Commission Implementing Regulation (EU) 2020/1098 of 24 July 2020 concerning the authorisation of cardamom essential oil from Elettaria cardamomum (L.) Maton as a feed additive for all animal species (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1098

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concerning the authorisation of cardamom essential oil from *Elettaria cardamomum* (L.) Maton 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 nutrition[(1)], 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 authorisation. Article 10(2) of Regulation (EC) No 1831/2003 provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC[(2)].

(2) Cardamom oil from *Elettaria cardamomum* (L.) Maton was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for all animal species under the group 'Flavouring and appetising substances'. The product was subsequently entered in the Register of feed additives as an existing product, in accordance with point (b) of Article 10(1) 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 re-evaluation of cardamom oil from *Elettaria cardamomum* (L.) Maton 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'. The 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 14 May 2019[(3)] that, under the proposed conditions of use, cardamom oil from *Elettaria cardamomum* (L.) Maton does not have an adverse effect on animal health, consumer safety or the environment. In the absence of studies to assess the safety for the user, the Authority could not conclude on the safety for the users when handling the additive. According to the opinion, the applicant produced a safety data sheet for cardamomum oil, where hazards have been identified. The hazards described in the safety data

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sheet are, in particular skin irritation, eye irritation, allergic skin reaction and fatal if swallowed. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive.

(5) The Authority further concluded that since the substance concerned is used in food as a flavouring and its function in feed is the same as that in food, no further demonstration of efficacy in feed is necessary. The Authority does not consider that there is a need for specific requirements of post-market monitoring. 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) Restrictions and conditions should be provided for to allow for a better control for this substance. For the feed additive concerned recommended contents should be indicated on the label. Where such contents are exceeded, certain information should be indicated on the label of premixtures containing the feed additive.

(7) The assessment of cardamom essential oil from *Elettaria cardamomum* (L.) Maton shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that additive should be authorised as specified in the Annex to this Regulation.

(8) 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 allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from this authorisation.

(9) The fact that cardamom essential oil from *Elettaria cardamomum* (L.) Maton is not authorised for use as a flavouring in water for drinking, does not preclude its use in compound feed, which is administered via water.

(10) 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

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

1 The substance specified in the Annex and premixtures containing that substance, which are produced and labelled before 16 February 2021 in accordance with the rules applicable before 16 August 2020 may continue to be placed on the market and used until the existing stocks are exhausted.

2 Compound feed and feed materials containing the substance as specified in the Annex which are produced and labelled before 16 August 2021 in accordance with the rules applicable before 16 August 2020 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

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3 Compound feed and feed materials containing the substance as specified in the Annex which are produced and labelled before 16 August 2022 in accordance with the rules applicable before 16 August 2020 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 3

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, 24 July 2020.

For the Commission

The President

Ursula VON DER LEYEN

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ANNEX

Identification number of the additive	**Additive**	**Composition, chemical formula, description, analytical method**	**Species or category of animal**	**Maximum age**	**Minimum content**	**Maximum content**	**Other provisions**	**End of period of authorisation**
					mg of active substance of kg of complete feedingstuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
2b180	Cardamom essential oil	*Additive composition:* Essential oil from the seeds of *Elettaria cardamomum* (L.) Maton. *Characterisation of the active substance:* Essential oil from the seeds of *Elettaria cardamomum* (L.) Maton as defined by the International Organisation for Standardization (ISO) 4733:2004 for Oil of Cardamom (*E. cardamomum* (L.) Maton).	All animal species				1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content	16.8.2030

a Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports