



Brussels, XXX
SANTÉ/
[...] (2026) XXX draft

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

of XXX

**concerning the renewal of the authorisation of a preparation of red carotenoid-rich
Paracoccus carotinifaciens as a feed additive for salmon and trout and repealing
Implementing Regulation (EC) No 721/2008**

(Text with EEA relevance)

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

of **XXX**

concerning the renewal of the authorisation of a preparation of red carotenoid-rich *Paracoccus carotinifaciens* as a feed additive for salmon and trouts and repealing Implementing Regulation (EC) No 721/2008

(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 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 authorisation.
- (2) The preparation of red carotenoid-rich *Paracoccus carotinifaciens* was authorised for a period of 10 years as a feed additive for salmon and trout by Commission Implementing Regulation (EC) No 721/2008².
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of preparation of red carotenoid-rich *Paracoccus carotinifaciens* as a feed additive for salmon and trouts, requesting the additive to be classified in the additive category ‘sensory additives’ and in the functional group ‘colourants: substances which when fed to animals add colours to food of animal origin’. That application was accompanied by the particulars and documents required under Article 14(2) of that Regulation. The applicant requested to delete the provision limiting the use of the additive in fish from the age of 6 months onwards or weight of 50 g and to lower the Maximum Residue Limits (MRLs) for salmon to 5 mg for the sum of adonirubin and canthaxanthin/kg muscle (wet tissue).
- (4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 26 June 2024³ that the applicant provided evidence that the preparation of red carotenoid-rich *Paracoccus carotinifaciens* remains safe for the target species, the consumer and the environment under the conditions of use currently authorised. The Authority considered that there is no need to restrict the use of the additive to fish older than 6 months or of more than 50 g. It also concluded that the preparation of red carotenoid-

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

² Commission Regulation (EC) No 721/2008 of 25 July 2008 concerning the authorisation of a preparation of red carotenoid-rich bacterium *Paracoccus carotinifaciens* as a feed additive (OJ L 198, 26.7.2008, p. 23, ELI: <http://data.europa.eu/eli/reg/2008/721/oj>).

³ EFSA Journal, 22(7), e8905. <https://doi.org/10.2903/j.efsa.2024.8905>.

rich *Paracoccus carotinifaciens* is not irritant to the skin but is considered an eye irritant, and a skin and respiratory sensitiser. Any exposure through skin and inhalation is considered a risk for the user. 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 additive. Therefore, it concluded that there is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation. The Authority recommended reducing the MRLs for the sum of canthaxanthin and adonirubin for both salmon and trout to 5 mg/kg muscle, since it would ensure compliance with the Acceptable Daily Intake for the sum of canthaxanthin and adonirubin. It also recommended avoiding the simultaneous use of the additive and blood meal in the feed of salmon and trout and that the mixture of the additive with other authorised feed additives containing astaxanthin, adonirubin and/or canthaxanthin would not result in the total concentration of the sum of astaxanthin, adonirubin and canthaxanthin exceeding 100 mg/kg of complete feed.

- (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 methods for the control of the astaxanthin, adonirubin and canthaxanthin in animal feed and marker residue in muscle tissue of salmon and trout in the context of the previous authorisation are valid and applicable for the current application. However, the Reference Laboratory subsequently updated the evaluation report submitted in the context of the previous authorisation, in order to take account of scientific and technological developments and to ensure a better suitability of the methods of analysis for official controls. The Authority verified the amended report on the methods of analysis of red carotenoid-rich *Paracoccus carotinifaciens* as a feed additive submitted by the Reference Laboratory.
- (6) In view of the above, the Commission considers that the preparation of red carotenoid-rich *Paracoccus carotinifaciens* satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed.
- (7) As a consequence of the renewal of the authorisation of the preparation of red carotenoid-rich *Paracoccus carotinifaciens* as a feed additive, Implementing Regulation (EC) No 721/2008 should be repealed.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation of red carotenoid-rich *Paracoccus carotinifaciens*, 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 preparation specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'colourants: substances which when

fed to animals add colours to food of animal origin', is renewed subject to the conditions laid down in that Annex.

Article 2

Repeal of Implementing Regulation (EC) No 721/2008

Implementing Regulation (EC) No 721/2008 is repealed.

Article 3

Transitional measures

1. The preparation of red carotenoid-rich *Paracoccus carotinifaciens*, as authorised by Commission Regulation (EC) No 721/2008 and premixtures containing that additive, 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 existing stocks 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 existing stocks are exhausted.

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