



Brussels, **XXX**
SANTE/6084594/2025 CIS
(POOL/G52025/6084594/6084594-EN
CIS.docx)
[...] (2026) **XXX** draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

concerning the authorisation of clove bud essential oil, clove leaf essential oil and beta-caryophyllene-rich fraction of clove leaf essential oil from *Syzygium aromaticum* (L.) Merr. & L.M. Perry as feed additives for all animal species

(Text with EEA relevance)

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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 nutrition¹, 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/EEC².
- (2) The substances clove bud essential oil and clove leaf essential oil from *Syzygium aromaticum* (L.) Merr. & L.M. Perry were authorised without a time limit in accordance with Directive 70/524/EEC as feed additives for all animal species. These substances were subsequently entered in the Register of Feed Additives as existing products, 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 bud essential oil, clove leaf essential oil and beta-caryophyllene-rich fraction of clove leaf essential oil from *Syzygium aromaticum* (L.) Merr. & L.M. Perry as feed additives for all animal species, requesting the additives to be classified in the additive category 'sensory additives' and in the functional group 'flavouring compounds'. The

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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>).

application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

- (4) The applicant requested the 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 these additives in water for drinking should not be allowed.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 5 July 2023³ that clove bud essential oil, clove leaf essential oil and beta-caryophyllene-rich fraction of clove leaf essential oil from *Syzygium aromaticum* (L.) Merr. & L.M. Perry are of no concern for target species for fattening and are considered very unlikely to induce adverse effects in any other species and in long-living and reproductive animals at certain maximum concentrations further specified for each species. Furthermore, the Authority concluded that no concerns for consumers were identified following the use of clove bud essential oil, clove leaf essential oil and beta-caryophyllene-rich fraction of clove leaf essential oil from *Syzygium aromaticum* (L.) Merr. & L.M. Perry, under the proposed conditions, and that their use, under the proposed conditions, is not expected to pose a risk to the environment. The Authority concluded that clove bud essential oil, clove leaf essential oil and beta-caryophyllene-rich fraction of clove leaf essential oil from *Syzygium aromaticum* (L.) Merr. & L.M. Perry should be considered as irritants to skin and eyes and as skin and respiratory sensitisers. The Authority indicated that unprotected users may be exposed to methyleugenol when handling the additives and that the exposure of the users should therefore be minimised to reduce that risk. The Authority further concluded that since clove bud essential oil, clove leaf essential oil and beta-caryophyllene-rich fraction of clove leaf essential oil from *Syzygium aromaticum* (L.) Merr. & L.M. Perry 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. The Authority also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (6) In view of the above, the Commission considers that clove bud essential oil, clove leaf essential oil and beta-caryophyllene-rich fraction of clove leaf essential oil from *Syzygium aromaticum* (L.) Merr. & L.M. Perry satisfy the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of these substances should be authorised as specified in the Annex to this Regulation. The Commission considers that the presence of methyleugenol, a substance of concern belonging to the group of *p*-allylalkoxybenzenes, in clove bud essential oil, clove leaf essential oil and beta-caryophyllene-rich fraction of clove leaf essential oil from *Syzygium aromaticum* (L.) Merr. & L.M. Perry, requires the setting of maximum content of those additives in complete feed. It also considers that the simultaneous use of clove bud essential oil, clove leaf essential oil and beta-caryophyllene-rich fraction of clove leaf essential oil from *Syzygium aromaticum* (L.) Merr. & L.M. Perry with other feed additives is permitted provided that the combined content of *p*-allylalkoxybenzenes (methyleugenol, estragole, elemicin, safrole, myristicin, dillapiol, and apiole) in feed materials and compound feed remains below the content that would result from using the authorised feed additive with the highest content of those substances at its maximum or recommended maximum content for the relevant animal species or

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EFSA Journal; 21(7):8183. <https://doi.org/10.2903/j.efsa.2023.8183>.

category. As regards clove bud essential oil from *Syzygium aromaticum* (L.) Merr. & L.M. Perry, which can contain up to 0,13% of methyleugenol, the Commission considers that this additive should not be used in combination with other additives containing methyleugenol. 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 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 feed additives clove bud essential oil, clove leaf essential oil and beta-caryophyllene-rich fraction of clove leaf essential oil 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 [6 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] 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 additives referred to in paragraph 1, which are produced and labelled before [12 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] 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 additives referred to in paragraph 1, which are produced and labelled before [24 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] 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,

For the Commission
The President
Ursula VON DER LEYEN