



EUROPEAN
COMMISSION

Brussels, XXX
SANTE/3115131/2025 CIS
(POOL/G5/2025/3115131/3115131-EN
CIS.docx)
[...] (2025) XXX draft

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

of XXX

amending and correcting Implementing Regulation (EU) 2020/1097 as regards the terms of the authorisation of lutein-rich and lutein/zeaxanthin extracts from *Tagetes erecta* as feed additives for poultry (except turkeys) for fattening and laying and for minor poultry species for fattening and laying and amending Implementing Regulation (EU) 2025/1928 as regards the terms of the authorisation of lutein-rich extract of *Tagetes erecta* L. for turkeys for fattening

(Text with EEA relevance)

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amending and correcting Implementing Regulation (EU) 2020/1097 as regards the terms of the authorisation of lutein-rich and lutein/zeaxanthin extracts from *Tagetes erecta* as feed additives for poultry (except turkeys) for fattening and laying and for minor poultry species for fattening and laying and amending Implementing Regulation (EU) 2025/1928 as regards the terms of the authorisation of lutein-rich extract of *Tagetes erecta* L. 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) and Article 13(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 and modifying such authorisation.
- (2) Lutein-rich and lutein/zeaxanthin extracts from *Tagetes erecta* were authorised for 10 years as feed additives for poultry (except turkeys) for fattening and laying and for minor poultry species for fattening and laying by Commission Implementing Regulation (EU) 2020/1097². In addition, a preparation of lutein-rich extract of *Tagetes erecta* L. was authorised for 10 years as a feed additive for turkeys for fattening by Commission Implementing Regulation (EU) 2025/1928³.
- (3) In the context of the submission of the application for the authorisation of a new use of the additive lutein-rich extract from *Tagetes erecta* in feed for turkeys for fattening in accordance with Article 7 of Regulation (EC) No 1831/2003, the European Food Safety Authority ('the Authority') considered in its opinion of 18 September 2024⁴ that the manufacturing process and the composition of the additive were not substantially changed in comparison with the lutein-rich extract as authorised by Implementing Regulation (EU) 2020/1097. The first part of the manufacturing process, which is similar to that used for the production of lutein/zeaxanthin extract, as

¹ OJ L 268, 18.10.2003, p. 29; ELI: <http://data.europa.eu/eli/reg/2003/1831/2021-03-27>.

² Commission Implementing Regulation (EU) 2020/1097 of 24 July 2020 concerning the authorisation of lutein-rich and lutein/zeaxanthin extracts from *Tagetes erecta* as feed additives for poultry (except turkeys) for fattening and laying and for minor poultry species for fattening and laying (Text with EEA relevance) (OJ L 241, 27.7.2020, p. 23; ELI: http://data.europa.eu/eli/reg_impl/2020/1097/oj).

³ 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 (OJ L, 2025/1928, 26.9.2025, ELI: http://data.europa.eu/eli/reg_impl/2025/1928/oj).

⁴ EFSA Journal, 22(10), e9027. <https://doi.org/10.2903/j.efsa.2024.9027>.

mentioned in the Authority's opinion of 3 April 2019⁵, is the extraction with hexane of the dried flower petals of *Tagetes erecta*. In its opinion of 18 September 2024 regarding the specifications of the additive lutein-rich extract, the Authority recommended that the presence of hexane in the additive should be below the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) Guideline limit of 290 mg/kg. The Authority, in its plenary meeting of the Panel on Additives and Products or Substances used in Animal Feed ('FEEDAP') of 24-26 June 2025⁶, stated that the same recommendation would also apply to the lutein/zeaxanthin extract currently authorised in the Union.

- (4) In order to ensure that the additives lutein-rich and lutein/zeaxanthin extracts from *Tagetes erecta* still meet the conditions provided for in Article 5 of Regulation (EC) No 1831/2003, the specification regarding the limit of 290 mg/kg of hexane in those additives should be reflected in the respective authorisations granted by Implementing Regulation (EU) 2020/1097, and hexane should be mentioned as solvent used in the extraction during the manufacturing process. Implementing Regulation (EU) 2020/1097 should therefore be amended accordingly.
- (5) Implementing Regulation (EU) 2020/1097 provides that the additives lutein-rich extract and lutein/zeaxanthin extract of *Tagetes erecta* must be placed on the market and used as additives consisting of a preparation, but the composition of such preparations has erroneously not been specified in the terms of the authorisation. A more accurate description of the additives authorised as preparations by Implementing Regulation (EU) 2020/1097 should be provided for, by specifying that the composition of the additives includes a total carotenoid content equal to or above 0,5%, as specified in the Authority's opinion of 3 April 2019. Implementing Regulation (EU) 2020/1097 should therefore be corrected accordingly.
- (6) Implementing Regulation (EU) 2020/1097 also provides that the mixture of the additives lutein-rich extract and lutein/zeaxanthin extract of *Tagetes erecta* with other authorised carotenoids and xanthophylls should not exceed the maximum content set for the corresponding animal categories. The Authority's opinion of 3 April 2019 recommended to remove the reference to xanthophylls in that context. Implementing Regulation (EU) 2020/1097 should therefore be corrected accordingly.
- (7) The authorisation of the additive lutein-rich extract of *Tagetes erecta* by Implementing Regulation (EU) 2020/1097 and by Implementing Regulation (EU) 2025/1928 provides for similar terms of authorisation of that additive and should therefore include the same identification number. Implementing Regulation (EU) 2025/1928 should therefore be amended accordingly.
- (8) On 15 January 2025, the Reference Laboratory set up by Regulation (EC) No 1831/2003 updated the report on the methods of analysis of lutein. The new method also applies to lutein-rich and lutein/zeaxanthin extracts from *Tagetes erecta* as authorised by Implementing Regulation 2020/1097. Implementing Regulation (EU) 2020/1097 should therefore be amended accordingly.
- (9) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of lutein-rich and lutein/zeaxanthin extracts from

⁵ EFSA Journal 2019;17(5):5698. <https://doi.org/10.2903/j.efsa.2019.5698>.

⁶ [Minutes of the 183rd Plenary meeting of 24-26 June 2025 of the Scientific Panel on Additives and Products or Substances used in animal feed.](#)

Tagetes erecta, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from those modifications.

- (10) 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

Correction and amendment to Implementing Regulation (EU) 2020/1097

The Annex to Implementing Regulation (EU) 2020/1097 is replaced by the Annex to this Regulation.

Article 2

Amendment to Implementing Regulation (EU) 2025/1928

In the first column of the Annex to Implementing Regulation (EU) 2025/1928, the identification number “2a161bii” is replaced by “2a161b”.

Article 3

Transitional measures

1. The feed additives lutein-rich extract of *Tagetes erecta* and lutein/zeaxanthin extract from *Tagetes erecta*, as authorised by Implementing Regulation (EU) 2020/1097, and the feed additive lutein-rich extract from *Tagetes erecta* L., as authorised by Implementing Regulation (EU) 2025/1928, and premixtures containing those additives, 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 additives referred to in paragraph 1, which are produced and labelled before [12 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 4

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