

## COMMISSION IMPLEMENTING REGULATION (EU) 2021/420

of 9 March 2021

**correcting Implementing Regulation (EU) 2020/1097 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)

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 <sup>(1)</sup>, 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 authorisation. Article 10(2) of Regulation (EC) No 1831/2003 provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC <sup>(2)</sup> and Article 4 for the authorisation of a new use of an additive.
- (2) Lutein-rich and lutein/zeaxanthin extracts from *Tagetes erecta* were authorised by Commission Implementing Regulation (EU) 2020/1097 <sup>(3)</sup> 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.
- (3) The European Food Safety Authority ('the Authority') concluded in its opinion of 3 April 2019 <sup>(4)</sup> that the maximum proposed use level of 80 mg total carotenoids/kg of complete feed for lutein-rich and lutein/zeaxanthin extracts is safe for poultry for fattening (except turkeys), minor poultry for fattening, poultry for laying (except turkeys) and minor poultry for laying. By mistake, the heading of the sixth and seventh columns of the Annex to Implementing Regulation (EU) 2020/1097 refers to '*mg of active substance of kg of complete feedingstuff with a moisture content of 12 %*'. That reference is not correct as the EFSA opinion refers to the 'total carotenoids'. It is therefore appropriate to correct the heading of the sixth and seventh columns of the table in the Annex to that Implementing Regulation to reflect the wording appearing in the EFSA opinion of 3 April 2019.
- (4) The references to 'poultry for fattening (except turkeys)' and 'poultry for laying, (except turkeys)' have been modified to 'chickens for fattening' and 'laying hens'. This change does not affect or modify the categories of animals currently authorised, as the term 'poultry' covers turkeys for laying and fattening, chickens for fattening and laying hens. Therefore, it is more appropriate to refer directly to chickens for fattening and laying hens.
- (5) The EFSA opinion also indicated that the maximum use level of the lutein/zeaxanthin extract is 80 mg total carotenoids/kg of complete feed in poultry for fattening (except turkeys), minor poultry for fattening, poultry for laying (except turkeys) and minor poultry for laying. In addition, the EFSA opinion stated that in breeding minor poultry the maximum level should not exceed 50 mg total carotenoids/kg complete feed, considering the toxicological potential of zeaxanthin on reproduction. The EFSA opinion further stated that, since the breeding husbandry in minor poultry species does not differentiate between laying and breeding, it cannot be excluded that the additive contained in a layer diet would be given to minor breeding poultry. By mistake, the table in the Annex

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).

<sup>(3)</sup> 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 (OJ L 241, 27.7.2020, p. 23).

<sup>(4)</sup> EFSA Journal 2019; 17(5):5698.

to Implementing Regulation (EU) 2020/1097 set the maximum level of carotenoids of lutein/zeaxanthin extract for poultry for fattening (except turkeys), minor poultry for fattening, poultry for laying (except turkeys) and minor poultry for laying at 50 mg total carotenoids/kg feed, while this level should apply only to minor poultry for laying, to prevent any misuse on breeding animals. The rest of the poultry categories should have a maximum level of use of 80 mg total carotenoids/kg of complete feed.

- (6) Implementing Regulation (EU) 2020/1097 should therefore be corrected.
- (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*

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

*Article 2*

This Regulation shall enter into force on the day 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, 9 March 2021.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

---

Identification number of the 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 of total carotenoids/kg of complete feedingstuff with a moisture content of 12 %			

**Category: Sensory additives. Functional group: Colourants.** (ii) substances which, when fed to animals, add colours to food of animal origin

2a161b	Lutein-rich extract	<p><i>Additive composition</i> Lutein-rich extract of <i>Tagetes erecta</i> Benzene ≤ 2mg/kg</p>	Chickens for fattening and minor poultry for fattening	-	-	80	<ol style="list-style-type: none"> <li>In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated.</li> <li>Lutein-rich extract must be placed on the market and used as an additive consisting of a preparation.</li> <li>The mixture of lutein-rich extract with other authorised carotenoids and xanthophylls shall not exceed a total carotenoids and xanthophylls content of 80 mg/kg of complete feed.</li> <li>For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including eye and skin protection</li> </ol>	30.3.2031
		<p><i>Characterisation of the active substance</i> Lutein from a saponified extract of <i>Tagetes erecta</i> (dried flowers petals) obtained via extraction and saponification: — Total carotenoids (TC): ≥ 60g/kg — Lutein ≥ 75 % of total carotenoids (TC) — Zeaxanthin ≥ 4 % of total carotenoids (TC) Chemical formula: C<sub>40</sub>H<sub>56</sub>O<sub>2</sub> CAS number 127-40-2 (lutein) CAS number 144-68-3 (zeaxanthin) CoE number: 494 Liquid form</p>						
		<p><i>Analytical method</i> <sup>(1)</sup> — For the determination of lutein (all-trans-lutein isomer only), zeaxanthin and total carotenoids and xanthophylls in the feed additive: high Performance Liquid Chromatography (HPLC) with spectrophotometry – Commission Regulation (EU) No 231/2012 referring to FAO JECFA monograph “lutein from <i>Tagetes erecta</i>” monograph No 3 (2006), Combined Compendium for Food Additive Specifications</p>						

		<ul style="list-style-type: none"> <li>— For the determination of lutein (all-trans-lutein isomer only) in premixtures and feedingstuffs: high Performance Liquid Chromatography with visible detection (HPLC-Vis)</li> <li>— For the determination of total carotenoids and xanthophylls in premixtures and feedingstuffs: liquid chromatography with visible detection (LC-Vis) – AOAC official method 970.64</li> </ul>						
2a161bi	Lutein/zeaxanthin extract	<p><i>Additive composition</i> Lutein/zeaxanthin extract of <i>Tagetes erecta</i>. Benzene ≤ 2mg/kg</p>	Chickens for fattening and minor poultry for fattening	-	-	80	<ol style="list-style-type: none"> <li>1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated.</li> <li>2. Lutein/zeaxanthin extract must be placed on the market and used as an additive consisting of a preparation.</li> <li>3. The mixture of lutein/zeaxanthin extract with other authorised carotenoids and xanthophylls shall not exceed a total carotenoids and xanthophylls content of:               <ol style="list-style-type: none"> <li>a. 80 mg/kg of complete feed for chickens for fattening, minor poultry for fattening and laying hens.</li> <li>b. 50 mg/kg of complete feed for minor poultry for laying.</li> </ol> </li> <li>4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including eye and skin protection.</li> </ol>	30.3.2031
		<p><i>Characterisation of the active substance</i> Lutein/zeaxanthin saponified/isomerised extract of <i>Tagetes erecta</i> (dried flowers petals) obtained via extraction, saponification and isomerisation: — Total carotenoids (TC): ≥ 60g/kg — Lutein ≥ 37 % of TC; — Zeaxanthin ≥ 36 % of TC. Liquid form CAS number 127-40-2(lutein) CAS number 144-68-3 (zeaxanthin) CoE number: 494 Chemical formula: C<sub>40</sub>H<sub>56</sub>O<sub>2</sub></p>	Laying hens		80			
			Minor poultry for laying.		50			
		<p><i>Analytical method</i> (1) For the determination of lutein (all-trans-lutein isomer only), zeaxanthin and total carotenoids and xanthophylls in the feed additive: — High Performance Liquid Chromatography (HPLC) with spectrophotometry – Commission Directive 2008/128/EC referring to FAO JECFA monograph “lutein from <i>Tagetes erecta</i>” monograph No 3 (2006), Combined Compendium for Food Additive Specifications</p>		-	-			

		<p>For the determination of lutein (all-trans-lutein isomer only) in premixtures and feedingstuffs:  — High Performance Liquid Chromatography with visible detection (HPLC-Vis)</p> <p>For the determination of total carotenoids and xanthophylls in premixtures and feedingstuffs:  — Liquid chromatography with visible detection (LC-Vis) – AOAC official method 970.64</p>						
--	--	---	--	--	--	--	--	--

(<sup>1</sup>) Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>