COMMISSION IMPLEMENTING REGULATION (EU) 2017/60

of 14 December 2016

concerning the authorisation of isoeugenol as a feed additive for pigs, ruminants and horses except those producing milk for human consumption and pets

(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) Isoeugenol, was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for all animal species. That product was 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 isoeugenol as a feed additive for all animal species except for poultry, ruminants producing milk for human consumption and fish. The applicant requested that additive 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 opinion of 14 December 2011 ([3]) that, under the proposed conditions of use in feed, isoeugenol does not have adverse effects on animal health, human health or the environment. Isoeugenol should not be allowed for those categories of mammal species intended for the production of milk for human consumption. The Authority further concluded that the function of isoeugenol in feed is similar to that on food. The Authority has already concluded that for food isoeugenol is efficacious, as it increases the food smell or palatability. Therefore, that conclusion can be extrapolated for feed. The Authority concluded that the simultaneous use in feed and water for drinking should be avoided. However, those substances can be used within compound feeds which are subsequently administered via water.

(5) Restrictions and conditions should be provided for 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, 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, compound feeds and feed materials.

(6) The Authority concluded that isoeugenol is an irritant to the respiratory tract, skin and eyes and it is also a skin and respiratory 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 additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(7) The assessment of the substance 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 that substance should be authorised as specified in the Annex to this Regulation.

([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(1):2532.

(8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for that substance 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 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 substance 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 substance 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

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									
2b04004	—	Isoeugenol	*Additive composition* Isoeugenol *Characterisation of the active substance* Isoeugenol Produced by chemical synthesis Purity: min. 99 % Chemical formula: $C_{10}H_{12}O_2$ CAS number 97-54-1 FLAVIS No 04.004 *Method of analysis* (1) For the identification of isoeugenol in the feed additive and flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	Pigs Ruminants and horses except those producing milk for human consumption Pets	—	—	—	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. The recommended maximum content of the active substance shall be: 5 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 with a moisture content of 12 %: 5 mg/kg'. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg.	6 February 2027

								6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including safety glasses and gloves.	

([1]) 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