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

of **XXX**

concerning the renewal of 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 and repealing Implementing Regulation (EU) 2015/1152

(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 and renewing such an authorisation.
- (2) Tocopherol extracts from vegetable oils, tocopherol-rich extracts from vegetable oils (delta rich) and alpha-tocopherol were authorised for a period of 10 years as feed additives for all animal species by Commission Implementing Regulation (EU) 2015/1152².
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of 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, requesting the additive to be classified in the additive category 'technological additives' and in the functional group 'antioxidants'. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 27 January 2026³ that, the use of vitamin E in the form of tocopherol extracts from vegetable oils, tocopherol-rich extracts from vegetable oils (delta rich) and alpha-tocopherol remains safe for the target species, consumers and the environment under the conditions of use currently authorised. It also concluded that tocopherol extracts from vegetable oils, tocopherol-rich extracts from vegetable oils (delta rich) and alpha-tocopherol, should be considered skin and respiratory sensitisers. Exposure of users by inhalation and dermal routes is considered a risk. It could not conclude on the eye

¹ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

² 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 (OJ L 187, 15.7.2015, pp. 5, ELI: http://data.europa.eu/eli/reg_impl/2015/1152/oj).

³ EFSA Journal. 2026;24:e9917. <https://doi.org/10.2903/j.efsa.2026.9917>.

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irritation potential due to the lack of data. The Authority also stated that the application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of the additives. Therefore, it concluded that there is no need for assessing the efficacy of the additives in the context of the renewal of the authorisation.

- (5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in a previous assessment concerning another application for the authorisation of the same additive and verified by the Authority in its opinions of 12 June 2012⁴⁵ are valid and applicable for the current application. In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005⁶, an evaluation report of the Reference Laboratory was therefore not required.
- (6) In view of the above, the Commission considers that the tocopherol extracts from vegetable oils, tocopherol-rich extracts from vegetable oils (delta rich) and alpha-tocopherol satisfy the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of those additives should be renewed. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additives. Those protective measures should be without prejudice to other workers' safety requirements under Union law.
- (7) As a consequence of the renewal of the authorisation of tocopherol extracts from vegetable oils, tocopherol-rich extracts from vegetable oils (delta rich) and alpha-tocopherol as feed additives, Implementing Regulation (EU) 2015/1152 should be repealed.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of tocopherol extracts from vegetable oils, tocopherol-rich extracts from vegetable oils (delta rich) and alpha-tocopherol for all animal species, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of 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

Renewal of the authorisation

The authorisations of the substances specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'antioxidants', are renewed subject to the conditions laid down in that Annex.

⁴ EFSA Journal 2012;10(7):2783. <https://doi.org/10.2903/j.efsa.2012.2783>.

⁵ EFSA Journal 2012;10(7):2784. <https://doi.org/10.2903/j.efsa.2012.2784>.

⁶ Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8, ELI: <http://data.europa.eu/eli/reg/2005/378/oj>).

Article 2

Repeal

Implementing Regulation (EU) 2015/1152 is repealed.

Article 3

Transitional measures

1. Tocopherol extracts from vegetable oils, tocopherol-rich extracts from vegetable oils (delta rich) and alpha-tocopherol, as authorised by Implementing Regulation (EU) 2015/1152, and premixtures containing those additives, which are intended for all animal species, and which are produced and labelled before ...*[OJ please insert the date falling 6 months from the date of entry into force of this Regulation]* in accordance with the rules applicable before ...*[OJ please insert the date of entry into force of this Regulation]* may continue to be placed on the market and used until the stocks concerned are exhausted.
2. Compound feed and feed materials containing the feed additives referred to in paragraph 1, which are intended for all animal species and which are produced and labelled before *[OJ please insert the date falling 12 months from the date of entry into force of this Regulation]* in accordance with the rules applicable before *[OJ please insert the date of entry into force of this Regulation]* may continue to be placed on the market and used until the stocks concerned are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the feed additives referred to in paragraph 1, which are intended for all animal species and which are produced and labelled before *[OJ please insert the date falling 24 months from the date of entry into force of this Regulation]* in accordance with the rules applicable before *[OJ please insert the date of entry into force of this Regulation]* may continue to be placed on the market and used until the stocks concerned are exhausted if they are intended for non-food producing animals.

Article 4

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
Ursula VON DER LEYEN