



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/6175038/2025 CIS
(POOL/G5/2025/AN/6175038/6175038-
EN CIS.docx)
[...](2025) **XXX** draft

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

of **XXX**

**concerning the authorisation of ponceau 4R as a feed additive for its use in baits for
freshwater food-producing finfish**

(Text with EEA relevance)

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

of **XXX**

concerning the authorisation of ponceau 4R as a feed additive for its use in baits for freshwater food-producing finfish

(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 such an authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of ponceau 4R as a feed additive for its use in baits for freshwater fish. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of ponceau 4R as a feed additive for use in baits for freshwater fish, requesting that additive to be classified in the category ‘sensory additives’ and in the functional group ‘colourants, (i) substances that add or restore colour in feedingstuffs’. The additive is intended to be incorporated in fishing baits to colour them and attract fish in freshwater and is not intended for use in aquaculture.
- (4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 15 October 2024² that the use of ponceau 4R in the preparation of baits for freshwater fish under the proposed conditions of use is of no concern for the target animals and is safe for consumers and the environment. It also concluded that the additive is not skin irritant but it should be considered a skin and respiratory sensitiser. The Authority could not conclude on the eye irritation potential of the additive. In the opinion of 6 May 2025³, the Authority concluded that ponceau 4R has the potential to be efficacious in colouring fishing baits at the recommended dose of 15 mg/kg.
- (5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in a previous assessment regarding the methods used for the control of the ponceau 4R in animal feed are valid and applicable for the current application. In accordance with Article 5(4), point (a), of Commission

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

² EFSA Journal, 22(11), e9072. <https://doi.org/10.2903/j.efsa.2024.9072>.

³ EFSA Journal, 23(6), e9462. <https://doi.org/10.2903/j.efsa.2025.9462>.

Regulation (EC) No 378/2005⁴, an evaluation report of the Reference Laboratory is therefore not required.

- (6) In view of the above, the Commission considers that ponceau 4R satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, this substance should be authorised with specific regard to its use in fishing baits which fall within the definition of feed laid down in Article 3(4) of Regulation (EC) No 178/2002 of the European Parliament and of the Council⁵, where they are designed to be scattered to attract fish to an area. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (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 **Authorisation**

The substance specified in the Annex, belonging to the additive category ‘sensory additives’ and in the functional group ‘colourants, (i) substances that add or restore colour in feedingstuffs’, is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2 **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

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

⁵ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1, ELI: <http://data.europa.eu/eli/reg/2002/178/oj>