



EUROPEAN
COMMISSION

Brussels, **XXX**
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[...] (2025) **XXX** draft

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

of **XXX**

**concerning the authorisation of a preparation of lutein-rich extract of *Tagetes erecta* L.
as a feed additive for turkeys for fattening**

(Text with EEA relevance)

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

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**concerning the authorisation of a preparation of lutein-rich extract of *Tagetes erecta* L.
as a feed additive for turkeys for fattening**

(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 a preparation of lutein-rich extract of *Tagetes erecta* L. 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 a preparation of lutein-rich extract of *Tagetes erecta* L. as a feed additive for use in feed for turkeys for fattening, requesting that additive to be classified in the category ‘sensory additives’ and in the functional group ‘colourants (ii), substances which, when fed to animals, add colours to food of animal origin’.
- (4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 18 September 2024² that, under the proposed conditions of use, the additive is safe for the target species, for consumers and for the environment. Regarding user safety, it concluded that the lutein-rich extract of *Tagetes erecta* is irritant to skin and eyes and any exposure is considered a risk. The Authority further concluded that the substance has the potential to colour the skin of turkeys for fattening at 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 the assessment carried out regarding the methods of analysis of lutein-rich extract of *Tagetes erecta* as a feed additive in the context of the previous authorisation are valid and applicable for the current application. However, the Reference Laboratory subsequently updated the evaluation report submitted in the context of the previous authorisation, in order to take account of scientific and technological developments and to ensure a better suitability of the methods of analysis for official controls. The Authority verified the amended report on

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

² EFSA Journal, 22(10), e9027. <https://doi.org/10.2903/j.efsa.2024.9027>.

the methods of analysis of lutein as a feed additive submitted by the Reference Laboratory³.

- (6) In view of the above, the Commission considers that the preparation of lutein-rich extract of *Tagetes erecta* L. satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. As regards the methods of analysis, account should be taken of the updated evaluation report of the Reference Laboratory. Accordingly, the use of that substance as a feed additive should be authorised. 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 preparation specified in the Annex, belonging to the additive category ‘sensory additives’ and to the functional group ‘colourants (ii), substances which, when fed to animals, add colours to food of animal origin’, 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

³ Minutes of the meeting of 28-29 January 2025 of the Scientific Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), accessible at: https://www.efsa.europa.eu/sites/default/files/2025-02/feedap250128-29_m.pdf