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

of **XXX**

concerning the authorisation of celery seed essential oil from *Apium graveolens* L. and caraway essential oil from *Carum carvi* L. as feed additives for certain animal species

(Text with EEA relevance)

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

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concerning the authorisation of celery seed essential oil from *Apium graveolens* L. and caraway essential oil from *Carum carvi* L. 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 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 celery seed essential oil from *Apium graveolens* L. and caraway essential oil from *Carum carvi* L. 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 celery seed essential oil from *Apium graveolens* L. and caraway essential oil from *Carum carvi* L. 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.
- (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 these additives in water for drinking should not be allowed.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinions of 27 June 2024^{3,4} that celery seed essential oil from *Apium graveolens* L. and caraway

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 feedstuffs (OJ L 270, 14.12.1970, p. 1, ELI: <http://data.europa.eu/eli/dir/1970/524/oj>).

³ EFSA Journal, 22(7), e8907. <https://doi.org/10.2903/j.efsa.2024.8907>.

⁴ EFSA Journal, 22(7), e8906. <https://doi.org/10.2903/j.efsa.2024.8906>.

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essential oil from *Carum carvi* L. are of no concern up to certain maximum concentrations further specified for individual species. However, no conclusions could be drawn for cats, ornamental fish and other species. Furthermore, it concluded that celery seed essential oil from *Apium graveolens* L. is safe for consumers and it is not expected to pose a risk to the environment at the proposed use levels in feed. The Authority also found that caraway essential oil from *Carum carvi* L. is safe for the consumers and the environment at the proposed use levels in feed. It further concluded that celery seed essential oil from *Apium graveolens* L. and caraway essential oil from *Carum carvi* L. should be considered as irritants to skin and eyes, and as dermal and respiratory sensitisers. Furthermore, the Authority concluded that since celery seed essential oil from *Apium graveolens* L. and caraway essential oil from *Carum carvi* L. 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.

- (6) Subsequently, the applicant withdrew the application for authorisation of celery seed essential oil from *Apium graveolens* L. and caraway essential oil from *Carum carvi* L. for all animal species and categories except turkeys for fattening, chickens for fattening and minor poultry for fattening, all poultry reared for laying or breeding, ornamental birds, all poultry for laying or breeding, pigs for fattening, pigs for fattening of minor *Suidae*, piglets (suckling and weaned) of all *Suidae*, all *Suidae* for reproduction, calves for fattening, sheep and goats, cattle for fattening, other ruminants for fattening and all other ruminants, *Camelidae* for fattening and all other *Camelidae*, *Equidae*, *Leporidae*, salmonids, minor finfish and dogs.
- (7) In view of the above, the Commission considers that celery seed essential oil from *Apium graveolens* L. and caraway essential oil from *Carum carvi* L. satisfy the conditions provided for in Article 5 of Regulation (EC) No 1831/2003 as regards turkeys for fattening, chickens for fattening and minor poultry for fattening, all poultry reared for laying or breeding, ornamental birds, all poultry for laying or breeding, pigs for fattening, pigs for fattening of minor *Suidae*, piglets (suckling and weaned) of all *Suidae*, all *Suidae* for reproduction, calves for fattening, sheep and goats, cattle for fattening, other ruminants for fattening and all other ruminants, *Camelidae* for fattening and all other *Camelidae*, *Equidae*, *Leporidae*, salmonids, minor finfish and dogs. Accordingly, the use of these additives should be authorised as specified in the Annex to this Regulation.
- (8) For celery seed essential oil from *Apium graveolens* L., the Commission considers that the presence of substances of concern, perillaldehyde and furocoumarins, requires the setting of maximum content for the additive in complete feed and that a mixture of celery seed essential oil from *Apium graveolens* L. with other botanical additives is permitted provided that the levels of perillaldehyde and furocoumarins in feed materials and compound feed remain below those that would result from the use of a single additive at the maximum or recommended content for the relevant species or animal category. For caraway essential oil from *Carum carvi* L., the Commission considers that the presence of the substance of concern perillaldehyde requires the setting of maximum content for the additive in complete feed and that a mixture of caraway essential oil from *Carum carvi* L. with other botanical additives is permitted provided that the levels of perillaldehyde in feed materials and compound feed are below those what would result from the use of a single additive at the maximum or recommended content for the relevant species or animal 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 before the deadline laid down in Article 10(2) of Regulation (EC) No 1831/2003. Similarly, a Regulation should 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, celery seed essential oil from *Apium graveolens* L. and caraway essential oil from *Carum carvi* 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 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.
- (13) 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 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 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 celery seed essential oil from *Apium graveolens* L. and caraway essential oil from *Carum carvi* 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 additives celery seed essential oil from *Apium graveolens* L. and caraway essential oil from *Carum carvi* L., as authorised pursuant to Directive 70/524/EEC and premixtures containing these additives, which are intended for turkeys for fattening, chickens for fattening and minor poultry for fattening, all poultry reared for laying or breeding, ornamental birds, all poultry for laying or breeding, pigs for fattening, pigs for fattening of minor *Suidae*, piglets (suckling and weaned) of all *Suidae*, all *Suidae* for reproduction, calves for fattening, sheep and goats, cattle for fattening, other ruminants for fattening and all other ruminants, *Camelidae* for fattening and all other *Camelidae*, *Equidae*, *Leporidae*, salmonids, minor finfish, 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.
2. Compound feed and feed materials containing the feed additives 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 additives 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 4

Transitional measures related to the withdrawal from the market

1. Existing stocks of the feed additives celery seed essential oil from *Apium graveolens* L. and caraway essential oil from *Carum carvi* 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 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 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*