This document is meant purely as a documentation tool and the institutions do not assume any liability for its contents

►**B**

COMMISSION REGULATION (EU) No 26/2011

of 14 January 2011

concerning the authorisation of vitamin E as a feed additive for all animal species

(Text with EEA relevance)

(OJ L 11, 15.1.2011, p. 18)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Implementing Regulation (EU) 2015/1747 of 30 September 2015	L 256	7	1.10.2015

▼B

COMMISSION REGULATION (EU) No 26/2011

of 14 January 2011

concerning the authorisation of vitamin E as a feed additive 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) Vitamin E was authorised without time limit as a feed additive for use in all animal species by Directive 70/524/EEC as part of the group 'Vitamins, pro-vitamins and chemically well-defined substances having similar effect'. That additive 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 of that Regulation, an application was submitted for the re-evaluation of vitamin E as a feed additive for all animal species, requesting that additive to be classified in the additive category 'nutritional additives'. The 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 25 May 2010 that, under the proposed conditions of use, vitamin E does not have an adverse effect on animal health, consumer health or the environment ([3]). It also verified the report on the method of analysis of the feed additive in feed submitted by the Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) OJ L 270, 14.12.1970, p. 1.
([3]) EFSA Journal 2010; 8(6):1635 (Summary).

▼B

(5) The assessment of vitamin E 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 additive should be authorised as specified in the Annex to this Regulation.

(6) Since the modifications on the conditions of the authorisation are not related to safety reasons, it is appropriate to allow a transitional period for the disposal of existing stocks of the premixtures and compound feed.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The preparations specified in the Annex, belonging to the additive category 'nutritional additives' are authorised as additives in animal nutrition subject to the conditions laid down in that Annex.

Article 2

Feed containing vitamin E labelled in accordance with Directive 70/524/EEC or Regulation (EC) No 1831/2003 may continue to be placed on the market and used until stocks are exhausted.

Article 3

This Regulation shall enter into force on the 20th day following 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.

ANNEX

Identification number of the additive	Additive	Chemical formula, description, methods of analysis	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
Nutritional additives: Vitamins, pro-vitamins and chemically well-defined substances having similar effect								
3a700	►**M1** ‘Vitamin E’ or ‘all-rac-alpha-tocopheryl acetate’ ◄	*Active substance* all-rac-alpha-tocopheryl acetate: $C_{31}H_{52}O_3$ CAS No 7695-91-2 Purity criteria: all-rac-alpha-tocopheryl acetate > 93 % *Methods of analysis* 1. For the determination of vitamin E (oil form) in feed additives: European Pharmacopoeia EP-0439. 2. For the determination of vitamin E (powder form) in feed additives: European Pharmacopoeia EP-0691. 3. For the determination of the level of authorised vitamin E in feed: Commission Regulation (EC) No 152/2009 ([1]).	All animal species	—	—	—	1. If vitamin E content is mentioned in the labelling, the following equivalencies for the units of measurement of the contents shall be used: — 1 mg all-rac-alpha-tocopheryl acetate = 1 IU — 1 mg RRR-alpha-tocopherol = 1,49 IU — 1 mg RRR-alpha-tocopheryl acetate = 1,36 IU 2. Vitamin E may be used also via water for drinking. ►**M1** 3. Vitamin E may be placed on the market and used as an additive consisting of a preparation. ◄	4 February 2021

▼B

Identification number of the additive	Additive	Chemical formula, description, methods of analysis	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
	►M1 'Vitamin E' or 'RRR alpha tocopheryl acetate' ◄	*Active substance* RRR alpha tocopheryl acetate: $C_{31}H_{52}O_3$ CAS No 58-95-7 Purity criteria: RRR-alpha-tocopheryl acetate > 40 % *Methods of analysis* 1. For the determination of vitamin E (oil form) in feed additives: European Pharmacopoeia EP-1257. 2. For the determination of vitamin E (powder form) in feed additives: European Pharmacopoeia EP-1801. 3. For the determination of the level of authorised vitamin E in feed: Commission Regulation (EC) No 152/2009.						
	►M1 'Vitamin E' or 'RRR alpha tocopherol' ◄	*Active substance* RRR alpha tocopherol: $C_{29}H_{50}O_2$ CAS No 59-02-9 Purity criteria: RRR-alpha-tocopherol > 67 % *Methods of analysis* 1. For the determination of vitamin E (oil form) in feed additives: European Pharmacopoeia EP-1256.						

▼B

Identification number of the additive	Additive	Chemical formula, description, methods of analysis	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
		2. For the determination of vitamin E (powder form) in feed additives: European Pharmacopoeia EP-1801. 3. For the determination of the level of authorised vitamin E in feed: Commission Regulation (EC) No 152/2009.						

([1]) OJ L 54, 26.2.2009, p. 1.