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

of **XXX**

concerning the authorisation of laurel leaf essential oil from *Laurus nobilis* L. as a feed additive for certain animal species and its withdrawal from the market for all other animal species

(Text with EEA relevance)

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

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(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 laurel leaf essential oil, previously identified as laurel leaves oil, from *Laurus nobilis* L. was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for all animal species. That substance was subsequently entered in the Register of Feed Additives as an existing product belonging to the category ‘sensory additives’ and to the functional group ‘flavouring compounds’, 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 laurel leaf essential oil from *Laurus nobilis* 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’. That 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 that additive in water for drinking should not be allowed.
- (5) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 1 February 2023³ that, under the proposed conditions of use, laurel leaf essential oil

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, 21(3):7875. <https://doi.org/10.2903/j.efsa.2023.7875>.

from *Laurus nobilis* L. presents no safety concern for short-living animals (animals intended for fattening) and is very unlikely to induce adverse effects in dogs and cats. For other long-living and reproductive animals, including those animals reared for laying/breeding/reproduction, the use of the additive at the proposed level of 10 mg/kg complete feed is considered of concern. The Authority also concluded that the use of laurel leaf essential oil from *Laurus nobilis* L. up to the highest proposed use level in feed is expected to be of no concern for consumers and is not expected to pose a risk for the environment. In addition, the Authority concluded that laurel leaf essential oil from *Laurus nobilis* L. should be considered as an irritant to skin, eyes and a respiratory tract, and as a skin sensitiser. It also stated that, due to the high concentration of methyleugenol ($\geq 1\%$), the additive is classified as suspected of causing genetic defects and cancer and should be handled accordingly. The Authority further concluded that since the leaves of *Laurus nobilis* L. and their preparations are recognised to flavour food and since 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 additive 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 laurel leaf essential oil from *Laurus nobilis* L. for all animal species except turkeys for fattening, chickens for fattening and minor poultry for fattening, pigs for fattening, pigs for fattening of minor *Suidae*, cattle for fattening, other ruminants for fattening, *Camelidae* for fattening, rabbits for fattening, salmonids and minor finfish except brood stock, dogs and cats.
- (7) In view of the above, the Commission considers that laurel leaf essential oil from *Laurus nobilis* L. satisfies the conditions for authorisation 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*, cattle for fattening, other ruminants for fattening, *Camelidae* for fattening, rabbits for fattening, salmonids and minor finfish except brood stock, dogs and cats. Accordingly, the use of that substance should be authorised as specified in the Annex to this Regulation.
- (8) The Commission considers that the presence of methyleugenol, estragole and elemicin, substances of concern belonging to *p*-allylalkoxybenzenes group, in laurel leaf essential oil from *Laurus nobilis* L. requires setting a maximum content for this feed additive in complete feed. Furthermore, the Commission considers that a simultaneous use of laurel leaf essential oil from *Laurus nobilis* L. with other feed additives is permitted provided that the combined content of *p*-allylalkoxybenzenes (methyleugenol, estragole, elemicin, safrole, myristicin, dillapiole, 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 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 as required by Article 10(2) of Regulation (EC) No 1831/2003 before the deadline provided for in that provision. Similarly, a Regulation is to be adopted 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, laurel leaf essential oil from *Laurus nobilis* L. 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 an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2 **Withdrawal from the market**

The feed additive laurel leaf essential oil from *Laurus nobilis* L., 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 laurel leaf essential oil from *Laurus nobilis* L., as authorised pursuant to Directive 70/524/EEC and premixtures containing that additive, which are intended for animal species and categories specified in the Annex, 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 food-producing animal species and categories

specified in the Annex , 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.

3. Compound feed and feed materials containing the feed additives referred to in paragraph 1, which are intended for non-food-producing animal species and categories specified in the Annex, and 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.

Article 4

Transitional measures related to the withdrawal from the market

1. Existing stocks of the feed additive laurel leaf essential oil from *Laurus nobilis* L. 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