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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

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

(Text with EEA relevance)

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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 nutrition¹, 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/EEC².
- (2) The substance linalool oxide was authorised by Directive 70/524/EEC as feed additives 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. 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 opinions of 13 June 2012³ that, under the proposed conditions of use, linalool oxide does not have adverse effects on animal health, human health or the environment. As regard consumer safety, the conclusions of the opinion on the same chemical group adopted on 5 March 2014⁴ are applicable to linalool oxide. 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 demonstration of efficacy is necessary. Therefore, that conclusion can be extrapolated to feed. The applicant withdrew the application for use

¹ OJ L 268, 18.10.2003, p. 29.

² Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).

³ EFSA Journal 2012;10(7):2786

⁴ EFSA Journal 2014;12(3):3608

of linalool in water for drinking. However, it should be possible to use the substances concerned within compound feeds which are subsequently administered via water.

- (5) Restrictions and conditions should be provided 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 additive. Where such content is exceeded, certain information should be indicated in the label of premixtures, and on the labelling of feed materials and compound feed.
- (6) The Authority 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.
- (7) 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.
- (8) 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.
- (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 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.

Article 2 *Transitional measures*

1. The substance specified in the Annex and premixtures containing that substance, which are produced and labelled before *[6 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]* in accordance with the rules applicable before *[the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]* 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 *[12 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]* in accordance with the rules applicable before *[the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the*

publication] 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 *[24 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]* in accordance with the rules applicable before *[the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]* 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,

For the Commission
The President
Jean-Claude JUNCKER