Commission Implementing Regulation (EU) 2020/1396 of 5 October 2020 concerning the authorisation of geraniol, citral, 3,7,11-trimethyldodeca-2,6,10-trien-1-ol, (Z)-nerol, geranyl acetate, geranyl butyrate, geranyl formate, geranyl propionate, neryl propionate, neryl formate, neryl acetate, neryl isobutyrate, geranyl isobutyrate and prenyl acetate as feed additives for all animal species except for marine animals (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1396

of 5 October 2020

concerning the authorisation of geraniol, citral, 3,7,11-trimethyldodeca-2,6,10-trien-1-ol, (Z)-nerol, geranyl acetate, geranyl butyrate, geranyl formate, geranyl propionate, neryl propionate, neryl formate, neryl acetate, neryl isobutyrate, geranyl isobutyrate and prenyl acetate as feed additives for all animal species except for marine animals

(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 that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC[(2)].

(2) The substances geraniol, citral, 3,7,11-trimethyldodeca-2,6,10-trien-1-ol, (Z)-nerol, geranyl acetate, geranyl butyrate, geranyl formate, geranyl propionate, neryl propionate, neryl formate, neryl acetate, neryl isobutyrate, geranyl isobutyrate and prenyl acetate ('the substances concerned') were authorised without a time limit by Directive 70/524/EEC as feed additives for all animal species. Those additives substances were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1)(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 re-evaluation of the substances concerned as feed additives for all animal species. The applicant requested those 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 European Food Safety Authority ('the Authority') concluded in its opinion of 25 May 2016[3] that, under the proposed conditions of use the substances concerned do not have adverse effects on animal health, human health or the environment. The Authority concluded that for the marine environment, the safe use level is estimated to be 0,05 mg/kg feed. The levels of use proposed for the substances concerned exceeds the safe level for the marine environment, therefore, the use for marine animals is not authorised. The Authority also concluded in the opinion that, since the substances concerned are efficacious when used as flavourings in food and their function in feed is essentially the same as in food, no further demonstration of efficacy was necessary. Therefore, that conclusion could be extrapolated to feed. Although the applicant withdrew the application for water for drinking, it should be possible to use the substances concerned within compound feeds which are subsequently administered via water.

(5) The Authority concluded that in the absence of data the substances concerned should be considered hazardous for the skin, and eye contact and for respiratory exposure. Geraniol, citral and 3,7,11-trimethyldodeca-2,6,10-trien-1-ol, are also reported to be skin sensitisers. Consequently, appropriate protective measures should be taken. 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 additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of the substances concerned shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of the substances concerned should be authorised as specified in the Annex to this Regulation.

(7) Restrictions and conditions should be provided for to allow better control. Since safety reasons do not require the setting of a maximum content and taking into account the re-evaluation performed by the Authority, a recommended content should be indicated on the label of the feed additive. Where such content is exceeded, certain information should be indicated on the label of premixtures.

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

(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

Authorisation

The substances specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds', are authorised as feed additives in animal nutrition subject to the conditions laid down in that Annex.

Article 2

Transitional measures

1 The substances specified in the Annex and premixtures containing those substances, which are produced and labelled before 26 April 2021 in accordance with the rules applicable before 26 October 2020 may continue to be placed on the market and used until the existing stocks are exhausted.

2 Feed materials and compound feed containing the substances specified in the Annex which are produced and labelled before 26 October 2021 in accordance with the rules applicable before 26 October 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.

3 Feed materials and compound feed containing the substances specified in the Annex which are produced and labelled before 26 October 2022 in accordance with the rules applicable before 26 October 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

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, 5 October 2020.

For the Commission

The President

Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the holder of authorisation	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/kg of complete feedingstuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds									
2b02012		Geraniol	*Additive composition* Geraniol *Characterisation of the active substance* Geraniol Produced by fractional distillation of an essential oil or by chemical synthesis Purity: min. 95 % assay Chemical formula: $C_{10}H_{18}O$ CAS number: 106-24-1 FLAVIS No: 02.012 *Method of analysis*[a] For the determination of geraniol	All animal species except marine animals				1. The additive shall be incorporated into the feed in the form of a premixture of flavourings. 2. In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated. 3. The recommended maximum content of	*16.10.2030*

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

			in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.						the active substance shall be 25 mg/kg of complete feedingstuff with a moisture content of 12 %.
								4.	On the label of the additive the following shall be indicated: Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 25 mg/kg.
								5.	The functional

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