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SCIENTIFIC OPINION

Safety and efficacy of a feed additive consisting of lutein-rich extract of *Tagetes erecta* L. for turkeys for fattening (EW Nutrition)

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Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the safety and efficacy of lutein-rich extract of *Tagetes erecta* L. as sensory additive (functional group: Colourants (ii) substances which, when fed to animals, add colours to food of animal origin) for turkeys for fattening. The additive is already authorised for use in feed for chickens for fattening and minor poultry for fattening and laying hens and minor poultry for laying. The FEEDAP Panel concluded that the use of lutein-rich extract of *T. erecta* is safe for turkeys for fattening when used up to the maximum proposed use level of 80 mg total carotenoids/kg complete feed. The Panel concluded that the use of lutein-rich extract of *T. erecta* in feed for turkeys for fattening under the proposed conditions of use would not be of concern for the consumer, considering also its use in other poultry for fattening and for laying hens. Regarding user safety, the lutein-rich extract of *T. erecta* extract is irritant to skin and eyes and any exposure is considered a risk. The conclusions on user safety reached for the lutein-rich extract of *T. erecta* would, in principle, apply to preparations made with it. The use of the additive in feed for turkeys for fattening under the proposed conditions of use is safe for the environment. The FEEDAP Panel concluded that the additive has the potential to colour the skin of turkeys for fattening at the proposed conditions of use.

KEYWORDS

colouring agents, efficacy, extracts of *Tagetes erecta*, lutein, safety, sensory additives, turkeys for fattening, zeaxanthin

CONTENTS

1 | INTRODUCTION

1.1 | Background and Terms of Reference

Regulation (EC) No 1831/2003[1] establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 4(1) of that Regulation lays down that any person seeking authorisation for a feed additive or for a new use of feed additive shall submit an application in accordance with Article 7.

The European Commission received a request from EW Nutrition GmbH[2] for the authorisation of the additive consisting of lutein-rich extract of *Tagetes erecta*, when used as a feed additive for turkeys for fattening (category: sensory additives; functional group: colourants).

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 4(1) (authorisation of a feed additive or new use of a feed additive). The dossier was received on 11 July 2023 and the general information and supporting documentation are available at https://open.efsa.europa.eu/questions/EFSA-Q-2023-00483. The particulars and documents in support of the application were considered valid by EFSA as of 9 October 2023.

According to Article 8 of Regulation (EC) No 1831/2003, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animals, consumer, user and the environment and on the efficacy of the feed additive consisting of lutein-rich extract of *Tagetes erecta*, when used under the proposed conditions of use (see Section 3.1.3).

1.2 | Additional information

The additive lutein-rich extract of *T. erecta* is currently authorised in the EU for chickens for fattening and minor poultry for fattening and laying hens and minor poultry for laying (2a161b).[3] EFSA issued an opinion on the safety and efficacy of this product (EFSA FEEDAP Panel, 2019a).

2 | DATA AND METHODOLOGIES

2.1 | Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier[4] in support of the authorisation request for the use of lutein as a feed additive.

The confidential version of the technical dossier was subject to a target consultation of the interested Member States from 9 October 2023 to 9 January 2024; the comments received were considered for the assessment.

In accordance with Article 38 of the Regulation (EC) No 178/2002[5] and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation, and of the Decision of EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,[6] a non-confidential version of the dossier has been published on Open.EFSA.

According to Article 32c(2) of Regulation (EC) No 178/2002 and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations, EFSA carried out a public consultation on the non-confidential version of the technical dossier from 14 May to 4 June 2024 for which no comments were received.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA or other expert bodies, peer-reviewed scientific papers and other scientific reports to deliver the present output.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment regarding the methods used for the control of lutein in animal feed are valid and applicable for the current application.[7]

[1]Regulation (EC) No 1831/2003 of the European Parliament and of the council of 22 September 2003 on the additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.

[2]Hogenbögen 1, 49429 Visbek, Germany.

[3]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. OJ L 83, 3.10.2021, p. 17.

[4]Dossier reference FEED-2023-014631.

[5]Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–48.

[6]Decision available at: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements.

[7]Evaluation report available on the EU Science Hub: Final report FAD-2010-0372 Lutein (europa.eu).

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of lutein is in line with the principles laid down in Regulation (EC) No 429/2008[8] and the relevant guidance documents: Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017a), Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017b), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017c), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2024) and Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019b) and Guidance on the assessment of the safety of feed additives for the users (EFSA FEEDAP Panel, 2023).

3 | ASSESSMENT

The additive lutein-rich extract of *T. erecta* L. is currently authorised as a sensory additive (functional group: Colourants (ii) substances which, when fed to animals, add colours to food of animal origin) in feed for chickens for fattening and minor poultry for fattening and laying hens and minor poultry for laying. The applicant is requesting the authorisation of a new use of the additive in feed for turkeys for fattening. The additive will be referred to in this opinion as lutein-rich extract.

3.1 | Characterisation

The additive lutein-rich extract is the saponified extract of the dried flower petals of *T. erecta* L. According to the current authorisation, the lutein-rich extract must be placed on the market and used as an additive in the form of a preparation.

The additive was fully characterised in a previous opinion of the FEEDAP Panel (EFSA FEEDAP Panel, 2019a). The additive lutein-rich extract appears as a viscous paste which is further formulated to obtain the preparations (either solid or liquid) to be placed on the market. The previous opinion included the characterisation of the carotenoid profile, the proximate composition,[9] fatty acid distribution and lipid fraction. The applicant stated that the manufacturing process and the composition of the additive has not been substantially changed, with the exception of the change in the antioxidant used (butylated hydroxytoluene (BHT) instead of ethoxyquin).[10] Consequently, the data on physico-chemical properties of the additive already assessed in the last opinion are considered to apply to the current application. The new data provided in the current application with regards the characterisation of the additive is described below.

3.1.1 | Characterisation of the lutein-rich extract

Lutein-rich extract is specified to contain ≥ 60 g total carotenoids (TCs)/kg. For the fraction of total carotenoids, lutein is specified not less than 75% and zeaxanthin not less than 4%. These specifications are in line with the current authorisation.[11] The applicant specified a maximum content of BHT of [redacted].[12]

Analytical data to confirm the specifications for the carotenoids were provided for five batches of the extract. The results showed an average of 101.1 g/kg TCs (90.39–111.69); the fraction of TCs contained 90.2% lutein (80.7–93.1) and 8.2% zeaxanthin (6.5–11.8).[13] BHT, measured in one batch, was [redacted].[14] These values are in compliance with the specifications.

Three batches of the lutein-rich extract were analysed for impurities. Cadmium, lead, mercury and arsenic concentrations were below their limit of quantification (LOQ).[15] The analysis of aflatoxins B1, B2, G1, G2 and ochratoxin A showed values below their LOQs.[16]

Polychlorinated dibenzodioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and co-planar dioxin-like polychlorinated biphenyls (Co-planar PCBs) were analysed in three batches of the lutein-rich *extract*. The calculated (upper bound) levels of dioxins and the sum of dioxins and dioxin-like-PCBs ranged from 0.20 to 0.23 ng WHO-PCDD/F-TEQ/kg and from 0.34 to 0.37 ng WHO-PCDD/F-PCB-TEQ/kg respectively. The calculated (upper bound) levels for non dioxin-like PCBs (ICES-6) ranged from 1.65 to 1.73 µg/kg.[17]

[8]Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1.

[9]Main components: crude fat 45.5%, crude ash 18.2%, crude fibre 1.26%, crude protein 0.98%.

[10]The oleoresin of *T. erecta* is prepared by evaporation of the hexane extract of the dried flower petals. The oleoresin is subject to saponification (using potassium or sodium hydroxide), yielding the lutein extract (saponified) from *T. erecta*. BHT is added to protect carotenoids against oxidation.

[11]Identification_and_characterisation_Lutein.

[12]Annex_II_10_antioxidant.

[13]Annex_II_02_COAs_Additive.

[14]Annex_II_10_antioxidant.

[15]Annex_II_04_Impurities LOQs in mg/kg were: 0.50 for arsenic and lead, 0.20 for cadmium and 0.02 for mercury.

[16]Annex_II_04_Impurities Annex_II_05_Impurities LOQs in µg/kg were: 1.0 for ochratoxin A and aflatoxins.

[17]Annex_II_04_Impurities. Upper bound concentrations are calculated on the assumption that all values of the different congeners below the limit of quantification are equal to the limit of quantification. TEQ = toxic equivalency factors for PCDD/Fs and DL-PCBs established by WHO in 2005 (van den Berg et al., 2006)

Pesticides were analysed in three batches of the lutein-rich extract and found below the corresponding LOQ.[18]

During the manufacturing process, hexane is used in the extraction. Residual solvent analysis was performed in three batches of the lutein-rich extract. In one batch the quantity of hexane was found to be higher than the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) Guideline limit (290 mg/kg)[19] with value of 1778 mg/kg. Methanol (six batches) was below 100 mg/kg which is below the VICH Guideline limit (3000 mg/kg).[20]

The FEEDAP Panel notes that the current authorisation contains a specification on the maximum content of benzene (≤2 mg/kg). The applicant confirmed that benzene is not used in any step of the manufacturing process and the only possible source could be the hexane used in the extraction phase, since benzene is a known impurity of food grade hexane. The applicant also provided the description of the measures in place to monitor the concentration of benzene and provided analytical results for benzene in the oleoresin (*T. erecta* extract before saponification) and in the lutein-rich extract. In the latter, the benzene content was an average of 0.028 mg/kg from five batches (0.011–0.077).[21]

The FEEDAP Panel considers that the amounts of the detected impurities do not raise safety concerns. Feed additive preparations based on lutein-rich extract of *T. erecta*.

3.1.2 | Feed additive preparations based on lutein-rich extract

Lutein-rich extract is placed on the market in the form of diluted and stabilised preparations. The preparations may be solid or liquid and may contain carriers, antioxidants, anticaking agents and emulsifying agents.

The applicant reported that the commercial preparations typically contain 0.5%–7.0% TCs, 0.3%–6.7% lutein and 0.02%–2.1% zeaxanthin.[22] The specification for BHT is [redacted].[23]

The applicant analysed a feed additive preparation which composition was declared as: total xanthophylls 20 g/kg; lutein 17 g/kg, zeaxanthin 1.0 g/kg; BHT [redacted]; silicic acid, precipitated and dried (E 551a) [redacted]; calcium carbonate up to 100%.

Batch to batch variation data provided for five batches of this preparation showed a content of TCs of 21.8 g/kg (range: 21.4–22.0), lutein 20.2 g/kg (19.6–20.8), zeaxanthin 1.9 g/kg (1.8–2.1).[24] Hexane showed values below the LOQ in two batches and 0.25 mg/kg in one batch, methanol and benzene were found below the LOQ in all three batches.[25] BHT concentration was [redacted].[26]

The same preparation appears as an ochre yellow free-flowing powder, with a dusting potential of 1.68 g/m^3 determined using the Stauber–Heubach method.[27]

One batch of another preparation containing 6% TCs[28] was analysed for the particle size distribution by descriptive and quantitative scanning electron microscopy (SEM) combined with energy-dispersive X-ray spectroscopy (EDX). The methodology used does not allow to differentiate unequivocally the particles of each substance composing the feed additive preparation tested.

The FEEDAP Panel notes that the carotenoids present in the additive are naturally present in food or feedingstuffs therefore, no further characterisation of the fraction of small/nano particles is needed.[29]

The shelf-life of three solid lutein preparations (with BHT) containing 2%, 4% or 6% TCs (three batches each) was studied when stored at 25°C at 60% relative humidity (RH) in multilayer bags. The content of TCs, lutein and zeaxanthin were monitored over a period of 36 months of storage. No significant losses at the end of storage period were detected.[30]

3.1.3 | Conditions of use

The applicant proposes to use the lutein-rich extract of *T.* erecta in the feed for turkeys for fattening to provide a maximum level of 80 mg total carotenoids/kg of complete feed, in line with the current authorisation for other poultry for fattening.

The applicant proposes to keep the same 'other provisions' as in the current authorisation:

[18]Annex_II_04_Impurities.

[19]https://www.ema.europa.eu/en/vich-gl18-residual-solvents-new-veterinary-medicinal-products-active-substances-excipients

[20]Reply_RFI_25Mar24_Annex_03.

[21]Annex_II_02_COAs_Additive.

[22]Identification_and_characterisation_Lutein.

[23]Annex_II_10_antioxidant.

[24]Annex_III_03_COAs_Preparation.

[25]Annex_II_06_Residual solvents Preparation LOQs in mg/kg were: 0.1 for hexane and benzene and 20 for methanol.

[26]Annex_II_10_antioxidant.

[27]Annex_02_Dusting_Potential.

[28]Annex_II_16_Label_Preparation Preparation composition: Colourant: Lutein-rich extract (2a161b) [Total xanthophylls 60 g/kg; Lutein 5.1%, Zeaxanthin 0.3%]; Antioxidants: BHT (E 321) [redacted]; Anticaking agents: Silicic acid, precipitated and dried (E 551a) [redacted]; Carrier: Calcium carbonate.

[29]https://www.efsa.europa.eu/sites/default/files/2024-07/-minutes_2.pdf.

[30]Annex_II_12_Stability.

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.

3.2 | Safety

3.2.1 | Extensive literature search

The applicant provided an extensive literature search[31] (ELS) to support the safety of the additive. The ELS covered the period January 2010 until January 2023; the search terms and search strategy were provided. The main search terms regarded the additive, the active substances (lutein, zeaxanthin) and included terms concerning the safety and the toxicity for the target species, consumers, users and the environment. A total of 37 publications were considered relevant by the applicant. Only one paper providing information on deposition of lutein in turkey (Shanmugasundaram & Selvaraj, 2011) was considered relevant by the Panel for the current assessment (see Section 3.2.3).

3.2.2 | Safety for the target species

In its former opinion, based on the results of tolerance studies with chickens for fattening performed with lutein-rich extract, the FEEDAP Panel concluded that the proposed level of 80 mg TC/kg complete feed is safe for chickens for fattening with a margin of safety of at least 2.5 (EFSA FEEDAP Panel, 2019a). The conclusion was extrapolated to minor poultry species for fattening (e.g. ducks, partridges and quail).

No new data have been provided in this application. The FEEDAP Panel considers that the conclusions reached on chickens for fattening can be extrapolated to turkeys for fattening. Therefore, the Panel concludes that the use of lutein-rich extract of *T. erecta* is safe for turkeys for fattening when used up to the maximum proposed use level of 80 mg TC/kg.

3.2.3 | Absorption, distribution, metabolism, excretion and deposition

ADME of lutein and zeaxanthin

In its previous opinion, the FEEDAP Panel reviewed the absorption, distribution, metabolism and excretion (ADME) properties of lutein and zeaxanthin in poultry (EFSA FEEDAP Panel, 2019a). No new ADME studies have been submitted in the present application. No new information was identified on the ADME of lutein and zeaxanthin in poultry from the ELS (Section 3.2.1), compared to the former assessment of the Panel, which is reported below:

In the chicken, the absorption and distribution of lutein have been established following administration of free lutein or its diacylester(s) from *Tagetes* petals. Lutein esters are hydrolysed in the intestinal tract and free lutein is absorbed in the duodenum and jejunum. A linear increase of total lutein (free plus esters) with dietary lutein is observed in blood serum, liver and toe web. Lutein occurs in blood mainly in its free form (96%) and to a minor extent (4%) as monoester(s). In the liver, the distribution is similar (80% and 20%, respectively, plus traces of diester). Biotransformation occurs mainly in the liver where two major metabolites that correspond to the oxidation (dehydrogenation) of one hydroxyl group (3 or 30-oxolutein) followed by a second reaction on a second hydroxyl group (lutein-3,30-dione) have been identified. No cleavage of the lutein molecules occurred, which is consistent with the fact that lutein does not exhibit vitamin A activity. In the laying hen, lutein/lutein metabolites deposition in the egg following free lutein administration showed that the ratio 3 or 30-oxolutein vs. lutein reached a plateau at 14 days that amounted to 0.12. Limited information is available concerning the absorption, distribution and fate of zeaxanthin in poultry. Zeaxanthin is predominantly absorbed in the ileum, but the absorption rate has not been established. The metabolic fate in the laying hen indicated: (i) its biotransformation in the liver, where esterified zeaxanthin was found, (ii) a deposition rate in the egg yolk of 25% of the administered dose (multi-dose for 4 weeks, 16 mg/kg in the diet), (iii) that free zeaxanthin represented 90% of the whole residues in the egg, a metabolite identified as 3 and 3′-oxozeaxanthin amounting to 5%–10% and a minor oxidised metabolite identified as (6S,6'S)-ε,ε-caroten-3,3′-dione, 3% (iv) that the isomeric composition of zeaxanthin deposited in the egg yolk reflected that of the compound administered.

[31]Four cumulative databases: LIVIVO8, NCBI, Ovid9 and Toxinfo; 13 single databases and 12 publisher databases.

Although no specific information was made available on ADME in turkeys, the FEEDAP Panel assumes a similar metabolic behaviour of lutein and zeaxanthin in the different poultry species.

Deposition of lutein and zeaxanthin

No new studies performed with the extract under assessment were provided.

In the previous opinion (EFSA FEEDAP Panel, 2019) deposition data of lutein and zeaxanthin in poultry skin/fat was obtained from a published study in chickens for fattening (Perez-Vendrell et al., 2001). From this study, the following tissue concentrations were derived: 3.3 and 2.4 mg lutein/kg skin and 2.4 mg lutein/kg abdominal fat; the respective values for zeaxanthin were 0.85 and 0.45 mg/kg tissue. Similarly, zeaxanthin concentration in liver of 0.88 mg/kg was derived from a published study in quails (Toyoda et al., 2002). No data on the deposition of lutein and zeaxanthin in meat, liver and kidney was available.

In the current dossier, lutein deposition data in turkey liver was made available from a published paper which was designed to study the effect of lutein supplementation on turkey production, cytokine production and oxidative status (Shanmugasundaram & Selvaraj, 2011). Forty-eight 1-day-old turkeys were fed a control diet (lutein lower than 40 ng/kg) or a diet supplemented with lutein at 25 or 50 mg/kg feed. On day 50, half of the animals were killed, and blood and liver samples were collected for lutein analysis. In both tissue samples the lutein contents were significantly higher and diet concentration dependent as compared with the control group. The value at the maximum inclusion rate (50 mg lutein/kg diet) corresponds to approximately 273 mg lutein/kg liver. The FEEDAP Panel noted the following limitations of the study: the low number of animals used (group size four animals), the body weight of the animals was not given, the lower levels of lutein supplementation with respect to the current proposed conditions of use, and the lutein residue in liver was shown only in graphs. However, the Panel considers the data on liver deposition from this study as relevant for the exposure assessment.

Information was also submitted on the deposition of lutein in chicken meat in a publication (Englmaierova et al., 2021). However, the lutein supplementation level was two orders of magnitude lower than the intended supplementation with the additive under assessment, and therefore, the study was not further considered.

3.2.4 | Toxicology

When administering *Tagetes* extracts to turkeys, the consumer is exposed essentially to lutein and zeaxanthin deposited in tissues. In its previous opinion (EFSA FEEDAP Panel, 2019), the FEEDAP Panel assessed the toxicology profile of the additive and established the relevant health-based guidance values to be used in the assessment of consumer safety. The FEEDAP Panel concluded that the saponified *Tagetes* extract is not genotoxic and that lutein and zeaxanthin are of low acute toxicity; acceptable daily intake (ADI) values of 1 mg lutein/kg bw and 0.75 mg zeaxanthin/kg bw were retained for the assessment of consumer safety.

No new relevant information was identified by the literature search, and therefore, the conclusions reached in the former opinion are retained for the current assessment.

3.2.5 | Assessment of consumer exposure and consumer safety

An exposure assessment was performed by the FEEDAP Panel in its previous opinion considering the chronic exposure of consumers to lutein and zeaxanthin residues in a limited set of poultry tissues and products (EFSA FEEDAP Panel, 2019). The FEEDAP Panel concluded that consumer exposure to lutein and zeaxanthin related to the consumption of animal products from treated animals is very low compared to the exposure from other sources, and of no concern for the consumer.

In the current evaluation, the former exposure assessment is updated based on the new data made available on the deposition of lutein in turkey liver. The FEEDAP Panel further notes that no deposition data in meat and kidney is available in any poultry species. Based on the ADME properties of lutein and zeaxanthin, it is expected that the highest deposition will occur in skin/fat and in the liver. Therefore, as a conservative approach, the FEEDAP Panel applied the deposition data in skin/fat to meat and kidney. As the additive is already authorised for use in other poultry for fattening and laying hens, consumer exposure should consider all sources including eggs. The input values to be used in the consumer exposure calculation are detailed in Table 1.

TABLE 1 Input values used to calculate consumer exposure to lutein and zeaxanthin residues in poultry tissues and products (mg/kg tissue or product).

	Lutein	Zeaxanthin
Birds fat tissue	9[1]	3.8[1]
Birds liver	273[2]	1[3]
Birds meat	9[1]	3.8[1]

(Continues)

TABLE 1 (Continued)

	Lutein	Zeaxanthin
Birds offal and slaughtering products (other than liver)	9[1]	3.8[1]
Whole eggs	9.5[4]	2.7[4]

[1]EFSA FEEDAP Panel (2019), Perez-Vendrell et al. (2001).
[2]Shanmugasundaram and Selvaraj (2011).
[3]EFSA FEEDAP Panel (2019), Toyoda et al. (2002).
[4]EFSA FEEDAP Panel (2019), Steinberg et al. (2000).

The results of the calculation for the different population classes are presented in Table 2 (for detailed results, see Appendix A).

TABLE 2 Chronic dietary exposure to lutein and zeaxanthin residues in poultry tissues and products and comparison to the acceptable daily intake (ADI).

	Lutein		Zeaxanthin	
Population class	**Highest exposure estimate[1] (mg/kg bw per day)**	**% ADI[2]**	**Highest exposure estimate[1] (mg/kg bw per day)**	**% ADI[3]**
Infants	0.0832	8	0.0292	4
Toddlers	0.1157	11	0.0338	5
Other children	0.1192	12	0.0285	4
Adolescents	0.0461	5	0.0180	2
Adults	0.0969	9	0.0108	1
Elderly	0.0358	4	0.0105	1
Very elderly	0.0368	4	0.0092	1

Abbreviation: ADI, acceptable daily intake.
[1]Expressed as maximum highest reliable percentile.
[2]ADI = 1 mg/kg bw.
[3]ADI = 0.75 mg/kg bw.

The results of the calculation showed that exposure to lutein and zeaxanthin resulting from the use of the additive in poultry for fattening and laying hens are well below the respective ADI values.

The FEEDAP Panel is aware that the dataset available to calculate consumer safety is very limited and several assumptions have been made. However, considering the magnitude of the exposure in comparison to the ADI and the fact that exposure to lutein and zeaxanthin from the consumption of animal products is very low compared to the exposure from other sources (EFSA FEEDAP Panel, 2019), the FEEDAP Panel concludes that no concern for the consumer would arise from the use of the additive in poultry for fattening and laying hens under the proposed and the approved conditions of use (maximum 80 mg total carotenoids/kg complete feed).

Conclusions on safety for the consumer

The FEEDAP Panel concludes that the use of lutein-rich extract of *T. erecta* in feed for turkeys under the proposed conditions of use (maximum 80 mg total carotenoids/kg complete feed) would not be of concern for the consumer, considering also its use in other poultry for fattening and laying hens.

3.2.6 | Safety for the user

In its previous opinion (EFSA FEEDAP Panel, 2019), the Panel concluded that the lutein-rich extract of *T. erecta* is a viscous paste and as such users would not be exposed by inhalation. It was recognised as irritant to skin and eyes. Due to lack of data, the Panel could not conclude on the potential of any preparation to be toxic by inhalation, skin/eye irritant or skin sensitiser.

No new data have been provided in the present application, and the literature search performed by the applicant (see Section 3.2.1) did not provide any relevant information. The Panel considers that the new use of the additive in turkeys for fattening would not introduce hazards not already considered in previous assessments. Therefore, the Panel concludes that the lutein-rich extract is irritant to skin and eyes and any exposure is considered a risk. The conclusions reached for the lutein-rich extract would, in principle, apply to preparations made with it.

3.2.7 | Safety for the environment

In its previous opinion (EFSA FEEDAP Panel, 2019), the FEEDAP Panel concluded that 'The use of *Tagetes* extracts in poultry feed as a source of lutein and zeaxanthin would not alter the concentration or distribution of these carotenoids in the environment given their natural occurrence and oxidative susceptibility. Therefore, the FEEDAP Panel considers that use of extracts from *T. erecta* in poultry feed will not adversely affect the environment'.

The proposed extension of use in turkeys for fattening would not introduce additional hazards not already considered in the previous assessment. Therefore, the Panel concludes that the use of the additive in feed for turkeys for fattening under the proposed conditions of use is safe for the environment.

3.3 | Efficacy

In its previous opinion (EFSA FEEDAP Panel, 2019), the FEEDAP Panel concluded that the *Tagetes* extracts have the potential to colour the skin of chickens for fattening at levels below and up to the proposed use level of 80 mg TC/kg complete feed. The Panel considers that this conclusion can be extended to turkeys for fattening at the same use level. Therefore, the FEEDAP Panel concludes that the additive lutein-rich extract of *T. erecta* has the potential to colour the skin of turkeys for fattening at the proposed conditions of use.

4 | CONCLUSIONS

The Panel concludes that the use of lutein-rich extract of *T. erecta* L. is safe for turkeys for fattening when used up to the maximum proposed use level of 80 mg TC/kg complete feed.

The use of lutein-rich extract of *T. erecta* in feed for turkeys for fattening under the proposed conditions of use would not be of concern for the consumer, considering also its use in other poultry for fattening and for laying hens.

Regarding user safety, the lutein-rich extract of *T. erecta* is irritant to skin and eyes and any exposure is considered a risk. The conclusions reached for the lutein-rich extract of *T. erecta* would, in principle, apply to preparations made with it.

The use of the additive in feed for turkeys for fattening under the proposed conditions of use is safe for the environment.

The additive has the potential to colour the skin of turkeys for fattening at the proposed conditions of use.

5 | RECOMMENDATIONS

The FEEDAP Panel recommends regarding the specifications of the lutein-rich extract that hexane should be below the VICH Guideline limit 290 mg/kg.

Considering the data provided by the applicant, the FEEDAP Panel recommends to lower the specifications of lutein-rich extract of *T. erecta* for benzene from 2 to ≤ 0.1 mg/kg.

The FEEDAP Panel recommends that the provision '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' should be corrected as follows: 'The mixture of lutein-rich extract with other authorised carotenoids shall not exceed a total carotenoids content of 80 mg/kg of complete feed'.

ABBREVIATIONS

ADI	acceptable daily intake
ADME	absorption, distribution, metabolism and excretion
ANS	EFSA Scientific Panel on Additives and Nutrient Sources added to Food
BW	body weight
EDX	energy-dispersive X-ray spectroscopy
ELS	extensive literature search
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
LOQ	limit of quantification
PCBs	polychlorinated biphenyls
PCDDs	polychlorinated dibenzo-para-dioxins
PCDFs	polychlorinated dibenzofurans
SEM	scanning electron microscopy

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CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

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European Commission

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APPENDIX A

Detailed results on chronic exposure calculation

TABLE A.1 Chronic dietary exposure per population class, country and survey of consumers (mg/kg bw per day) to lutein residues in poultry tissues and products.

Population class	Survey's country	Number of subjects	HRP[a]	HRP description
Infants	Bulgaria	523	0.0832188836	95th
Infants	Germany	142	0.0188516253	95th
Infants	Denmark	799	0.0171181453	95th
Infants	Finland	427	0.0207031845	95th
Infants	Italy	9	0.0000000000	50th
Infants	United Kingdom	1251	0.0397991791	95th
Toddlers	Belgium	36	0.0422440792	90th
Toddlers	Bulgaria	428	0.1157079098	95th
Toddlers	Germany	348	0.0351388683	95th
Toddlers	Denmark	917	0.0253994840	95th
Toddlers	Spain	17	0.0554098368	75th
Toddlers	Finland	500	0.0359207116	95th
Toddlers	Italy	36	0.0335674242	90th
Toddlers	Netherlands	322	0.0421930496	95th
Toddlers	United Kingdom	1314	0.0482884169	95th
Toddlers	United Kingdom	185	0.0409507411	95th
Other children	Austria	128	0.0348330569	95th
Other children	Belgium	625	0.0441529328	95th
Other children	Bulgaria	433	0.1192199748	95th
Other children	Germany	293	0.0342369568	95th
Other children	Germany	835	0.0338706592	95th
Other children	Denmark	298	0.0265556372	95th
Other children	Spain	399	0.0541939757	95th
Other children	Spain	156	0.0791545633	95th
Other children	Finland	750	0.0547032516	95th
Other children	France	482	0.0543999531	95th
Other children	Greece	838	0.0459673386	95th
Other children	Italy	193	0.0421650389	95th
Other children	Latvia	187	0.0387078840	95th
Other children	Netherlands	957	0.0371194974	95th
Other children	Netherlands	447	0.0362031267	95th
Other children	Sweden	1473	0.0317551117	95th
Other children	Czechia	389	0.0671194300	95th
Other children	United Kingdom	651	0.0385858309	95th
Adolescents	Austria	237	0.0285125021	95th
Adolescents	Belgium	576	0.0199321366	95th
Adolescents	Cyprus	303	0.0213561090	95th
Adolescents	Germany	393	0.0253440418	95th
Adolescents	Germany	1011	0.0171690556	95th
Adolescents	Denmark	377	0.0167412304	95th
Adolescents	Spain	651	0.0327610160	95th
Adolescents	Spain	209	0.0460677709	95th
Adolescents	Spain	86	0.0340802780	95th
Adolescents	Finland	306	0.0188822870	95th

TABLE A.1 (Continued)

Population class	Survey's country	Number of subjects	HRP[a]	HRP description
Adolescents	France	973	0.0334098657	95th
Adolescents	Italy	247	0.0228336536	95th
Adolescents	Latvia	453	0.0262702551	95th
Adolescents	Netherlands	1142	0.0274005540	95th
Adolescents	Sweden	1018	0.0212877630	95th
Adolescents	Czechia	298	0.0441199781	95th
Adolescents	United Kingdom	666	0.0244133719	95th
Adults	Austria	308	0.0219519657	95th
Adults	Belgium	1292	0.0206292063	95th
Adults	Germany	10,419	0.0169604299	95th
Adults	Denmark	1739	0.0119128606	95th
Adults	Spain	981	0.0263148305	95th
Adults	Spain	410	0.0244743388	95th
Adults	Finland	1295	0.0223184436	95th
Adults	France	2276	0.0248059032	95th
Adults	Hungary	1074	0.0374528916	95th
Adults	Ireland	1274	0.0241815712	95th
Adults	Italy	2313	0.0169566899	95th
Adults	Latvia	1271	0.0230717761	95th
Adults	Netherlands	2055	0.0227233540	95th
Adults	Romania	1254	0.0969185505	95th
Adults	Sweden	1430	0.0243905900	95th
Adults	Czechia	1666	0.0242032736	95th
Adults	United Kingdom	1265	0.0186068890	95th
Elderly	Austria	67	0.0198016446	95th
Elderly	Belgium	511	0.0165209726	95th
Elderly	Germany	2006	0.0141478837	95th
Elderly	Denmark	274	0.0112560579	95th
Elderly	Finland	413	0.0179382787	95th
Elderly	France	264	0.0248342376	95th
Elderly	Hungary	206	0.0280991923	95th
Elderly	Ireland	149	0.0201565988	95th
Elderly	Italy	289	0.0157239993	95th
Elderly	Netherlands	173	0.0169013682	95th
Elderly	Netherlands	289	0.0165576175	95th
Elderly	Romania	83	0.0358154065	95th
Elderly	Sweden	295	0.0204738645	95th
Elderly	United Kingdom	166	0.0165065887	95th
Very elderly	Austria	25	0.0093396226	75th
Very elderly	Belgium	704	0.0187481555	95th
Very elderly	Germany	490	0.0154613467	95th
Very elderly	Denmark	12	0.0087232126	75th
Very elderly	France	84	0.0193874431	95th
Very elderly	Hungary	80	0.0203047127	95th
Very elderly	Ireland	77	0.0208786377	95th
Very elderly	Italy	228	0.0154017628	95th
Very elderly	Netherlands	450	0.0155329405	95th
Very elderly	Romania	45	0.0368389794	90th
Very elderly	Sweden	72	0.0210295729	95th
Very elderly	United Kingdom	139	0.0127042405	95th

[a]Maximum of the highest reliable percentile values across European dietary surveys.

TABLE A.2 Chronic dietary exposure per population class, country and survey of consumers (mg/kg bw per day) to zeaxanthin residues in poultry tissues and products.

Population class	Survey's country	Number of subjects	HRP[a]	HRP description
Infants	Bulgaria	523	0.0292330068	95th
Infants	Germany	142	0.0062050067	95th
Infants	Denmark	799	0.0065521192	95th
Infants	Finland	427	0.0084884864	95th
Infants	Italy	9	0.0000000000	50th
Infants	United Kingdom	1251	0.0143464371	95th
Toddlers	Belgium	36	0.0151819036	90th
Toddlers	Bulgaria	428	0.0338344610	95th
Toddlers	Germany	348	0.0119351850	95th
Toddlers	Denmark	917	0.0086852467	95th
Toddlers	Spain	17	0.0212179700	75th
Toddlers	Finland	500	0.0142564583	95th
Toddlers	Italy	36	0.0129378571	90th
Toddlers	Netherlands	322	0.0167885869	95th
Toddlers	United Kingdom	1314	0.0171794535	95th
Toddlers	United Kingdom	185	0.0146609206	95th
Other children	Austria	128	0.0135646890	95th
Other children	Belgium	625	0.0170565705	95th
Other children	Bulgaria	433	0.0275316903	95th
Other children	Germany	293	0.0123345888	95th
Other children	Germany	835	0.0122587459	95th
Other children	Denmark	298	0.0098835873	95th
Other children	Spain	399	0.0193316194	95th
Other children	Spain	156	0.0284675174	95th
Other children	Finland	750	0.0133708480	95th
Other children	France	482	0.0139029766	95th
Other children	Greece	838	0.0160797615	95th
Other children	Italy	193	0.0160776467	95th
Other children	Latvia	187	0.0141714123	95th
Other children	Netherlands	957	0.0130510993	95th
Other children	Netherlands	447	0.0151779332	95th
Other children	Sweden	1473	0.0116307592	95th
Other children	Czechia	389	0.0251393938	95th
Other children	United Kingdom	651	0.0137466095	95th
Adolescents	Austria	237	0.0106448670	95th
Adolescents	Belgium	576	0.0077893848	95th
Adolescents	Cyprus	303	0.0084260208	95th
Adolescents	Germany	393	0.0088130293	95th
Adolescents	Germany	1011	0.0066025124	95th
Adolescents	Denmark	377	0.0062551934	95th
Adolescents	Spain	651	0.0114865564	95th
Adolescents	Spain	209	0.0165576095	95th
Adolescents	Spain	86	0.0117190075	95th
Adolescents	Finland	306	0.0076523427	95th
Adolescents	France	973	0.0081798244	95th
Adolescents	Italy	247	0.0074703605	95th
Adolescents	Latvia	453	0.0098304343	95th
Adolescents	Netherlands	1142	0.0106841387	95th

TABLE A.2 (Continued)

Population class	Survey's country	Number of subjects	HRP[a]	HRP description
Adolescents	Sweden	1018	0.0084610907	95th
Adolescents	Czechia	298	0.0179755747	95th
Adolescents	United Kingdom	666	0.0098634514	95th
Adults	Austria	308	0.0089035298	95th
Adults	Belgium	1292	0.0073889266	95th
Adults	Germany	10,419	0.0062516566	95th
Adults	Denmark	1739	0.0044877509	95th
Adults	Spain	981	0.0099774359	95th
Adults	Spain	410	0.0097261109	95th
Adults	Finland	1295	0.0080043002	95th
Adults	France	2276	0.0065618331	95th
Adults	Hungary	1074	0.0093101809	95th
Adults	Ireland	1274	0.0093297138	95th
Adults	Italy	2313	0.0057991098	95th
Adults	Latvia	1271	0.0085583375	95th
Adults	Netherlands	2055	0.0087003496	95th
Adults	Romania	1254	0.0108430689	95th
Adults	Sweden	1430	0.0091342084	95th
Adults	Czechia	1666	0.0092301274	95th
Adults	United Kingdom	1265	0.0070697707	95th
Elderly	Austria	67	0.0067787028	95th
Elderly	Belgium	511	0.0060420093	95th
Elderly	Germany	2006	0.0050463724	95th
Elderly	Denmark	274	0.0040809893	95th
Elderly	Finland	413	0.0066093759	95th
Elderly	France	264	0.0055400363	95th
Elderly	Hungary	206	0.0077360629	95th
Elderly	Ireland	149	0.0079448415	95th
Elderly	Italy	289	0.0057126901	95th
Elderly	Netherlands	173	0.0064594594	95th
Elderly	Netherlands	289	0.0060157185	95th
Elderly	Romania	83	0.0104854572	95th
Elderly	Sweden	295	0.0080109556	95th
Elderly	United Kingdom	166	0.0058217647	95th
Very elderly	Austria	25	0.0024151724	75th
Very elderly	Belgium	704	0.0069425949	95th
Very elderly	Germany	490	0.0056333036	95th
Very elderly	Denmark	12	0.0028996464	75th
Very elderly	France	84	0.0061128389	95th
Very elderly	Hungary	80	0.0077540553	95th
Very elderly	Ireland	77	0.0081600074	95th
Very elderly	Italy	228	0.0056566535	95th
Very elderly	Netherlands	450	0.0058551719	95th
Very elderly	Romania	45	0.0092051624	90th
Very elderly	Sweden	72	0.0073574726	95th
Very elderly	United Kingdom	139	0.0047946310	95th

[a]Maximum of the highest reliable percentile values across European dietary surveys.