was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for all animal species. This substance was subsequently entered in the Register of Feed Additives as an existing product, in accordance with Article 10(1), point (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 authorisation of clove tincture from *Syzygium aromaticum* (L.) Merr. & L.M. Perry 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'. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The applicant requested the additive to be authorised for use also 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 this additive in water for drinking should not be allowed.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 17 April 2024 ⁽³⁾ that clove tincture from *Syzygium aromaticum* (L.) Merr. & L.M. Perry is very unlikely to be of safety concern for the target species at the proposed use level. Furthermore, it concluded that no safety concern would arise for consumers and the environment from the use of clove tincture from *Syzygium aromaticum* (L.) Merr. & L.M. Perry at the proposed use levels in feed. The Authority concluded that clove tincture from *Syzygium aromaticum* (L.) Merr. & L.M. Perry should be considered as irritant to skin and eyes, and as a dermal and respiratory sensitiser. The Authority further concluded that since the flower buds of *Syzygium aromaticum* (L.) Merr. & L.M. Perry and their preparations are recognised to flavour food and 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 method 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, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1, ELI: <http://data.europa.eu/eli/dir/1970/524/oj>).

⁽³⁾ EFSA Journal 2024; 22(5):8791.

- (6) In view of the above, the Commission considers that clove tincture from *Syzygium aromaticum* (L.) Merr. & L.M. Perry satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that substance should be authorised as specified in the Annex to this Regulation. The Commission considers that the presence of the substances of concern, methyleugenol and estragole, requires the setting of maximum content in complete feed and that a mixture of clove tincture from *Syzygium aromaticum* (L.) Merr. & L.M. Perry with other botanical additives is permitted provided that the amounts of the same substances of concern in feed materials and compound feed are lower than the one resulting from the use of a single additive at the maximum or recommended content for the species or animal category. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (7) 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 provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (8) 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 feed additive clove tincture from *Syzygium aromaticum* (L.) Merr. & L.M. Perry, as authorised pursuant to Directive 70/524/EEC and premixtures containing this additive, which are produced and labelled before 5 September 2025 in accordance with the rules applicable before 5 March 2025 may continue to be placed on the market and used until the stocks concerned are exhausted.
2. Compound feed and feed materials containing the feed additive referred to in paragraph 1, which are produced and labelled before 5 March 2026 in accordance with the rules applicable 5 March 2025 may continue to be placed on the market and used until the stocks concerned are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the feed additive referred to in paragraph 1, which are produced and labelled before 5 March 2027 in accordance with the rules applicable before 5 March 2025 may continue to be placed on the market and used until the stocks concerned 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, 12 February 2025.

For the Commission
The President
Ursula VON DER LEYEN

Identification number of the feed 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 additive/kg of complete feedingstuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
2b188-t	Clove tincture	<i>Additive composition</i> Tincture from the dried flower buds of <i>Syzygium aromaticum</i> (L.) Merr. & L.M. Perry (synonym: <i>Eugenia caryophyllata</i> Thunb.)	All animal species except <i>Equidae</i>	—	—	50	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 the stability to heat treatment shall be indicated.	5 March 2035
		Liquid form <i>Characterisation of active substance</i> Clove tincture Tincture as defined by the Council of Europe ⁽¹⁾ obtained from the dried flower buds of <i>Syzygium aromaticum</i> (L.) Merr. & L.M. Perry by extended extraction with a water/ethanol solvent mixture, pressing and filtration. CoE number: 188 <i>Specifications</i> — Dry matter content: 1,57–1,77 % — Total polyphenols ⁽²⁾ : ≤ 0,541 % — Flavonoids: ≤ 0,0418 % — Eugenol: ≤ 0,00497 % — Eugenyl acetate: < 0,00017 mg/mL — Methyleugenol: ≤ 0,00022 % — Estragole: ≤ 0,00009 %	<i>Equidae</i>	—	—	200		

Identification number of the feed 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 additive/kg of complete feedingstuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
		<i>Analytical method</i> ⁽³⁾ For the characterisation of the feed additive: — spectrophotometry for the determination of total polyphenols and total flavonoids — gas chromatography coupled with flame ionisation detection (GC-FID) for the determination of eugenol (phytochemical marker), estragole, methyleugenol and eugenyl acetate					4. 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 by such procedures and measures, the additive and premixtures shall be used with personal skin, eye and breathing protective equipment.	

⁽¹⁾ Natural sources of flavourings – Report No 2 (2007).

⁽²⁾ Expressed as gallic acid equivalent (GAE).

⁽³⁾ 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.