



**COMMISSION IMPLEMENTING REGULATION (EU) 2025/714
of 10 April 2025**

concerning the authorisation of indigo carmine as a feed additive for cats, dogs and ornamental fish

(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. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC (²).
- (2) The substance indigo carmine was authorised under the name 'indigotine' without a time limit in accordance with Directive 70/524/EEC as a feed additive for ornamental fish belonging to the group 'colourants, including pigments', under the heading 'other colourants'. It was also authorised without a time limit as a feed additive for dogs and cats belonging to the group 'colourants, including pigments', under the heading 'colouring agents authorised for colouring foodstuffs by Community rules'. That substance was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1)(b) 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 indigo carmine as a feed additive for cats, dogs and ornamental fish. The applicant requested the additive to be classified in the additive category 'sensory additives' and in the functional group 'colourants: substances that add or restore colour in feedingstuffs'. The 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') concluded in its opinions of 28 April 2015 (³) and 27 June 2024 (⁴) that indigo carmine (purity of at least 85 % colouring matter) is safe for cats and dogs at levels up to 250 mg/kg complete feed, and for ornamental fish up to 1 000 mg/kg complete feed. The Authority concluded that it would be prudent to regard users as being at risk of inhalation exposure to dust from the additive and that in the absence of information on the inhalation toxicity of indigo carmine, such exposure is regarded as hazardous. Indigo carmine is not an irritant to skin and eyes but it should be considered a potential skin and respiratory sensitisier in humans. Indigo carmine is effective in adding colour to feedingstuffs for dogs, cats and ornamental fish. The Authority also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) In view of the above, the Commission considers that indigo carmine satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that substance should be authorised as specified in the Annex to this Regulation. 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) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1, ELI: <http://data.europa.eu/eli/dir/1970/524/oj>).

(³) EFSA Journal 2015; 13(5):4108, <https://doi.org/10.2903/j.efsa.2015.4108>.

(⁴) EFSA Journal 2024; 22(7):e8909, <https://doi.org/10.2903/j.efsa.2024.8909>.

(6) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the substance concerned, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(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 to the functional group 'colourants: substances that add or restore colour in feedstuffs', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Transitional measures

1. The feed additive indigotine as authorised pursuant to Directive 70/524/EEC, and premixtures containing this additive, which are intended for cats, dogs and ornamental fish, and which are produced and labelled before 1 November 2025 in accordance with the rules applicable before 1 May 2025 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 1 May 2027 in accordance with the rules applicable before 1 May 2025 may continue to be placed on the market and used until the stocks concerned are exhausted if they are intended for cats, dogs and ornamental fish.

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, 10 April 2025.

For the Commission

The President

Ursula VON DER LEYEN

ANNEX

Identification number of the feed additive	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 additive/kg complete feedingstuff with 12 % moisture content				
Category: sensory additives. Functional group: colourants: (i) substances that add or restore colour in feedingstuffs									
2a132	Indigo carmine	<p><i>Additive composition:</i> Indigo carmine Solid form</p> <p><i>Characterisation of the active substance:</i> Indigo carmine, described as the sodium salt, consists essentially in a mixture of disodium 3,3'-dioxo-2,2'-bi-indolylidene-5,5'-disulfonate, and disodium 3,3'-dioxo-2,2'-bi-indolylidene-5,7'-disulfonate</p> <p>Calcium and potassium salts are also allowed with the same characterisation as sodium salt.</p> <p>Produced by chemical synthesis</p> <p>Chemical formula: $C_{16}H_8N_2Na_2O_8S_2$</p> <p>CAS No: 860-22-0 / 54947-75-0</p> <p>Total colouring matter $\geq 85\%$</p> <p>Disodium 3,3'-dioxo-2,2'-bi-indolylidene-5,7'-disulphonate $\leq 18\%$</p> <p>Subsidiary colouring matter $\leq 1\%$</p>	<p>Cats Dogs</p> <p>Ornamental fish</p>			250	1 000	<ol style="list-style-type: none"> 1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. 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 and breathing protective equipment. 	1.5.2035

Identification number of the feed additive	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 additive/kg complete feedingstuff with 12 % moisture content				
Category: sensory additives. Functional group: colourants: (i) substances that add or restore colour in feedingstuffs									
		<p>Organic compounds other than colouring matters (isatin-5-sulphonic acid, 5-sulphoanthranilic acid and anthranilic acid) ≤ 0,5 %</p> <p>Unsulphonated primary aromatic amines ≤ 0,01 %</p> <p>Ether extractable matter ≤ 0,2 % under neutral conditions</p> <p>Lead ≤ 2 mg/kg</p> <p><i>Analytical method</i></p> <p>For the quantification of total colouring matters content of indigo carmine in the feed additive:</p> <ul style="list-style-type: none"> — Spectrophotometry at 610 nm (FAO JECFA monographs n. 1, Vol. 4 and Commission Regulation (EU) No 231/2012) (1) for indigo carmine <p>For the quantification of indigo carmine in compound feed:</p> <ul style="list-style-type: none"> — High performance liquid chromatography coupled to tandem mass spectrometry (LC-MS/MS) 							

(1) Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1, ELI: <http://data.europa.eu/eli/reg/2012/231/oj>).