

Brussels, **XXX**  
SANTE/8332590/2025 CIS  
(POOL/G5/2025/8332590/8332590-EN  
CIS.docx)  
[...](2025) **XXX** draft

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

**of **XXX****

**concerning the renewal of the authorisation of beta-carotene and a preparation of beta-carotene as feed additives for all animal species and repealing Implementing Regulation (EU) 2015/1103**

(Text with EEA relevance)

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

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**concerning the renewal of the authorisation of beta-carotene and a preparation of beta-carotene as feed additives for all animal species and repealing Implementing Regulation (EU) 2015/1103**

(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<sup>1</sup>, 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) Beta-carotene was authorised for 10 years as a feed additive for all animal species by Commission Implementing Regulation (EU) 2015/1103<sup>2</sup>. The terms of authorisation allow the use of beta-carotene as an additive consisting of a preparation.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of beta-carotene and a preparation of beta-carotene as feed additives for all animal species, requesting the additives to be classified in the additive category ‘nutritional additives’ and in the functional group ‘vitamins, pro-vitamins and chemically well-defined substances having similar effect’. 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 25 June 2025<sup>3</sup> that, the applicant has provided evidence that the use of beta-carotene and of the preparation of beta-carotene produced by chemical synthesis remains safe for all animal species as well as for consumers, users and the environment under the conditions currently authorised. In addition, the Authority stated that among food-producing animals, the consumption of liver from veal calves may result in additional exposure, so unlimited use of beta-carotene as an additive in milk replacers may be a concern for consumer safety. The Authority further concluded that beta-carotene is not a skin and eye irritant nor a skin sensitiser. One of the evaluated preparations

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

<sup>2</sup> Commission Implementing Regulation (EU) 2015/1103 of 8 July 2015 concerning the authorisation of beta-carotene as a feed additive for all animal species. (OJ L 181, 9.7.2015, p. 57 ELI: [http://data.europa.eu/eli/reg\\_impl/2015/1103/oj](http://data.europa.eu/eli/reg_impl/2015/1103/oj)).

<sup>3</sup> EFSA Journal. 2025;23:e9549. <https://doi.org/10.2903/j.efsa.2025.9549>.

containing 10% beta-carotene was shown not to be a skin sensitiser. However, no conclusions on the safety for the user could be reached for other preparations. The Authority 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. The Authority considered that there is no need for specific requirements of post-market monitoring.

- (5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the assessment carried out regarding the method of analysis of beta-carotene as a feed additive in the context of the previous authorisation are valid and applicable for the current application. In accordance with Article 5(4), point (c), of Commission Regulation (EC) No 378/2005<sup>4</sup>, an evaluation report of the Reference Laboratory is therefore not required.
- (6) In view of the above, the Commission considers that beta-carotene and the preparation of beta-carotene 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. The Commission further considers that due to the risk for consumer safety by the consumption of liver from veal calves, a maximum level should be set for calves. 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 beta-carotene and the preparation of beta-carotene, Implementing Regulation (EU) 2015/1103 should be repealed.
- (8) Since the identification number of the additives has been modified and a maximum content level has been authorised for calves (milk-replacers), 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 authorisation of the substance and the preparation 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 renewed subject to the conditions laid down in that Annex.

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<sup>4</sup> 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 additive (OJ L 59, 5.3.2005, p. 8, ELI: <http://data.europa.eu/eli/reg/2005/378/oj>).

## *Article 2*

### **Repeal**

Implementing Regulation (EU) 2015/1103 is repealed.

## *Article 3*

### **Transitional measures**

1. The feed additive beta-carotene, as authorised by Implementing Regulation (EU) 2015/1103, and premixtures containing that additive, which are intended for all animal species and which are produced and labelled before *[6 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]* in accordance with the rules applicable before *[the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]* 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 additive referred to in paragraph 1, which are produced and labelled before *[12 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]* in accordance with the rules applicable before *[the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]* 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 additive referred to in paragraph 1, which are produced and labelled before *[24 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]* in accordance with the rules applicable before *[the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]* 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*