Commission Implementing Regulation (EU) 2018/246 of 15 February 2018 concerning the authorisation of linalool oxide as a feed additive for all animal species except fish (Text with EEA relevance)

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concerning the authorisation of linalool oxide as a feed additive for all animal species except fish

(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) The substance linalool oxide was authorised by Directive 70/524/EEC as a feed additive for all animal species. That substance was subsequently entered in the Register of feed additives as existing product, 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 linalool oxide as a feed additive for all animal species except fish. The applicant requested that this additive 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 opinion of 13 June 2012[(3)] that, under the proposed conditions of use, linalool oxide does not have adverse effects on animal health, human health or the environment. In addition, as regards consumer safety, the conclusions of the opinion adopted on 5 March 2014[(4)] are applicable to linalool oxide since linalool oxide belongs to the same chemical group as the substances examined in that opinion. The terminal metabolism of this additive through glucuronidation among mammals, birds and fish allows the conjugates of the additive to be rapidly excreted. The Authority has concluded that, since linalool is used in food as flavouring and its function in feed is essentially the same as in food, no further

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demonstration of efficacy is necessary. Therefore, that conclusion can be extrapolated to feed. The applicant withdrew the application for use of linalool in water for drinking.

(5) The Authority further concluded that, linalool oxide should be treated as potentially hazardous to the respiratory tract, skin and eyes and also as irritating to the skin. 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 additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of linalool oxide 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 substance should be authorised as specified in the Annex to this Regulation.

(7) The applicant proposed use levels for linalool oxide to the Authority. Having regard to that proposal, the Authority considered that certain use levels are safe ('levels considered by the Authority'). For the purpose of official controls along the food chain, certain labelling requirements should be provided for. In particular, where the use levels exceed the levels considered by the Authority, it is appropriate to require that the label of premixtures and the labelling of feed materials and compound feed containing the substances concerned include certain information including reference to the levels considered by the Authority.

(8) The fact that the use of the substance concerned in water for drinking is not authorised does not preclude its use in compound feed which is administered via water.

(9) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for linalool oxide, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(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

Authorisation

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

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Article 2

Transitional measures

1 The substance specified in the Annex and premixtures containing that substance, which are produced and labelled before 15 September 2018 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted.

2 Feed materials and compound feed containing the substance as specified in the Annex which are produced and labelled before 15 March 2019 in accordance with the rules applicable before 15 March 2018 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 substance as specified in the Annex which are produced and labelled before 15 March 2020 in accordance with the rules applicable before 15 March 2018 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, 15 February 2018.

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 %			
Category: Sensory additives. Functional group: Flavouring compounds									
2b13140	—	Linalool oxide	*Additive composition* Linalool oxide *Characterisation of the active substance* Produced by chemical synthesis Purity: min. 95 % assay Chemical formula: $C_{10}H_{18}O_2$ CAS number: 1365-19-1 FLAVIS No: 13.140 *Method of analysis*[a] For the determination of linaloool oxide in the feed additive and in	All animal species except fish	—	—	—	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated:	15.3.2028

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 flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: — 0,3 mg/kg for pigs and poultry, — 0,5 mg/kg for other species and categories except fish.	
								4. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the	

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