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

**of **XXX****

**concerning the authorisation of cinnamon bark essential oil and cinnamon leaf essential oil from *Cinnamomum verum* J. Presl as feed additives for certain animal species**

(Text with EEA relevance)

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

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**concerning the authorisation of cinnamon bark essential oil and cinnamon leaf essential oil from *Cinnamomum verum* J. Presl as feed additives 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 nutrition<sup>1</sup>, 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/EEC<sup>2</sup>.
- (2) The substances cinnamon bark essential oil and cinnamon leaf essential oil from *Cinnamomum verum* J. Presl were authorised without a time limit in accordance with Directive 70/524/EEC as feed additives for all animal species. These substances were subsequently entered in the Register of Feed Additives as existing products, 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 cinnamon bark essential oil and cinnamon leaf essential oil from *Cinnamomum verum* J. Presl as feed additives for all animal species. The applicant requested the additives 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 additives 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 those additives in water for drinking should not be allowed.
- (5) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 27 September 2022<sup>3</sup> that, under the proposed conditions of use, cinnamon bark essential oil and cinnamon leaf essential oil from *Cinnamomum verum* J. Presl are safe for short-living animals (animals intended for fattening), including piglets and other minor *Suidae*. It also concluded that both additives are safe for the consumers and the

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

<sup>2</sup> Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1). <http://data.europa.eu/eli/dir/1970/524/oj>

<sup>3</sup> EFSA Journal 2022;20(10):7601.

environment. The Authority indicated that, owing to the presence of styrene in cinnamon bark essential oil and cinnamon leaf essential oil, it is not in the position to conclude on the safety of the additives for long-living animals and reproductive animals including those animals reared for laying/breeding/reproduction. In addition, the Authority concluded that cinnamon bark essential oil and cinnamon leaf essential oil from *Cinnamomum verum* J. Presl should be considered as irritant to skin and eyes, and as dermal and respiratory sensitisers. It also stated that, based on the presence of safrole  $\geq 0.1\%$ , cinnamon leaf oil and bark oil are classified as carcinogen (category 1B) and should be handled accordingly. The Authority further concluded that since the substances 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 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 cinnamon bark essential oil and cinnamon leaf essential oil from *Cinnamomum verum* J. Presl for all animal species and categories except: piglets, piglets of minor Suidae, animal species for fattening other than Equidae and salmonids and minor fin fish other than brood stock.
- (7) In view of the above, the Commission considers that cinnamon bark essential oil and cinnamon leaf essential oil from *Cinnamomum verum* J. Presl satisfy the conditions provided for in Article 5 of Regulation (EC) No 1831/2003 as regards: animal species for fattening except Equidae, salmonids and fin fish except brood stock, piglets and piglets of minor Suidae. Accordingly, the use of those additives should be authorised. For cinnamon bark essential oil and cinnamon leaf essential oil from *Cinnamomum verum* J. Presl, the Commission considers that the presence of the substances of concern safrole, methyleugenol and styrene requires to set a maximum content in complete feed and to prohibit the combination of these additives with other additives containing the same substances of concern. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additives.
- (8) Article 10(5) of Regulation (EC) No 1831/2003 imposes an obligation on the Commission to adopt a Regulation requiring the withdrawal from the market of feed additives for which no applications as required by Article 10(2) of Regulation (EC) No 1831/2003 were submitted before the deadline provided for in that provision. Similarly, a Regulation should be adopted concerning feed additives for which an application was submitted but subsequently withdrawn.
- (9) 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.
- (10) Therefore, cinnamon bark essential oil and cinnamon leaf essential oil from *Cinnamomum verum* J. Presl 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.
- (11) In so far as this Regulation authorises cinnamon bark essential oil and cinnamon leaf essential oil from *Cinnamomum verum* J. Presl as a feed additives, safety reasons do not require the immediate application of the modifications to the conditions of authorisation of that substance in respect of the animal species and categories which are covered by the authorisation granted by this Regulation. It is therefore appropriate

to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

- (12) In addition, in so far as the feed additives are withdrawn from the market, it is also appropriate to allow for a transitional period within which existing stocks of the additives, premixtures, feed materials and compound feed which have been produced with those additives, 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.
- (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 the Annex, 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*  
*Withdrawal from the market*

The feed additives cinnamon bark essential oil and cinnamon leaf essential oil from *Cinnamomum verum* J. Presl 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 additives referred to in Article 2 and premixtures containing those additives, 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 [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 in respect of the animal species and categories mentioned in the Annex until the stocks concerned are exhausted.
2. Compound feed and feed materials containing the feed additives referred to in Article 2, 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 [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 in respect of the animal species and categories mentioned in the Annex until the stocks concerned are exhausted.

#### *Article 4*

##### *Transitional measures related to the withdrawal from the market*

1. Existing stocks of the feed additives referred to in Article 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 *[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 additives 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 additives 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 used 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*