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

of XXX

concerning the authorisation of bitter fennel essential oil from *Foeniculum vulgare* Mill. ssp. *vulgare* var. *vulgare* as a feed additive for all animal species, the authorisation of sweet fennel essential oil from *Foeniculum vulgare* Mill. ssp. *vulgare* var. *dulce* (Mill.) Batt. & Trab as a feed additive for dogs and cats and the withdrawal from the market of sweet fennel essential oil from *Foeniculum vulgare* Mill. ssp. *vulgare* var. *dulce* (Mill.) Batt. & Trab as a feed additive for all animal species other than dogs and cats

(Text with EEA relevance)

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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 substances bitter fennel essential oil from *Foeniculum vulgare* Mill. ssp. *vulgare* var. *vulgare* and sweet fennel essential oil from *Foeniculum vulgare* Mill. ssp. *vulgare* var. *dulce* (Mill.) Batt. & Trab, previously respectively identified as fennel oil bitter and fennel oil sweet, 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 bitter fennel essential oil from *Foeniculum vulgare* Mill. ssp. *vulgare* var. *vulgare* and sweet fennel essential oil from *Foeniculum vulgare* Mill. ssp. *vulgare* var. *dulce* (Mill.) Batt. & Trab as feed additives for all animal species, requesting the additives 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.

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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>).

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- (4) Subsequently, the applicant withdrew the application for authorisation of sweet fennel essential oil from *Foeniculum vulgare* Mill. ssp. *vulgare* var. *dulce* (Mill.) Batt. & Trab for all animal species and categories except dogs and cats.
- (5) The applicant requested the additives 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 these additives in water for drinking should not be allowed.
- (6) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 28 September 2023³ that, under the proposed conditions of use, bitter fennel essential oil from *Foeniculum vulgare* Mill. ssp. *vulgare* var. *vulgare* presents no safety concern for target short-living animals and is considered very unlikely to induce adverse effects for any other species and for long-living and reproductive animals (including those animals reared for laying/breeding/reproduction). As regards sweet fennel essential oil from *Foeniculum vulgare* Mill. ssp. *vulgare* var. *dulce* (Mill.) Batt. & Trab, the Authority concluded that, under the proposed conditions of use further specified in that opinion, the use of the additive is considered very unlikely to induce adverse effects in dogs and cats. In addition, the Authority concluded that no concern would be expected for the consumer from the use of bitter fennel essential oil from *Foeniculum vulgare* Mill. ssp. *vulgare* var. *vulgare* up to certain maximum concentrations further specified for individual species in that opinion and that the use of bitter fennel essential oil from *Foeniculum vulgare* Mill. ssp. *vulgare* var. *vulgare*, under the proposed conditions of use further specified for each species in that opinion, is not expected to pose a risk for the environment. The Authority stated that no environmental risk assessment is necessary for the use of sweet fennel essential oil from *Foeniculum vulgare* Mill. ssp. *vulgare* var. *dulce* (Mill.) Batt. & Trab for dogs and cats. It further concluded that bitter fennel essential oil from *Foeniculum vulgare* Mill. ssp. *vulgare* var. *vulgare* and sweet fennel essential oil from *Foeniculum vulgare* Mill. ssp. *vulgare* var. *dulce* (Mill.) Batt. & Trab should be considered as irritants to skin and eyes and the respiratory tract and as dermal and respiratory sensitisers. It also stated that due to the high concentration of estragole (> 1%), bitter fennel essential oil from *Foeniculum vulgare* Mill. ssp. *vulgare* var. *vulgare* and sweet fennel essential oil from *Foeniculum vulgare* Mill. ssp. *vulgare* var. *dulce* (Mill.) Batt. & Trab are classified as suspected of causing genetic defects and of causing cancer and should be handled accordingly. It recommended that bitter fennel essential oil from *Foeniculum vulgare* Mill. ssp. *vulgare* var. *vulgare* and sweet fennel essential oil from *Foeniculum vulgare* Mill. ssp. *vulgare* var. *dulce* (Mill.) Batt. & Trab should contain the lowest possible concentrations of estragole. Furthermore, the Authority concluded that since bitter fennel essential oil from *Foeniculum vulgare* Mill. ssp. *vulgare* var. *vulgare* and sweet fennel essential oil from *Foeniculum vulgare* Mill. ssp. *vulgare* var. *dulce* (Mill.) Batt. & Trab 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.
- (7) In view of the above, the Commission considers that bitter fennel essential oil from *Foeniculum vulgare* Mill. ssp. *vulgare* var. *vulgare* and sweet fennel essential oil from *Foeniculum vulgare* Mill. ssp. *vulgare* var. *dulce* (Mill.) Batt. & Trab satisfy the

³ EFSA Journal, 21(10):8348. <https://doi.org/10.2903/j.efsa.2023.8348>.

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conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of these additives should be authorised as specified in the Annex to this Regulation. For bitter fennel essential oil from *Foeniculum vulgare* Mill. ssp. *vulgare* var. *vulgare* and sweet fennel essential oil from *Foeniculum vulgare* Mill. ssp. *vulgare* var. *dulce* (Mill.) Batt. & Trab, the Commission considers that the high concentration of estragole (a substance of concern belonging to the group of *p*-allylalkoxybenzenes) requires the setting of maximum content for these additives in complete feed. In addition, the Commission considers that simultaneous use of bitter fennel essential oil from *Foeniculum vulgare* Mill. ssp. *vulgare* var. *vulgare* and sweet fennel essential oil from *Foeniculum vulgare* Mill. ssp. *vulgare* var. *dulce* (Mill.) Batt. & Trab 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. Furthermore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of users of the additives.

- (8) 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 laid down in Article 10(2) of that Regulation. 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, sweet fennel essential oil from *Foeniculum vulgare* Mill. ssp. *vulgare* var. *dulce* (Mill.) Batt. & Trab 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) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the substances 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.
- (12) In addition, in so far as 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 these additives, may be used up in respect of the animal species and categories of animals which are not covered by the authorisation granted by this Regulation, so that the interested parties can 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 additive sweet fennel essential oil from *Foeniculum vulgare* Mill. ssp. *vulgare* var. *dulce* (Mill.) Batt. & Trab, 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 for that feed additive.

Article 3
Transitional measures related to the authorisation

1. The feed additive bitter fennel essential oil from *Foeniculum vulgare* Mill. ssp. *vulgare* var. *vulgare*, as authorised pursuant to Directive 70/524/EEC, and premixtures containing that 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. The feed additive sweet fennel essential oil from *Foeniculum vulgare* Mill. ssp. *vulgare* var. *dulce* (Mill.) Batt. & Trab, as authorised pursuant to Directive 70/524/EEC, and premixtures containing that additive, which are intended for cats and dogs 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.
3. 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.
4. Compound feed and feed materials containing the feed additives referred to in paragraphs 1 and 2, 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.

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 4

Transitional measures related to the withdrawal from the market

1. Existing stocks of the feed additive sweet fennel essential oil from *Foeniculum vulgare* Mill. ssp. *vulgare* var. *dulce* (Mill.) Batt. & Trab 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 for that feed additive 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 for that feed additive 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 for that feed additive 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