COMMISSION IMPLEMENTING REGULATION (EU) No 1076/2014

of 13 October 2014

concerning the authorisation of a preparation containing a smoke flavouring extract-2b0001 as feed additive for dogs and cats

(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.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of an additive consisting of a preparation of a smoke flavouring extract as specified in the Annex to this Regulation. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of the preparation specified in the Annex as feed additive for dogs and cats, to be classified in the additive category 'sensory additives' and the functional group 'flavourings compounds'.

(4) The European Food Safety Authority (the Authority) concluded in its opinion of 24 May 2012 ([2]) that, under the proposed conditions of use in feed, the additive specified in the Annex does not have any adverse effects on animal and human health, or the environment. The Authority concluded that since this smoke flavouring extract is used in food as smoke flavour, and its function in feed is essentially the same as that in food, no further demonstration of efficacy is necessary.

(5) The Authority concluded that this additive is primarily defined by the manufacturing process and the mix of woods from which it derives, therefore the manufacturing process and the mix of woods need to be clearly specified in the annex to ensure that only smoke flavourings produced by such manufacturing method are placed on the market.

(6) The Authority also concluded that no safety concerns would arise for users provided that appropriate protective measures are 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 additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(7) The assessment of the preparation referred to in the Annex shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of preparations containing that smoke flavouring extract should be authorised as specified in the Annex to this Regulation.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2012; 10(6):2729.

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavourings compounds', is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

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, 13 October 2014.

For the Commission
The President
José Manuel BARROSO

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 of sensory additives. Functional group: Flavourings compounds.									
2b0001	—	Smoke flavouring	*Additive composition* Preparation of smoke flavouring extract Specifications: — Water: 0,3-0,9 wt. % — Acid (expressed as acetic acid): 0,06-0,25 meq/g — pH 1-4 — Carbonyl compounds: 1,2-3,0 wt. % — Phenols: 8-12 wt. %. *Characterisation of the active substance* Liquid smoke flavouring extract containing the following compounds: — Syringol 12,6-25,2 % — 4-Methyl syringol 6,2-9,2 % — 4-Propenyl syringol 0,8-3,6 % — 4-Ethyl syringol 2,7-3,1 % — 4-Methyl guaiacol 2,0-2,6 % — 4-Allyl syringol 1,8-2,3 % — 4-Ethyl guaiacol 1,8-2,40 % — 4-Propyl syringol 1-2,5 % — Guaiacol 1,1-1,6 %	Dogs and cats	—	—	40	1. In the directions for use of the additive and premixture, indicate the storage and stability conditions. 2. For user safety: breathing protection and safety glasses should be worn during handling. 3. Labelling of premixtures, feed materials and compound feed containing the additive: the name of the additive shall be accompanied by the identification number. 4. The preparation may only contain technological additives and/or other substances or products intended to modify the physico-chemical characteristics of the active substance of the preparation and which are used in conformity with their own conditions of authorisation. Physico-chemical and biological compatibility between the components of the preparation shall be ensured in relation to the effects desired.	3 November 2024

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						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
			— 2,4-Dimethyl phenol 0,9-1,40 % — Eugenol 1-1,40 % — Isoeugenol (trans) 0,9-1,3 % — 4-Propenyl syringol (cis) 0,3-1,7 % — o-Cresol 0,7-1,5 % — Phenol 0,5-1,2 % — p-Cresol 0,7-1,1 % — 4-Propyl guaiacol 0,5-1 % Chemical formula: — Syringol: $C_8H_{10}O_3$ — 4-Methyl syringol: $C_9H_{12}O_3$ — 4-Propenyl syringol: $C_{11}H_{14}O_3$ — 4-Ethyl syringol::$C_{10}H_{14}O_3$ — 4-Methyl guaiacol: $C_8H_{10}O_2$ — 4-Allyl syringol: $C_{11}H_{14}O_3$ — 4-Ethyl guaiacol: $C_9H_{12}O_2$ — 4-Propyl syringol: $C_{11}H_{16}O_3$ — Guaiacol: $C_7H_8O_2$ — 2,4-Dimethyl phenol: $C_8H_{10}O$ — Eugenol: $C_{10}H_{12}O_2$ — Isoeugenol (trans): $C_{10}H_{12}O_2$ — 4-Propenyl syringol (cis): $C_{11}H_{14}O_3$ — o-Cresol: C_7H_8O — Phenol: C_6H_6O — p-Cresol: C_7H_8O — 4-Propyl guaiacol: $C_{10}H_{14}O_2$. CAS number: — Syringol: 91-10-1					5. The following information shall be set out on the label or accompanying documents of the additive: — the name and identification number of any technological additive contained in the preparation; — the level of any technological additive contained in the preparation where maximum contents are set in the corresponding authorisation; — the name of any substance or product contained in the preparation, indicated in descending order by weight. 6. The following information shall be set out on the label or accompanying documents of the premixture containing the additive: the name, identification number and level of any technological additive for which maximum contents are set in the corresponding authorisation.	

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						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
			— 4-Methyl syringol: 6638-05-7 — 4-Propenyl syringol: 20675-95-0 — 4-Ethyl syringol:14059-92-8 — 4-Methyl guaiacol: 93-51-6 — 4-Allyl syringol: 6627-88-9 — 4-Ethyl guaiacol: 2785-89-9 — 4-Propyl syringol: 6766-82-1 — Guaiacol: 90-05-1 — 2,4-Dimethyl phenol: 105-67-9 — Eugenol: 97-53-0 — Isoeugenol (trans): 97-54-1 — 4-Propenyl syringol (cis): 26624-13-5 — o-Cresol: 95-48-7 — Phenol: 108-95-2 — p-Cresol: 106-44-5 — 4-Propyl guaiacol: 2785-87-7. Smoke flavouring, liquid form, produced by diethyl ether extraction from tar produced by pyrolysis of a ratio of the following woods: 35 % red oak (*Quercus rubra*), 35 % white oak (*Quercus alba*), 10 % maple (*Acer saccharum*), 10 % beech (*Fagus grandifolia*) and 10 % hickory (*Carya ovata*).						

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						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
			Purity criteria: — PAH components: Benzo[a]pyrene below 10 ppb and Benz[a]anthracene below 20 ppb — Residual Diethyl Ether below 2 ppm. *Method of analysis* (1) For the determination of the smoke flavouring extract — in feed additive: titration with sodium hydroxide for determination of total acids; and colour reactions with further spectrophotometry for determination of total carbonyls (at 430 nm) and total phenols (at 610 nm) (FAO JECFA Combined Compendium for Food Additive Specifications '*smoke flavourings*', Monograph No 1, 2006; Gas chromatography-mass spectrometry (GC-MS); and gas chromatography coupled with flame ionization detection (GC-FID) for characterisation of the volatile fraction of the product (FAO JECFA Combined Compendium for Food Additive Specifications-Monographs No 1, Vol. 4).					

(1) http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/authorisation/evaluation_reports/Pages/index.aspx