Commission Implementing Regulation (EU) 2017/66 of 14 December 2016 concerning the authorisation of tannic acid as a feed additive for all animal species (Text with EEA relevance)

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concerning the authorisation of tannic acid as a feed additive for all animal species

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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 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) Tannic acid 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 an 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 tannic acid as a feed additive for all animal species. 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 11 September 2014[(3)] that, under the proposed conditions of use in feed this substance does not have adverse effects on animal health, human health or the environment. The Authority further concluded that the function of tannic acid in feed is similar to that on food. The Authority has already concluded that for food tannic acid 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 tannic acid should be considered as potentially hazardous to the respiratory tract, skin, eyes and mucous membranes. 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 additives 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 tannic acid 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 tannic acid, 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 those substances, 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 as 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 as 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

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2017/66. (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									
2b16080	—	Tannic acid	*Additive composition* Tannic acid *Characterisation of the active substance* Tannic acid Produced by extraction from different plants. Purity: min. 93 % on dry matter basis Chemical formula: $C_{76}H_{52}O_{46}$ CAS number 72401-53-7 FLAVIS No: 16.080 *Method of analysis*[a] For the determination of	All animal species	—	—	—	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	6 February 2027

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

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2017/66. (See end of Document for details)*

			tannic acid, in the feed additive: Qualitative colorimetric or precipitation tests (Ph. Eur. 6th edition, monograph 1477) and quantitative gravimetric method (FAO JECFA tannic acid monograph). For the identification of tannic acid (as gallic acid) in the premixture of flavourings: Reversed Phase High Performance Liquid Chromatography coupled to UV detector(RP-HPLC-UV).					4.	the active substance shall be: 15 mg/kg of complete feedingstuff with a moisture content of 12 %. 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 %:15 mg/kg.
								5.	The functional group,

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