



2024/1201

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COMMISSION IMPLEMENTING REGULATION (EU) 2024/1201

of 26 April 2024

withdrawing from the market star anise terpenes from *Illicium verum* Hook.f. as a feed additive

(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 ⁽¹⁾, and in particular 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. In particular, Article 10(2) of that Regulation provides rules for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) The substance star anise terpenes 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. That 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 terpenes from *Illicium verum* Hook.f. as a feed additive for all animal species. The applicant requested 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 European Food Safety Authority ('the Authority') concluded in its opinion of 26 September 2023 ⁽³⁾ that the additive star anise terpenes contains up to 25 % estragole by specification and is obtained by a manufacturing process which results in the enrichment of this genotoxic carcinogen. In this regard, the Authority stated that this does not comply with the principles outlined in the general approach to assess the safety for the target species of botanical preparations which contain compounds that are genotoxic and/or carcinogenic when used as feed additives. Therefore, the Authority considered that it was inappropriate to perform an assessment of the safety and efficacy of star anise terpenes for its use as a feed additive.
- (5) The applicant subsequently withdrew the application for authorisation of star anise terpenes from *Illicium verum* Hook.f. for all animal species.
- (6) 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.
- (7) Therefore, the feed additive star anise terpenes from *Illicium verum* Hook.f. should be withdrawn from the market.

⁽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 2023;21(10):8341.

- (8) A transitional period should be allowed for interested parties to comply properly with the withdrawal obligation, providing for a limited period of time within which existing stocks of the additive and feed containing it may be used up. Such period of time should be as short as possible, taking account of the safety concerns raised by the Authority in its opinion of 26 September 2023 concerning the additive.
- (9) 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

Withdrawal from the market

The feed additive star anise terpenes from *Illicium verum* Hook.f., as authorised pursuant to Directive 70/524/EEC, shall be withdrawn from the market in respect of all animal species.

Article 2

Transitional measures

1. Existing stocks of the feed additive referred to in Article 1 may continue to be placed on the market and used until 19 June 2024.
2. Premixtures produced with the feed additive referred to in paragraph 1 may continue to be placed on the market and used until 19 July 2024.
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 until 19 August 2024.

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, 26 April 2024.

For the Commission
The President
Ursula VON DER LEYEN