



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/8517343/2024 CIS
(POOL/G5/2024/8517343/8517343-EN
CIS.docx)
[...] (2025) **XXX** draft

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

of **XXX**

concerning the authorisation of tea tree essential oil from *Melaleuca alternifolia* (Maiden & Betche) Cheel as a feed additive for all animal species

(Text with EEA relevance)

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

of **XXX**

concerning the authorisation of tea tree essential oil from *Melaleuca alternifolia* (Maiden & Betche) Cheel 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 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 substance tea tree essential oil from *Melaleuca alternifolia* (Maiden & Betche) Cheel 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 tea tree essential oil from *Melaleuca alternifolia* (Maiden & Betche) Cheel 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 18 September 2024³ that tea tree essential oil from *Melaleuca alternifolia* (Maiden & Betche) Cheel is of no concern for target species for fattening and that it is very unlikely to be of safety concern for any other species and for long-living and

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, 22(10), e9026. <https://doi.org/10.2903/j.efsa.2024.9026>.

reproductive animals at certain maximum concentrations further specified for each species. Furthermore, it concluded that no concerns for consumers were identified following the use of tea tree essential oil from *Melaleuca alternifolia* (Maiden & Betche) Cheel, under the proposed conditions, and that its use, under the proposed conditions, is not expected to pose a risk to the environment. The Authority concluded that tea tree essential oil from *Melaleuca alternifolia* (Maiden & Betche) Cheel should be considered as irritant to skin and eyes, as a dermal and respiratory sensitiser, and as a reprotoxic substance. The Authority indicated that, when handling the additive, exposure of unprotected users to methyleugenol may occur and that therefore, to reduce the risk, the exposure of the users should be minimised. The Authority further concluded that since tea tree essential oil from *Melaleuca alternifolia* (Maiden & Betche) Cheel is recognised to flavour food and its 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.

- (6) In view of the above, the Commission considers that tea tree essential oil from *Melaleuca alternifolia* (Maiden & Betche) Cheel 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 methyleugenol, a substance of concern, requires the setting of maximum content in complete feed and that a mixture of tea tree essential oil from *Melaleuca alternifolia* (Maiden & Betche) Cheel with other botanical additives is permitted provided that the amounts of the same substance 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 tea tree essential oil from *Melaleuca alternifolia* (Maiden & Betche) Cheel, 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 additive 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 additive 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