Commission Implementing Regulation (EU) 2017/65 of 14 December 2016 concerning the authorisation of 1-isopropyl-4-methylbenzene, pin-2(10)-ene, pin-2(3)-ene, beta-caryophyllene, camphene, 1-isopropenyl-4-methylbenzene, delta-3-carene and d-limonene as feed additives for all animal species (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2017/65

of 14 December 2016

concerning the authorisation of 1-isopropyl-4-methylbenzene, pin-2(10)-ene, pin-2(3)-ene, beta-caryophyllene, camphene, 1-isopropenyl-4-methylbenzene, delta-3-carene and d-limonene as feed additives 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 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC[(2)].

(2) 1-Isopropyl-4-methylbenzene, pin-2(10)-ene, pin-2(3)-ene, beta-caryophyllene, camphene, 1-isopropenyl-4-methylbenzene, delta-3-carene and d-limonene, were authorised without a time limit in accordance with Directive 70/524/EEC as feed additives for all animal species. Those products 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 1-isopropyl-4-methylbenzene, pin-2(10)-ene, pin-2(3)-ene, beta-caryophyllene, camphene, 1-isopropenyl-4-methylbenzene, delta-3-carene and d-limonene as feed additives for all animal species. The applicant requested those additives to be classified in the additive category ‘sensory additives’. That 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 opinions[(3)] of 10 March 2015 and of 1 December 2015 that, under the proposed conditions of use

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in feed 1-isopropyl-4-methylbenzene, pin-2(10)-ene, pin-2(3)-ene, beta-caryophyllene, camphene, 1-isopropenyl-4-methylbenzene, delta-3-carene and d-limonene do not have adverse effects on animal health, human health or the environment. The Authority further concluded that the function of 1-isopropyl-4-methylbenzene, pin-2(10)-ene, pin-2(3)-ene, beta-caryophyllene, camphene, 1-isopropenyl-4-methylbenzene, delta-3-carene and d-limonene in feed is similar to that on food. The Authority has already concluded that for food 1-isopropyl-4-methylbenzene, pin-2(10)-ene, pin-2(3)-ene, beta-caryophyllene, camphene, 1-isopropenyl-4-methylbenzene, delta-3-carene and d-limonene are efficacious, as it increases the food smell or palatability. The Authority could not conclude on the safety of for pin-2(3)-ene, pin-2(10)-ene, delta-3-carene, beta-caryophyllene and camphene used in water for drinking. The Authority concluded that for d-limonene, 1-isopropyl-4-methylbenzene and 1-isopropenyl-4-methylbenzene the absence of margin of safety would not allow simultaneous administration in feed and water. However, those substances can be used within a compound feed subsequently administered via water.

(5) Restrictions and conditions should be provided for to allow better control. For practical reasons and taking into account the re-evaluation performed by the Authority, maximum recommended contents should be set up. Where the recommended content of the additive in complete feedingstuff is exceeded, the identification number of the feed additive, its name and added amount should be indicated on the label of premixtures, compound feeds and feed materials.

(6) The Authority concluded that in the absence of data on user safety 1-Isopropyl-4-methylbenzene, pin-2(10)-ene, pin-2(3)-ene, beta-caryophyllene, camphene, 1-isopropenyl-4-methylbenzene, delta-3-carene and d-limonene should be considered as irritant to skin, eyes and respiratory tract and as a skin sensitiser. 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.

(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. Accordingly, the use of those substances 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 1-isopropyl- 4-methylbenzene, pin-2(10)-ene, pin-2(3)-ene, beta-caryophyllene, camphene, 1-isopropenyl-4-methylbenzene, delta-3-carene and d-limonene 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 as specified in the Annex and premixtures containing those substances, which are produced and labelled before 6 August 2017 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted.

2 Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 6 February 2018 in accordance with the rules applicable before 6 February 2017 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 Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 6 February 2019 in accordance with the rules applicable before 6 February 2017 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, 14 December 2016.

For the Commission

The President

Jean-Claude JUNCKER

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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 %			
(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
Category: Sensory additives. Functional group: Flavouring compounds									
2b01002	—	1-Isopropyl-4-methylbenzene	*Additive composition* 1-Isopropyl-4-methylbenzene *Characterisation of the active substance* 1-Isopropyl-4-methylbenzene Produced by chemical synthesis Purity: min 97 % $C_{10}H_{14}$ CAS No 99¬87-6 FLAVIS No: 01.002 *Method of analysis*[a] For the determination of 1-isopropyl-4-methylbenzene in the	All animal species	—	—	—	1. The feed 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 and stability conditions shall be indicated. 3. The recommended maximum content	7 February 2027

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

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			feed additive and in feed flavouring premixtures: Gas-chromatography mass spectrometry with retention time locking GC-MS-RTL.						of the active substance shall be: For cats: 14 mg/kg, and for other species and categories: 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

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