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

of **XXX**

**concerning the authorisation of basil tincture from *Ocimum basilicum* L. as a feed
additive for all animal species**

(Text with EEA relevance)

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concerning the authorisation of basil tincture from *Ocimum basilicum* L. 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 basil tincture from *Ocimum basilicum* L. 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 basil tincture from *Ocimum basilicum* L. 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 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 this additive in water for drinking should not be allowed.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 24 June 2025³ that basil tincture from *Ocimum basilicum* L. is of no safety concern for short-living animals (species for fattening) and that it is very unlikely to induce adverse effects in long-living and reproductive animals up to certain maximum

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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>).

³ EFSA Journal, 23(7), e9543. <https://doi.org/10.2903/j.efsa.2025.9543>.

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concentrations further specified in that opinion for each species. Furthermore, it concluded that no safety concerns for consumers and the environment were identified following the use of basil tincture from *Ocimum basilicum* L. The Authority also concluded that basil tincture from *Ocimum basilicum* L. should be considered an irritant to skin and eyes and a dermal and respiratory sensitiser. The Authority indicated that, when handling the additive, exposure of unprotected users to methyleugenol and estragole may occur and that therefore the exposure of the users should be minimised, in order to reduce the risk. The Authority further concluded that since basil tincture from *Ocimum basilicum* L. 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 basil tincture from *Ocimum basilicum* L. 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 and estragole, substances of concern, in basil tincture from *Ocimum basilicum* L. requires the setting of maximum content in complete feed. It also considers that a mixture of basil tincture from *Ocimum basilicum* L. with other additives is permitted provided that the contents of methyleugenol and estragole in feed materials and compound feed remain below those that would result from using the additive or additives with the highest contents of these substances of concern, 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.
- (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 basil tincture from *Ocimum basilicum* L., 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