



COMMISSION IMPLEMENTING REGULATION (EU) 2026/108

of 16 January 2026

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 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 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 2024 ⁽²⁾ 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 2025 ⁽³⁾, the Authority concluded that ponceau 4R has the potential to be efficacious in colouring fishing baits under the proposed conditions of use.
- (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 Regulation (EC) No 378/2005 ⁽⁴⁾, 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 Council ⁽⁵⁾, 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.

⁽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>.

⁽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>).

- (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, 16 January 2026.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the feed additive	Name of the 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 complementary feed with a moisture content of 12 %			
Category: Sensory additives. Functional group: Colourants: (i) substances that add or restore colour in feedingstuffs								
2a124	Ponceau 4R	<i>Additive composition</i> Ponceau 4R Solid form ----- <i>Characterisation of the active substance as the sodium salt</i> Ponceau 4R, described as the sodium salt, consists essentially of trisodium 2-hydroxy-1-(4-sulfonato-1-naphthylazo) naphthalene-6,8-disulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components. The calcium and the potassium salts are also allowed with the same characterisation as sodium salt Chemical formula: C₂₀H₁₁N₂O₁₀S₃Na₃ CAS No: 2611-82-7 Produced by chemical synthesis Purity criteria — Total colouring matters calculated as the sodium salt ≥ 80% (assay); — Subsidiary colouring matter ≤ 1%;	Freshwater food-producing finfish	-	-	15	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. The additive shall only be used in fishing baits. The additive shall not be used in aquaculture feed. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal skin, eye and breathing protective equipment.	8 February 2036

Identification number of the feed additive	Name of the 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 complementary feed with a moisture content of 12 %			
		— Organic compounds other than colouring matters ≤ 0,5%; — Unsulfonated primary aromatic amines (calculated as aniline) ≤ 0,01%. ----- Analytical method ⁽¹⁾ For the quantification of total colouring matters content of ponceau 4R in the feed additive: — Spectrophotometry at 505 nm and titration with Titanous chloride as described in Commission Regulation (EU) No 231/2012 referring to FAO JECFA Combined Compendium for Food Additive Specifications (Analytical methods Vol. 4); and the Monograph No. 11 (2011) 'Ponceau 4R'. For the quantification of ponceau 4R in compound feed: — High performance liquid chromatography coupled to tandem mass spectrometry (LC-MS/MS)						

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en