

ANNEX

Identi- fication 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 authorisa- tion
					mg total carotenoids/kg complete feedingstuff 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 of <i>Tagetes erecta</i> L.	Additive composition Preparation of lutein-rich extract of <i>Tagetes erecta</i> with total carotenoids $\geq 0,5\%$ Hexane ≤ 290 mg/kg Benzene ≤ 2 mg/kg Solid or liquid form Characterisation of the active substance 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: C ₄₀ H ₅₆ O ₂ CAS number 127-40-2 (lutein) CAS number 144-68-3 (zeaxanthin) CoE number: 494	Turkeys for fattening			80	<ol style="list-style-type: none">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.	<i>[to be completed by the OP: insert precise date]</i> <i>10 years from the date of entry into force of this Regulation]</i>

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		<p>Analytical method¹</p> <p>For the determination of lutein, zeaxanthin and total carotenoids in the feed additive:</p> <ul style="list-style-type: none">- High performance liquid chromatography (HPLC) with spectrophotometry - FAO JECFA monograph “lutein from Tagetes erecta”, Combined Compendium for Food Additive Specifications <p>For the determination of total carotenoids (including lutein) in premixtures and compound feed:</p> <ul style="list-style-type: none">- 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