



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/6329952/2024 CIS
(POOL/G5/2024/6329952/6329952-EN
CIS.docx)
[...] (2024) **XXX** draft

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

of **XXX**

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

(Text with EEA relevance)

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

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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. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC².
- (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 2015³ and 27 June 2024⁴ 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 1000 mg/kg complete feed. The Authority concluded that it

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), <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, 22(7), e8909. <https://doi.org/10.2903/j.efsa.2024.8909>

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 sensitiser 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.
- (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 feedingstuffs’, 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 produced and labelled before [6 months from 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 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 [24 months from 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 stocks concerned are exhausted.

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,

For the Commission
The President
Ursula VON DER LEYEN