Commission Implementing Regulation (EU) 2017/307 of 21 February 2017 concerning the authorisation of dry grape extract of Vitis vinifera spp. vinifera as a feed additive for all animal species except for dogs (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2017/307

of 21 February 2017

concerning the authorisation of dry grape extract of *Vitis vinifera* spp. *vinifera* as a feed additive for all animal species except for dogs

(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) Dry grape extract of *Vitis vinifera* spp. *vinifera*, 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 dry grape extract of *Vitis vinifera* spp. *vinifera* as feed additives for all animal species except for dogs. 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 20 April 2016[(3)] that, under the proposed conditions of use in feed, the substance concerned does not have adverse effect on animal health, human health or the environment. The Authority further concluded that the function of dry grape extract of *Vitis vinifera* spp. *vinifera* in feed is similar to that on food. The Authority has already concluded that for food dry grape extract of *Vitis vinifera* spp. *vinifera* is efficacious, as it increases the food smell or palatability. Therefore, that conclusion can be extrapolated for feed.

(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, a recommended content should be indicated on the label of the additive. Where such content is exceeded, certain information 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, dry grape extract of *Vitis vinifera* spp. *vinifera* should be considered as potentially hazardous to the respiratory tract, skin and eyes and as 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.

(8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for the substance concerned, 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 feed additives 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 14 October 2017 in accordance with the rules applicable before 14 March 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 as specified in the Annex which are produced and labelled before 14 March 2018 in accordance with the rules applicable before 14 March 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 as specified in the Annex which are produced and labelled before 14 March 2019 in accordance with the rules applicable

before 14 March 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, 21 February 2017.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2017/307. (See end of Document for details)*

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									
2b485	—	Dry grape extract	*Additive composition* Dry grape extract of *Vitis vinifera* spp. *vinifera* *Characterisation of the active substance* Mixture of seed and skin extract as defined by the Council of Europe[a] — — —	All animal species except dogs ≥ 80 % polyphenols expressed as catechin equivalent, ≥ 60 % proanthocyanidins, ≥ 0,75 %:	—	—	—	1. Dry grape extract of *Vitis vinifera* spp. *vinifera* may be placed on the market and used as an additive consisting of a preparation. 2. The additive shall be incorporated into the feed in the form of a premixture. 3. In the directions for use of the additive	14 March 2027

a Natural sources of flavourings — Report No 2 (2007)

b Details of the methods of analysis 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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				anthocyanins and anthocyanidins, ≤ 10 % water content. CoE No 485 CAS number 85594-37-2 FEMA 4045 *Method of analysis*[b] For the determination of dry grape extract in the feed additive: — high performance liquid chromatography coupled to UV detection (HPLC-UV) for the identification of gallic acid as the phytomarker, and — spectrophotometry at 280 nm			and premixtures, the storage and stability conditions shall be indicated. 4. The recommended maximum content of the active substance shall be 100 mg/kg of complete feedingstuff with a moisture content of 12 %. 5. On the label of the additive the following shall be indicated: Recommended maximum content of the active substance of complete feedingstuff with a

a Natural sources of flavourings — Report No 2 (2007)

b Details of the methods of analysis are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports