



2025/1928

26.9.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/1928

of 25 September 2025

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 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 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 2024 ⁽²⁾ 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* L. 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* L. 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 the methods of analysis of lutein as a feed additive submitted by the Reference Laboratory ⁽³⁾.
- (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,

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

⁽²⁾ EFSA Journal 2024; 22(10):e9027, <https://doi.org/10.2903/j.efsa.2024.9027>.

⁽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.

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, 25 September 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 total carotenoids/kg complete feed with 12 % moisture content			
Category: sensory additives. Functional group: colourants: (ii) substances which, when fed to animals, add colours to food of animal origin								
2a161bii	Lutein-rich extract	<i>Additive composition</i> Preparation of lutein-rich extract of <i>Tagetes erecta</i> L. with total carotenoids ≥ 0,5 % Benzene ≤ 2 mg/kg Hexane ≤ 290 mg/kg Solid or liquid form <i>Characterisation of the active substance</i> Lutein from a saponified extract of <i>Tagetes erecta</i> L. (dried flowers petals) obtained via extraction with hexane and saponification: — Total carotenoids (TC): ≥ 60 g/kg — Lutein ≥ 75 % of total carotenoids (TC) — Zeaxanthin ≥ 4 % of total carotenoids (TC) Chemical formula: C₄₀H₅₆O₂ CAS number 127-40-2 (lutein) CAS number 144-68-3 (zeaxanthin) CoE number: 494	Turkeys for fattening			80	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. The mixture of lutein-rich extract with other authorised carotenoids shall not exceed a total carotenoids content of 80 mg/kg of complete 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 and breathing protective equipment.	16 October 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 total carotenoids/kg complete feed with 12 % moisture content			
		<i>Analytical method ⁽¹⁾</i> For the determination of lutein, zeaxanthin and total carotenoids in the feed additive: — High performance liquid chromatography (HPLC) with spectrophotometry – FAO JECFA monograph 'lutein from Tagetes erecta', Combined Compendium for Food Additive Specifications For the determination of total carotenoids (including lutein) in premixtures and compound feed: — Reversed-phase high performance liquid chromatography (HPLC) coupled to UV detection – EN 17550						

⁽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.