



Brussels, XXX
SANTÉ/
[...] (2026) XXX draft

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

of XXX

concerning the authorisation of carmine as a feed additive for cats and dogs

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

of **XXX**

concerning the authorisation of carmine as a feed additive for cats and dogs

(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. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC².
- (2) The substance carmine was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for cats and dogs 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 carmine as a feed additive for cats and dogs. 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 opinion of 27 September 2022³ that carmine is safe for dogs and cats at the levels of 264 and 220 mg carmine/kg complete feed respectively, which correspond to 132 and 110 mg carminic acid/kg complete feed, for dogs and cats, respectively. Due to the nature of the additive, allergic reactions, unpredictable and linked to the individual sensitivity, may occur in the target species following the ingestion of feeds containing the additive. The Authority also concluded that carmine is a dermal and a respiratory sensitiser but, due to the lack of data, could not conclude on potential skin and eye

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 2022; 20(10):7609. <https://doi.org/10.2903/j.efsa.2022.7609>.

irritation of the additive. The Authority further concluded that the additive is considered to be efficacious in feeds for dogs and cats. 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, including the addendum published on 26 March 2026⁴.

- (5) In view of the above, the Commission considers that 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, considering the allergenic nature of the additive, the Commission considers that its name and identification number should be listed on the label of feed materials and compound feed. It also 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 carmine 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.

⁴

[Minutes of the FEEDAP Panel Plenary meeting](#)

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