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COMMISSION

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

of **XXX**

**concerning the authorisation of eucalyptus tincture from *Eucalyptus globulus* Labill. as a
feed additive for certain animal species**

(Text with EEA relevance)

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

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concerning the authorisation of eucalyptus tincture from *Eucalyptus globulus* Labill. as a feed additive for certain 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) and Article 10(5) 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 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 eucalyptus tincture from *Eucalyptus globulus* Labill. 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 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 eucalyptus tincture from *Eucalyptus globulus* Labill. 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.

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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>).

- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 18 April 2024³ that eucalyptus tincture from *Eucalyptus globulus* Labill. is of no concern for short-living animals (animal intended for fattening) up to certain maximum concentrations further specified for each species. It stated that no conclusions could be drawn for long-living animals and reproductive animals in the absence of analytical data on the occurrence of mono-or diformylated adducts of acylphloroglucinols with terpenes in the tincture and in the absence of toxicity data. Furthermore, it concluded that eucalyptus tincture from *Eucalyptus globulus* Labill., when used up to the specified maximum concentrations for each species, is not expected to pose a safety concern for consumers or a risk to the environment. The Authority concluded that eucalyptus tincture from *Eucalyptus globulus* Labill. should be considered as irritant to skin and eyes, and as a dermal and respiratory sensitiser. The Authority further concluded that since the leaves from *Eucalyptus globulus* Labill. 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 additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (6) Subsequently, the applicant withdrew the application for authorisation of eucalyptus tincture from *Eucalyptus globulus* Labill. for all animal species and categories except turkeys for fattening, chickens for fattening and minor poultry for fattening, pigs for fattening, pigs for fattening of minor *Suidae*, calves for fattening, sheep and goats for fattening, cattle for fattening and other ruminants for fattening, *Camelidae* for fattening, rabbits for fattening, salmonids (other than brood stock) and minor finfish (other than brood stock).
- (7) In view of the above, the Commission considers that eucalyptus tincture from *Eucalyptus globulus* Labill. satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003 as regards turkeys for fattening, chickens for fattening and minor poultry for fattening, pigs for fattening, pigs for fattening of minor *Suidae*, calves for fattening, sheep and goats for fattening, cattle for fattening and other ruminants for fattening, *Camelidae* for fattening, rabbits for fattening, salmonids (except brood stock) and minor finfish (except brood stock). Accordingly, the use of that additive should be authorised as specified in the Annex to this Regulation.
- (8) The Commission considers that the presence of a substance of concern, methyleugenol, requires the setting of a maximum content for the additive in complete feed and that a mixture of eucalyptus tincture from *Eucalyptus globulus* Labill. with other botanical additives is permitted provided that the levels of methyleugenol in feed materials and compound feed remain below those that would result from the use of a single additive at the 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.
- (9) According to Article 10(5) of Regulation (EC) No 1831/2003, the Commission is to adopt a Regulation requiring the withdrawal from the market of feed additives for which no applications were submitted before the deadline provided for in Article 10(2) of Regulation (EC) No 1831/2003. Similarly, a Regulation should be adopted

³ EFSA Journal, 22(5), e8801. <https://doi.org/10.2903/j.efsa.2024.8801>

concerning feed additives for which an application was submitted but subsequently withdrawn.

- (10) In the case of feed additives for which an application has been withdrawn for certain animal species or categories, the withdrawal from the market should only concern those animal species or categories.
- (11) Therefore, eucalyptus tincture from *Eucalyptus globulus* Labill. should be withdrawn from the market as regards the animal species and categories which are not the subject of the authorisation granted by this Regulation.
- (12) 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.
- (13) In addition, in so far as the feed additive is withdrawn from the market, it is also appropriate to allow for a transitional period within which existing stocks of the additive concerned, and of premixtures, feed materials and compound feed which have been produced with that additive, may be used up also in respect of the animal species and categories of animals which are not covered by the authorisation granted by this Regulation, in order to allow interested parties to adapt to the obligation to withdraw those products from the market.
- (14) 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 additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2 **Withdrawal from the market**

The feed additive eucalyptus tincture from *Eucalyptus globulus* Labill., as authorised pursuant to Directive 70/524/EEC, shall be withdrawn from the market in respect of the animal species and categories other than those mentioned in the Annex.

Article 3 **Transitional measures related to the authorisation**

- 1. The feed additive eucalyptus tincture from *Eucalyptus globulus* Labill., as authorised pursuant to Directive 70/524/EEC and premixtures containing that additive, which are intended for turkeys for fattening, chickens for fattening and minor poultry for fattening, pigs for fattening, pigs for fattening of minor *Suidae*, calves for fattening, sheep and goats for fattening, cattle for fattening and other ruminants for fattening, *Camelidae* for fattening, rabbits for fattening, salmonids (except brood stock) and minor finfish (except brood stock), and 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 intended for turkeys for fattening, chickens for fattening and minor poultry for fattening, pigs for fattening, pigs for fattening of minor *Suidae*, calves for fattening, sheep and goats for fattening, cattle for fattening and other ruminants for fattening, *Camelidae* for fattening, rabbits for fattening, salmonids (except brood stock) and minor finfish (except brood stock), and 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.

Article 4

Transitional measures related to the withdrawal from the market

1. Existing stocks of the feed additive eucalyptus tincture from *Eucalyptus globulus* Labill. may continue to be placed on the market and used in respect of the animal species and categories other than those mentioned in the Annex until *[12 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]*.
2. Premixtures produced with the feed additive referred to in paragraph 1 may continue to be placed on the market and used in respect of the animal species and categories other than those mentioned in the Annex until *[15 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]*.
3. Compound feed and feed materials produced with the feed additive referred to in paragraph 1 or with the premixtures referred to in paragraph 2 may continue to be placed on the market and used in respect of the animal species and categories other than those mentioned in the Annex until *[24 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]*.

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