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)

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 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 ([2]) 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 without a time limit in accordance with Directive 70/524/EEC as feed additives for poultry belonging to the group 'colourants, including pigments', under the heading 'carotenoids and xanthophylls'. These two extracts were authorised under the common name 'lutein' and 'zeaxanthin' without any specification so the request for this two forms lutein-rich and lutein/zeaxanthin fell within the generic entries 'lutein' and 'zeaxanthin'. The additives were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003.

(3) In accordance with Articles 4 and 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the authorisation of lutein-rich and lutein/zeaxanthin extracts from *Tagetes erecta* in water for drinking and the re-evaluation of lutein-rich and lutein/zeaxanthin extracts from *Tagetes erecta* as feed additives for poultry (except turkeys) for fattening and for laying and minor poultry species for fattening and for laying. The applicant requested the additives to be classified in the additive category 'sensory additives' and in the functional group 'colourants: (ii) substances which, when fed to animals, add colours to food of animal origin'. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 3 April 2019 ([3]) that, under the proposed conditions of use, lutein-rich and lutein/zeaxanthin extracts from *Tagetes erecta* do not have an adverse effect on animal health, consumer safety or the environment. It stated that the conclusion on the safety and efficacy of lutein-rich and lutein/zeaxanthin extracts from *Tagetes erecta* for poultry (except turkeys) for fattening and for laying can be extrapolated to minor poultry for fattening and for laying. It also concluded that the active substances are viscous substances, so operators will not be exposed by inhalation. The applicant recognises that the active substances may be irritant to skin and eyes. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human heath, in particular, as regards the users of the additive, including the use of the additives in the form of a preparation, where toxicity by inhalation or due to the potential skin/eye irritant nature of the substance cannot be excluded. The Authority further concluded that the additives concerned are effective in adding colour to food of animal origin. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the European Union Reference Laboratory set up by Regulation (EC) No 1831/2003.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).
([3]) EFSA Journal 2019; 17(5):5698.

(5) As regards the use in water for drinking, the Commission considers that the simultaneous use of the additives in water for drinking and feed is difficult to manage, as there are maximum levels established for safety reasons and there are also other additives containing xanthophylls and carotenoids that may be used in feed. The simultaneous use of lutein-rich and lutein/zeaxanthin extracts from *Tagetes erecta* in water for drinking and feed increases the ways of administration and the risk to exceed the maximum levels authorised for additives containing carotenoids and xanthophylls (for lutein-rich 80 mg/kg alone or with other carotenoids or xanthophylls and for lutein/zeaxanthin 50 mg/kg alone or with other carotenoids or xanthophylls). Consequently, the use in water for drinking is denied.

(6) The assessment shows that the conditions for authorisation for lutein-rich and lutein/zeaxanthin extracts from *Tagetes erecta*, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those additives should be authorised as specified in the Annex to this Regulation.

(7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the substances concerned, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(8) 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 substances 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', are authorised as feed additives in animal nutrition subject to the conditions laid down in that Annex.

Article 2

The authorised substances specified in the Annex shall not be used in water for drinking

Article 3

1. The substances specified in the Annex and premixtures containing those substances, which are produced and labelled before 16 February 2021 in accordance with the rules applicable before 16 August 2020 may continue to be placed on the market and used until the existing stocks are exhausted.

2. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 16 August 2021 in accordance with the rules applicable before 16 August 2020 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

Article 4

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, 24 July 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

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 active substance of 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	*Additive composition:* Lutein-rich extract of *Tagetes erecta* Benzene ≤ 2mg/kg	Poultry for fattening (except turkeys) and minor poultry for fattening	-	-	80	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. Lutein-rich extract must be placed on the market and used as an additive consisting of a preparation. 3. 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. 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	16.8.2030
		Characterisation of the active substance: Lutein from a saponified extract of *Tagetes erecta* (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: $C_{40}H_{56}O_2$ CAS number 127-40-2 (lutein) CAS number 144-68-3 (zeaxanthin) CoE number: 494 Liquid form	Poultry for laying (except turkeys) and minor poultry for laying	-	-	80		
		Analytical method (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 Regulation (EU) No 231/2012 referring to FAO JECFA monograph ‘						

		lutein from *Tagetes erecta*' monograph No 3 (2006), Combined Compendium for Food Additive Specifications — For the determination of lutein (all-trans-lutein isomer only) in premixtures and feedingstuffs: high Performance Liquid Chromatography with visible detection (HPLC-Vis) — For the determination of total carotenoids and xanthophylls in premixtures and feedingstuffs: liquid chromatography with visible detection (LC-Vis) – AOAC official method 970.64						
2a161bi	Lutein/zeaxanthin extract	*Additive composition:* Lutein/zeaxanthin extract of *Tagetes erecta*. Benzene ≤ 2mg/kg *Characterisation of the active substance:* Lutein/zeaxanthin saponified/isomerised extract from dried flowers petals of *Tagetes erecta* 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: $C_{40}H_{56}O_2$	Poultry for fattening (except turkeys) and minor poultry for fattening	-	-	50	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. Lutein/zeaxanthin extract must be placed on the market and used as an additive consisting of a preparation. 3. The mixture of lutein/zeaxanthin extract with other authorised carotenoids and xanthophylls shall not exceed a total carotenoids and xanthophylls content of 50 mg/kg of complete feed 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential	16.8.2030
			Poultry for laying (except turkeys) and minor poultry for laying.	-	-	50		

		Analytical method (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 *Tagetes erecta*' monograph No 3 (2006), Combined Compendium for Food Additive Specifications For the determination of lutein (all-trans-lutein isomer only) in premixtures and feedingstuffs: — High Performance Liquid Chromatography with visible detection (HPLC-Vis) For the determination of total carotenoids and xanthophylls in premixtures and feedingstuffs: — Liquid chromatography with visible detection (LC-Vis) – AOAC official method 970.64					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.	

(1) 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