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

of XXX

**concerning the authorisation of star anise essential oil from *Illicium verum* Hook.f. as a
feed additive for all animal species**

(Text with EEA relevance)

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

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concerning the authorisation of star anise essential oil from *Illicium verum* Hook.f. 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 star anise essential oil, previously identified as anise star oil, from *Illicium verum* Hook.f. 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 star anise essential oil from *Illicium verum* Hook.f. 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 5 July 2023³ that, under the proposed conditions of use, star anise essential oil from *Illicium verum* Hook.f. is considered of no safety concern for target short-living animals and is considered very unlikely to induce adverse effects for target long-living and reproductive animals and for any other animal species at certain maximum

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(7): 8182. <https://doi.org/10.2903/j.efsa.2023.8182>.

concentrations. Furthermore, it concluded that no safety concern would be expected for consumers from the use of star anise essential oil from *Illicium verum* Hook.f., up to the highest proposed use level in feed, and that its use, under the proposed conditions, is not expected to pose a risk to the environment. The Authority concluded that star anise essential oil from *Illicium verum* Hook.f. should be considered as irritant to skin and eyes, as skin and respiratory sensitiser. It also stated that, based on the presence of estragole ($\geq 1\%$), star anise essential oil from *Illicium verum* Hook.f. is classified as suspected of causing genetic defects and of causing cancer and exposure by any route should be minimised. The Authority further concluded that since star anise essential oil from *Illicium verum* Hook.f. 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 star anise essential oil from *Illicium verum* Hook.f. 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 estragole (substance of concern belonging to a group of *p*-allylalkoxybenzenes, compounds, which are genotoxic and carcinogenic) requires the setting of maximum content for this feed additive in complete feed. Furthermore, the Commission considers that star anise essential oil from *Illicium verum* Hook.f. should not be used in combination with other additives containing estragole. It considers that a simultaneous use of star anise essential oil from *Illicium verum* Hook.f. with other feed additives is permitted provided that the combined content of *p*-allylalkoxybenzenes (methyleugenol, estragole, elemicin, safrole, myristicin, dillapiol, 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.
- (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 star anise essential oil from *Illicium verum* Hook.f., 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