Commission Implementing Regulation (EU) 2015/1103 of 8 July 2015 concerning the authorisation of beta-carotene as a feed additive for all animal species (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2015/1103

of 8 July 2015

concerning the authorisation of beta-carotene 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) Beta-carotene was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for use on all animal species and 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 beta-carotene and its preparations for all animal species. The applicant requested that additive to be classified in the additive category ‘nutritional 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 23 May 2012[(3)] that, under the proposed conditions of use in feed, beta-carotene does not have an adverse effect on animal health, human health or the environment. The Authority also concluded that beta-carotene is used for the synthesis of retinol in almost all species (cats, in particular, were not able to use beta-carotene for the synthesis of retinol) 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 beta-carotene shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this substance 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 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 substance specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect', is authorised as a feed additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

1 The substance specified in the Annex and premixtures containing that substance, which are produced and labelled before 29 January 2016 in accordance with the rules applicable before 29 July 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 substance specified in the Annex which are produced and labelled before 29 July 2016 in accordance with the rules applicable before 29 July 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 substance specified in the Annex which are produced and labelled before 29 July 2017 in accordance with the rules applicable before 29 July 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, 8 July 2015.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2015/1103. (See end of Document for details)*

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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 of nutritional additives. Functional group: vitamins, provitamins and chemically well defined substances having a similar effect									
3a160(a)		Beta-carotene	*Additive composition* Beta-carotene. Triphenylphosphine oxide (TPPO) ≤ 100 mg/kg of the additive. *Characterisation of the active substance* Beta-carotene $C_{40}H_{56}$ CAS number: 7235-40-7 Beta-carotene, solid form, produced by fermentation or chemical synthesis. Strains used in the fermentation:	All animal species	—	—		1. Beta-carotene may be placed on the market and used as an additive consisting of a preparation. 2. In milk replacers for calves it is recommended a maximum content of 50 mg of beta-carotene/kg of milk replacer. 3. In the directions	29 July 2025

a China General Microbiological Culture Collection Centre.

b 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