



2024/752

1.3.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/752

of 29 February 2024

concerning the denial of authorisation of a preparation of astaxanthin-rich *Phaffia rhodozyma* (ATCC SD-5340) as a feed additive for salmon and trout

(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 or denying such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) A preparation of astaxanthin-rich *Phaffia rhodozyma* (ATCC SD-5340) was authorised for four years in accordance with Directive 70/524/EEC as a feed additive belonging to the group 'colourants, including pigments' for use for salmon and trout with the additive number E 161y. 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 thereof, an application was submitted for the authorisation of a preparation of astaxanthin-rich *Phaffia rhodozyma* (ATCC SD-5340) as a feed additive for salmon and trout, requesting that additive to be classified in the category 'sensory additives' and in the functional group 'colourants: (ii) 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 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') noted in its opinion of 27 January 2022 ⁽³⁾ that it could not conclude on the safety of the additive for the target species in the absence of a tolerance study with the additive under assessment. The Authority could not conclude on the safety of the additive for the consumer either, due to a lack of adequate toxicity and residue data. The Authority concluded that the additive is irritant to skin and eyes, is a skin and respiratory sensitiser, although exposure by inhalation is likely low. Furthermore, in the absence of adequate evidence, no conclusions could be drawn by the Authority on the efficacy of the additive. The Authority also verified the report on the method of analysis of the additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) By letter of 13 May 2022, the Commission gave the applicant the opportunity to submit supplementary information to address the inconclusive opinion of the Authority. In the absence of a reply, a new letter was sent to the applicant on 20 April 2023, asking for a clarification of the intention with the application, but no reaction was communicated to the Commission.
- (6) As provided for by Article 5(1) of Regulation (EC) No 1831/2003, it is for the applicant for an authorisation of a feed additive to adequately and sufficiently demonstrate, in accordance with the implementing rules referred to in Article 7 of that Regulation, that the conditions for authorisation set out in Article 5(2) and (3) of that Regulation are satisfied.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).

⁽³⁾ EFSA Journal 2022;20(2):7161.

- (7) It derives from the Authority's opinion of 27 January 2022 that it has not been established that the preparation of astaxanthin-rich *Phaffia rhodozyma* (ATCC SD-5340) does not have an adverse effect on animal health and human health, and that it is efficacious when used as a feed additive for salmon and trout in the additive category 'sensory additives' and the functional group 'colourants: (ii) substances which, when fed to animals, add colours to food of animal origin'.
- (8) In view of the above, it cannot be considered that the preparation of astaxanthin-rich *Phaffia rhodozyma* (ATCC SD-5340) satisfies the conditions for the authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that preparation as a feed additive belonging to the category 'sensory additives' and the functional group 'colourants: (ii) substances which, when fed to animals, add colours to food of animal origin' for use for salmon and trout, should be denied.
- (9) Therefore, the preparation of astaxanthin-rich *Phaffia rhodozyma* (ATCC SD-5340) and feed containing it should be withdrawn from the market as soon as possible as far as the use for salmon and trout is concerned. However, a limited period should be allowed for the withdrawal from the market of the existing stocks of those products, in order to enable operators to comply properly with the withdrawal obligation.
- (10) 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

Denial of authorisation

The authorisation of the preparation of astaxanthin-rich *Phaffia rhodozyma* (ATCC SD-5340) (E 161y) as an additive in animal nutrition belonging to the category 'sensory additives', functional group 'colourants: (ii) substances which, when fed to animals, add colours to food of animal origin' for use for salmon and trout, is denied.

Article 2

Transitional provisions

1. Existing stocks of the additive referred to in Article 1, which are intended for salmon and trout, and of premixtures containing it, shall be withdrawn from the market by 21 June 2024.
2. Feed materials and compound feed which have been produced with the additive or premixtures referred to in paragraph 1 before 21 June 2024 and which are intended for salmon and trout, shall be withdrawn from the market by 21 September 2024.

Article 3

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, 29 February 2024.

For the Commission
The President
Ursula VON DER LEYEN
