

ANNEX

**This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material**

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 %			
<b>Category: Sensory additives. Functional group: Colourants.</b> (ii) substances which, when fed to animals, add colours to food of animal origin								
2a161b	Lutein-rich extract	<b>Additive composition:</b> Lutein-rich extract of <i>Tagetes erecta</i> Benzene ≤ 2mg/kg ----- <b>Characterisation of the active substance:</b> 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 ----- <b>Analytical method<sup>1</sup></b> – For the determination of lutein (all-trans-lutein isomer only), zeaxanthin	Poultry for fattening (except turkeys) 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</li> </ol>	<i>[to be completed by the Service responsible for the publication: insert precise date]</i> [10 years from the date of entry into force of this Regulation]
		Poultry for laying (except turkeys) and minor poultry for laying	-	-	80			

<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>

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 %			
<b>Category: Sensory additives. Functional group: Colourants.</b> (ii) substances which, when fed to animals, add colours to food of animal origin								
		<p>and total carotenoids and xanthophylls in the feed additive: high Performance Liquid Chromatography (HPLC) with spectrophotometry – Commission Regulation (EU) 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>					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	

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 %			
<b>Category: Sensory additives. Functional group: Colourants.</b> (ii) substances which, when fed to animals, add colours to food of animal origin								
2a161bi	Lutein/ zeaxanthin extract	<p><b>Additive composition:</b> Lutein/zeaxanthin extract of <i>Tagetes erecta</i>. Benzene ≤ 2mg/kg</p> <p>-----</p> <p><b>Characterisation of the active substance:</b> Lutein/zeaxanthin saponified/isomerised extract from dried flowers petals of <i>Tagetes erecta</i> obtained via extraction, saponification and isomerisation:</p> <ul style="list-style-type: none"> <li>- Total carotenoids (TC): ≥ 60g/kg</li> <li>- Lutein ≥ 37% of TC;</li> <li>- Zeaxanthin ≥ 36% of TC.</li> </ul> <p>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> <p>-----</p> <p><b>Analytical method<sup>2</sup></b> For the determination of lutein (all-trans-lutein isomer only), zeaxanthin and total carotenoids and xanthophylls in the feed additive:</p> <p>- High Performance Liquid</p>	<p>Poultry for fattening (except turkeys) and minor poultry for fattening</p> <p>Poultry for laying (except turkeys)</p> <p>Minor poultry for laying.</p>	-	-	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 poultry for fattening , minor poultry for fattening and poultry for laying (except turkeys)</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</li> </ol>	<p>[to be completed by the Service responsible for the publication: insert precise date]</p> <p>[10 years from the date of entry into force of this Regulation]</p>

<sup>2</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>

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 %			
<b>Category: Sensory additives. Functional group: Colourants.</b> (ii) substances which, when fed to animals, add colours to food of animal origin								
		<p>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:</p> <ul style="list-style-type: none"> <li>- High Performance Liquid Chromatography with visible detection (HPLC-Vis)</li> </ul> <p>For the determination of total carotenoids and xanthophylls in premixtures and feedingstuffs:</p> <ul style="list-style-type: none"> <li>- Liquid chromatography with visible detection (LC-Vis) – AOAC official method 970.64</li> </ul>		-	-		<p>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.</p>	