Commission Implementing Regulation (EU) 2019/1977 of 26 November 2019 concerning the authorisation of phenylmethanethiol, benzyl methyl sulfide, sec-pentylthiophene, tridec-2-enal, 12-methyltridecanal, 2,5-dimethylphenol, hexa-2(trans),4(trans)-dienal and 2-ethyl-4-hydroxy-5-methyl-3(2H)-furanone as feed additives for cats and dogs (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2019/1977

of 26 November 2019

concerning the authorisation of phenylmethanethiol, benzyl methyl sulfide, sec-pentylthiophene, tridec-2-enal, 12-methyltridecanal, 2,5-dimethylphenol, hexa-2(trans),4(trans)-dienal and 2-ethyl-4-hydroxy-5-methyl-3(2H)-furanone as feed additives for cats and dogs

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

(2) Phenylmethanethiol, benzyl methyl sulfide, sec-pentylthiophene, tridec-2-enal, 12-methyltridecanal, 2,5-dimethylphenol, hexa-2(trans),4(trans)-dienal and 2-ethyl-4-hydroxy-5-methyl-3(2H)-furanone ('the substances concerned') were authorised as feed additives for cats and dogs without a time limit in accordance with Directive 70/524/EEC. Those feed additives were subsequently entered in the Register of feed additives as existing products, in accordance with 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 the substances concerned for cats and dogs, requesting those feed additives to be classified in the additive category 'sensory additives'. 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 27 February 2019[(3)] that, under the proposed conditions of use, the substances concerned do not have adverse effects on animal health or the environment. It also concluded

that hazards for users have been identified. The applicant as required produced a safety data sheet for each compound where hazards for users have been identified. No studies to assess the safety for the user were submitted. Therefore, the EFSA cannot conclude on the safety for the users when handling the additives. The hazards described in the safety data sheet are, in particular, hazards for skin and eye contact were recognised for 2,5-dimethylphenol, 12-methyltridecanal, hexa-2(trans),4(trans)-dienal, phenylmethanethiol, benzyl methyl sulfide, 2-ethyl-4-hydroxy-5-methyl-3(2H)-furanone and sec-pentylthiophene. Hazard for respiratory exposure was recognised for 12-methyltridecanal, benzyl methyl sulfide and 2-pentylthiophene. In the absence of data, the Authority could not conclude on the risk for the users. Therefore, the Commission considers that appropriate protective measures should be taken to prevent effects on human health, in particular as regards the users of the feed additive. For non-food-producing animals Commission Regulation (EC) No 429/2008[(4)], exempted additives intended for those animals from the environmental assessment as they do not have a significant environmental effect. Pets are not raised in large groups of animals so their effect on the environment is considered not significant. The Authority further concluded that since the substances concerned are used in food as flavourings and their function in feed is the same as that in food, no further demonstration of efficacy in feed is necessary.

(5) The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the reports on the method of analysis 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 the substances concerned recommended contents should be indicated on the label of the additive. Where such contents are exceeded, certain information should be indicated on the label of premixtures. and in the labelling compound feeds and feed materials.

(7) 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 for the use in feed. Accordingly, the use of those feed additives 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 for 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 the Annex.

Article 2

Transitional Measures

1 The substances specified in the Annex and premixtures containing those substances, which are produced and labelled before 19 December 2019 in accordance with the rules applicable before 19 December 2019 may continue to be placed on the market and used until 19 June 2020.

2 Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 19 December 2021 in accordance with the rules applicable before 19 December 2019 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for cats and dogs.

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 November 2019.

For the Commission

The President

Jean- Claude JUNCKER

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/1977. (See end of Document for details)*

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									
2b5169		12-Methyltridecanal	*Additive composition* 12-Methyltridecanal *Characterisation of the active substance:* 12-Methyltridecanal Produced by chemical synthesis Purity: min. 97 % Chemical formula: $C_{14}H_{28}O$ CAS number: 75853-49-5 FLAVIS: 05.169 *Method of analysis*[a]: For the determination of 12-methyltridecanal in the feed additive	Cats and dogs				1. 2. 3.	19.12.2029

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

1. In the additive shall be incorporated into the feed in the form of a premixture.
2. In the directions for use of the additive and premixture, the storage conditions, the stability to heat treatment shall be indicated.
3. On the

			and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.						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 %: 0,5 mg/kg’
								4.	The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label

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