

Brussels, XXX
SANTE/3535571/2025 CIS
(POOL/G5/2025/3535571/3535571-EN
CIS.docx)
[...] (2026) XXX draft

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

of XXX

concerning the authorisation of eugenol and trans-anethole as feed additives for poultry and ornamental birds, the renewal of trans-anethole produced by chemical synthesis as a feed additive for ornamental birds and amending implementing Regulation (EU) 2022/1452

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

of **XXX**

concerning the authorisation of eugenol and trans-anethole as feed additives for poultry and ornamental birds and the renewal of the authorisation of trans-anethole produced by chemical synthesis as a feed additive for ornamental birds, and amending Implementing Regulation (EU) 2022/1452

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 and renewing such an authorisation.
- (2) Eugenol produced by chemical synthesis or by the extraction from cloves or cloves oil and 1-methoxy-4-(prop-1(trans)-enyl)benzene, which is a synonym for trans-anethole, produced by chemical synthesis or by the extraction from pine oil, were authorised for a period of 10 years as feed additives for all animal species except poultry and fish by Commission Implementing Regulation (EU) 2022/1452².
- (3) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of eugenol produced by the extraction from dried clove leaves or clove leaf oil and for the authorisation of trans-anethole produced by chemical synthesis and by the extraction from leaves or fruit of star anise. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The application concerns the authorisation of eugenol produced by the extraction from dried clove leaves or clove leaf oil and of trans-anethole produced by chemical synthesis and by the extraction from leaves or fruit of star anise as feed additives for poultry and ornamental birds, requesting those additives to be classified in the category ‘sensory additives’ and in the functional group ‘flavouring compounds’.
- (5) However, the Commission considers that the application for the authorisation of trans-anethole produced by chemical synthesis for ornamental birds should be treated as an application for the renewal of the authorisation granted by Implementing Regulation (EU) 2022/1452, as that authorisation concerned the same additive and included the

¹ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

² Commission Implementing Regulation (EU) 2024/3166 of 18 December 2024 concerning the authorisation of 3-ethylcyclopentan-1,2-dione, 4-hydroxy-2,5-dimethylfuran-3(2H)-one, 4,5-dihydro-2-methylfuran-3(2H)-one, eugenol, 1-methoxy-4-(prop-1(trans)-enyl)benzene, apentylcinnamaldehyde, α-hexylcinnamaldehyde and 2-acetylpyridine as feed additives for certain animal species (OJ L 228, 2.9.2022, p. 17, ELI: http://data.europa.eu/eli/reg_impl/2022/1452/oj).

use for ornamental birds. In addition, the Commission considers that trans-anethole produced by pine oil authorised for ornamental birds by Regulation (EU) 2022/1452 should be authorised with a maximum content as it has the same specifications in terms of composition as the trans-anethole produced by chemical synthesis that is going to be renewed with a maximum content due to the zootechnical effects of this additive for those species. The maximum content will prevent to increase the zootechnical effects beyond the desired flavouring effect pursued in this authorisation.

- (6) The European Food Safety Authority ('the Authority') concluded in its opinion of 19 March 2025³ that, under the proposed conditions of use, eugenol produced by the extraction from dried clove leaves or clove leaf oil and trans-anethole produced by chemical synthesis and by the extraction from leaves or fruit of star anise are safe for poultry species for fattening (chickens and turkeys) at 25 mg/kg complete feed and are very unlikely to induce adverse effects in long-living and reproductive birds (poultry reared for laying/breeding, laying/breeding hens and ornamental birds) up to 25 mg/kg complete feed. These conclusions can be extrapolated to physiologically-related minor species. The Authority also concluded that eugenol and trans-anethole are safe for consumers and the environment. It also concluded that when handling eugenol produced by extraction from dried clove leaves or clove leaf oil and trans-anethole produced by extraction from leaves or fruit of star anise, exposure of unprotected users to estragole produced by the extraction from dried clove leaves or clove leaf oil and to methyleugenol, respectively, may occur, and that therefore, to reduce the risk, the exposure of the users should be minimised. In addition, the Authority concluded that eugenol produced by the extraction from dried clove leaves or clove leaf oil and trans-anethole produced by chemical synthesis and by the extraction from leaves or fruit of star anise are not irritant to skin but are dermal and respiratory sensitisers, that eugenol produced by the extraction from dried clove leaves or clove leaf oil is an eye irritant, but trans-anethole produced by chemical synthesis and by the extraction from leaves or fruit of star anise is not, and that any exposure to these additives is considered a risk. The Authority further concluded that since eugenol produced by the extraction from dried clove leaves or clove leaf oil and trans-anethole produced by chemical synthesis and by the extraction from leaves or fruit of star anise are used in food as flavourings, and their function in feed is essentially the same as that in food, no further demonstration of efficacy is necessary. The Authority did not consider that there is a need for specific requirements of post-market monitoring.
- (7) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in a previous assessment concerning another application for the authorisation of the same additives and verified by the Authority in its opinion of 15 November 2011⁴, are valid and applicable for the current application. In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005⁵, an evaluation report by the Reference Laboratory was therefore not required.
- (8) In view of the above, the Commission considers that eugenol produced by the extraction from dried clove leaves or clove leaf oil and trans-anethole produced by

³ EFSA Journal. 2025;23:e9367m <https://doi.org/10.2903/j.efsa.2025.9367>.

⁴ EFSA Journal 2011;9(12):2440 <https://doi.org/10.2903/j.efsa.2011.2440>.

⁵ Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8, ELI: <http://data.europa.eu/eli/reg/2005/378/oj>).

chemical synthesis and by the extraction from leaves or fruit of star anise satisfy the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of eugenol produced by the extraction from dried clove leaves or clove leaf oil should be authorised for poultry and ornamental birds, the use of trans-anethole produced by chemical synthesis should be authorised for poultry and should be renewed for ornamental birds and the use of trans-anethole produced by the extraction from leaves or fruit of star anise should be authorised for poultry and ornamental birds.

- (9) Eugenol and trans-anethole are already authorised as zootechnical additives by Commission Implementing Regulation (EU) 2019/898⁶ and Commission Implementing Regulation (EU) 2017/420⁷, respectively to produce zootechnical effects in poultry at levels of use of 5mg/kg for eugenol and 7.5 mg/kg for trans-anethole. Since ornamental birds are species physiologically related to poultry the same effects are expected in them. In order to prevent the use of the additives for poultry and ornamental birds at higher levels which could potentially increase the zootechnical effects, beyond the desired flavouring effect pursued in this authorisation, it is necessary to establish a maximum content of the additives in complete feed. In addition, the Commission considers that the presence of methyleugenol in eugenol produced by the extraction from dried clove leaves or clove leaf oil and of estragole in trans-anethole produced by the extraction from leaves or fruit of star anise requires the setting of maximum content in complete feed and that a mixture of eugenol or trans-anethole with other additives is permitted provided that the content of eugenol or trans-anethole in feed materials and compound feed remains below that which would result from using the additive with the highest content of eugenol or trans-anethole, among all authorised feed additives, at their maximum or recommended content for the relevant 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.
- (10) As regards trans-anethole, the characterisation of the active substance differs between the additive produced by chemical synthesis and the additive produced by the extraction from leaves or fruit of star anise, with the latter possibly containing estragole. It is therefore appropriate to differentiate between the terms of their authorisation accordingly. In addition, for reasons of clarity and consistency, it is appropriate to reflect the similar differentiation into the existing authorisation of trans-anethole between the additive produced by the extraction from pine oil and the additive produced by chemical synthesis. This differentiation should further allow to remove the use for ornamental birds as regards trans-anethole produced by chemical synthesis as a consequence of the renewal of the authorisation of the additive for ornamental birds and to set a maximum content for ornamental birds for trans-anethole produced from pine oil. Implementing Regulation (EU) 2022/1452 should therefore be amended accordingly.

⁶ Commission Implementing Regulation (EU) 2019/898 of 29 May 2019 concerning the authorisation of the preparation of eugenol as a feed additive for chickens for fattening (holder of authorisation Lidervet SL) (OJ L 144, 3.6.2019, pp. 291, ELI: http://data.europa.eu/eli/reg_impl/2019/898/oj)

⁷ Commission Implementing Regulation (EU) 2017/420 of 9 March 2017 concerning the authorisation of a preparation of thyme oil, synthetic star anise oil and quillaja bark powder as feed additive for chickens for fattening, chickens reared for laying, minor avian species for fattening and reared for laying (holder of the authorisation Delacon Biotechnik GmbH) (OJ L 64, 10.3.2017, p. 7, ELI: http://data.europa.eu/eli/reg_impl/2017/420/oj)

- (11) In addition, to simplify the labelling of trans-anethole and of feed containing it, the Commission considers appropriate to use the name of the additive “trans-anethole” instead of the synonym “1-methoxy-4-(prop-1(trans)-enyl)benzene”, which was referred to in Implementing Regulation (EU) 2022/1452. That Implementing Regulation should therefore be amended accordingly.
- (12) Since safety reasons do not require the immediate application of the modifications to the conditions of the authorisation of trans-anethole it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from those modifications.
- (13) 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 Annex I, 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

Renewal of the authorisation

The authorisation of the substance specified in Annex II, belonging to the additive category ‘sensory additives’ and to the functional group ‘flavouring compounds’, is renewed subject to the conditions laid down in that Annex.

Article 3

Amendment to Implementing Regulation (EU) 2022/1452

The Annex to Implementing Regulation (EU) 2022/1452 is amended in accordance with Annex III to this Regulation.

Article 4

Transitional measures

1. The feed additive 1-methoxy-4-(prop-1(trans)-enyl)benzene (synonym trans-anethole), as authorised by Implementing Regulation (EU) 2022/1452, and premixtures containing that additive, which are produced and labelled before [6 months after 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 after 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 after 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 5

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