Commission Implementing Regulation (EU) 2015/1152 of 14 July 2015 concerning the authorisation of tocopherol extracts from vegetable oils, tocopherol-rich extracts from vegetable oils (delta rich) and alpha-tocopherol as feed additives for all animal species (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2015/1152

of 14 July 2015

concerning the authorisation of tocopherol extracts from vegetable oils, tocopherol-rich extracts from vegetable oils (delta rich) and alpha-tocopherol as feed additives for all animal species

(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) Tocopherol extracts from vegetable oils, tocopherol-rich extracts from vegetable oils (delta rich) and alpha-tocopherol were authorised without a time limit in accordance with Directive 70/524/EEC as feed additives for all animal species. Those products were 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, two applications were submitted for the re-evaluation of tocopherol extracts from vegetable oils, tocopherol-rich extracts from vegetable oils (delta rich) and alpha-tocopherol as feed additives and their preparations for all animal species. The applicants requested these additives to be classified in the additive category ‘technological additives’. These applications were 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 12 June 2012[(3)] that, under the proposed conditions of use in feed, tocopherol extracts from vegetable oils, tocopherol-rich extracts from vegetable oils (delta rich) and alpha-tocopherol do not have adverse effects on animal health, human health or the environment. The Authority further concluded that these additives are efficacious as

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2015/1152. (See end of Document for details)*

antioxidants and that no safety concerns would arise for users. 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.

(5) The assessment of tocopherol extracts of natural origin, tocopherol-rich extracts of natural origin (delta rich) and alpha-tocopherol shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of these substances should be authorised as specified in the Annex to this Regulation.

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

(7) 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

The substances specified in the Annex, belonging to the additive category ‘technological additives’ and to the functional group ‘antioxidants’, are authorised as additives in animal nutrition subject to the conditions laid down in that Annex.

Article 2

1 The substances specified in the Annex and premixtures containing those substances, which are produced and labelled before 4 February 2016 in accordance with the rules applicable before 4 August 2015 may continue to be placed on the market and used until the existing stocks are exhausted.

2 Compound feed and feed materials containing the substances specified in the Annex which are produced and labelled before 4 August 2016 in accordance with the rules applicable before 4 August 2015 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 substances specified in the Annex which are produced and labelled before 4 August 2017 in accordance with the rules applicable before 4 August 2015 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

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 July 2015.

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: technological additives. Functional group: antioxidants									
1b306(i)	—	Tocopherol extracts from vegetable oils	*Additive composition* Alpha-, beta-, gamma- and delta-tocopherol. *Characterisation of the active substance* Alpha-, beta-, gamma- and delta-tocopherol: — $C_{29}H_{50}O_2$ — $C_{28}H_{48}O_2$ — $C_{28}H_{48}O_2$ — $C_{27}H_{46}O_2$ CAS No: — 59-02-9 — 490-23-3 — 54-28-4 — 119-13-1 Tocopherol extracts of natural origin, liquid oily form,	All animal species	—	—	—	1. Tocopherol extracts from vegetable oils may be placed on the market and used as an additive consisting of a preparation. 2. In the directions for use of the additive, indicate the storage and stability conditions and for the premixtures the storage conditions.	4 August 2025

a Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

b Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).

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			produced by extraction from vegetable oils. Purity criteria: total tocopherols min. 30 %. *Method of Analysis*[a] For the determination of tocopherol forms (alpha-, beta-, gamma- and delta-tocopherol) in the feed additive: Gas Chromatography coupled to Flame Ionisation Detection,GC/FID (AOAC 988.14). For the determination of tocopherol forms (alpha-, beta-, gamma- and delta-						

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