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SCIENTIFIC OPINION

Assessment of the feed additive consisting of red carotenoid-rich *Paracoccus carotinifaciens* NITE SD 00017 for salmon and trout for the renewal of its authorisation (ENEOS Techno Materials Corporation)

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Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on red carotenoid-rich *Paracoccus carotinifaciens* NITE SD 00017 for salmon and trout (category: sensory additives; functional group: colourants; substances which when fed to animals add colours to food of animal origin) for the renewal of its authorisation. The applicant provided evidence that the additive complies with the conditions of the authorisation. The Panel concludes that the use of the additive in salmon and trout remains safe for the target species, the consumer and the environment under the authorised conditions of use. When assessing consumer exposure to canthaxanthin and adonirubin at the level of the existing maximum residue limits (MRL) for poultry and the proposed MRL for trout/salmon (5 mg/kg muscle), the exposure of consumers exceeds the acceptable daily intake (ADI) in the population classes toddlers and other children. The Panel considers that there is no need to restrict the use of the additive to fish older than 6 months or of more than 50 g. Red carotenoid-rich *Paracoccus carotinifaciens* NITE SD 00017 is not irritant to the skin, but is irritant to the eyes. It is considered a dermal and respiratory sensitiser and any exposure via skin or the respiratory tract is a risk.

KEYWORDS

astaxanthin, colourant, Panaferd®-AX, *Paracoccus carotinifaciens*, red carotenoids, safety, salmon, sensory additive, trout

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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 14(1) of that Regulation lays down that an application for renewal shall be sent to the Commission at the latest 1 year before the expiry date of the authorisation.

The European Commission received a request from JX Nippon ANCI SAS (Europe) on behalf of JXTG Nippon Oil & Energy Corporation[2] for renewal of the authorisation of the product red carotenoid-rich *Paracoccus carotinifaciens* NITE SD 00017 for salmon and trout (category: sensory additives; functional group: colourants; substances which when fed to animals add colours to food of animal origin).

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 14(1) (renewal of the authorisation). The dossier was received on 22 August 2017 and the general information and supporting documentation are available at https://open.efsa.europa.eu/questions/EFSA-Q-2017-00694. The particulars and documents in support of the application were considered valid by EFSA as of 20 November 2017.

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 product red carotenoid-rich *Paracoccus carotinifaciens* NITE SD 00017, when used under the proposed conditions of use (see **Section 3.1.5**).

1.2 | Additional information

The additive, a natural source of red carotenoids containing as main colouring principle astaxanthin, adonirubin and canthaxanthin, is currently authorised for salmon and trout (2a(ii)167).[3] The FEEDAP Panel adopted two opinions on the safety and efficacy of Panaferd®-AX (red carotenoid-rich bacterium *Paracoccus carotinifaciens* NITE SD 00017) (EFSA, 2007; EFSA FEEDAP Panel, 2010).

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 red carotenoid-rich *Paracoccus carotinifaciens* NITE SD 00017 (Panaferd®-AX) as a feed additive.

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.

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of the astaxanthin, adonirubin and canthaxanthin in animal feed and marker residue in muscle tissue of salmon and trout.[5]

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of red carotenoid-rich *Paracoccus carotinifaciens* (Panaferd®-AX) is in line with the principles laid down in Regulation (EC) No 429/2008[6] and the relevant guidance documents: Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2021).

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

[2]On 31 October 2023 EFSA was informed by the applicant that the applicant company changed to ENEOS Techno Materials Corporation (1–5-2 Higashi-Shimbashi, Minato-ku, Tokyo 105-7109 Japan), represented in the EU by ANCI SAS (Les Collines de Cuques – B3, 6 avenue de l'Armée d'Afrique, F-13100 Aix-en-Provence, France).

[3]Commission Regulation (EC) No 721/2008 of 25 July 2008 concerning the authorisation of a preparation of red carotenoid-rich bacterium *Paracoccus carotinifaciens* as a feed additive. OK L 198, 26.7.2008, p. 23. And COMMISSION REGULATION (EU) No 334/2010 of 22 April 2010 amending Regulation (EC) No 721/2008 as regards the composition of feed additives. OJ L 102, 23.4.2010, p 21.

[4]FEED dossier reference: FAD-2017-0048.

[5]Evaluation report received on 12/07/2018 and available on the EU Science Hub https://joint-research-centre.ec.europa.eu/reports-and-technical-documentation/fad-2017-0048_en

[6]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.

3 | ASSESSMENT

The additive red carotenoid-rich *Paracoccus carotinifaciens* is currently authorised as a sensory additive (functional group: colourants; substances which when fed to animals add colours to food of animal origin) for use in feed for salmon and trout. The present application is for the renewal of the current authorisation. The additive will be referred to in this opinion with its trade name Panaferd®-AX.

3.1 | Characterisation

3.1.1 | Manufacturing process

The additive is obtained via fermentation with the strain *Paracoccus carotinifaciens* NITE SD 00017. The information submitted regarding the manufacturing process lists some modifications applied which have been developed since the first authorisation was granted.[7,8] [redacted][9] The applicant declared that no antimicrobials are used in the manufacturing process.[10]

3.1.2 | Characterisation of the strain

The strain under assessment was isolated from soil and is deposited in the National Institute of Technology and Evaluation (NITE) of Japan with accession number NITE SD 00017.[11] The strain is not genetically modified.

The taxonomic identification of the strain NITE SD 00017 was performed using [redacted][12] [redacted][13] the FEEDAP Panel considers that the identification of NITE SD 00017 as *P. carotinifaciens* is confirmed.

The susceptibility of the strain to the antimicrobials recommended by the FEEDAP Panel (EFSA FEEDAP Panel, 2018) was tested by broth microdilution following the Clinical and Laboratory Standards Institute (CLSI) performance standards [redacted] All the minimum inhibitory concentration (MIC) values determined were equal or fell below the corresponding cut-off values for *Enterobacteriaceae*, except for fosfomycin which was exceeded by five dilutions (256 mg/L vs. 8 mg/L).[14] Therefore, *P. carotinifaciens* NITE SD 00017 is considered susceptible to all relevant antibiotics except for fosfomycin.

The WGS data of the production strain were queried for the presence of genes coding for antimicrobial resistance (AMR) [redacted][15] No hits of concern were identified. Although the strain was resistant to fosfomycin, since no acquired AMR genes were found in the genome, this resistance does not raise safety concerns.

Antimicrobial activity was measured in culture supernatants of the strain by a broth microdilution method.[16] No inhibitory activity was detected against the 18 reference strains used, *Acinetobacter baumannii* NCTC 12156, *A. baumannii* ATCC 17978, *Bacillus subtilis* NC08236, *B. subtilis* ATCC 6633, *Escherichia coli* ATCC 25922, *E. coli* ATCC 35218, *Enterococcus faecalis* NCTC 12697, *E. faecalis* NCTC 12203, *Klebsiella pneumoniae* NCTC 13368, *K. pneumoniae* NCTC 13439, *Pseudomonas aeruginosa* BAA 2110, *P. aeruginosa* ATCC 27853, *Proteus vulgaris* ATCC 6380, *P. mirabilis* ATCC 7002, *Staphylococcus aureus* NCTC 12981, *S. aureus* ATCC 29213, *S. aureus* BAA 2312 and *Streptococcus pneumoniae* ATCC 49619.

3.1.3 | Characterisation of the additive

The additive is a preparation containing dried killed cells of *Paracoccus carotinifaciens* NITE SD 00017 and calcium carbonate. The additive is specified by the authorising regulation to contain 20–23 g/kg astaxanthin, 7–15 g/kg adonirubin and 1–5 g/kg canthaxanthin. The analysed values from five batches (Table 1) showed compliance with the specifications.

[7]Technical dossier/Section II/Annex 2.13.
[8]Technical dossier/Supplementary Information January 2021/Annex_14.
[9]Technical dossier/Supplementary Information January 2021/Annex_07.
[10]Technical dossier/Section II.
[11]Technical dossier/Supplementary Information January 2021/Annex_01.
[12]Technical dossier/Supplementary Information January 2021/Annex_02.
[13]Technical dossier/Section II/Annex 2.12.
[14]Technical dossier/Section II/Annex 3.2 and Supplementary Information January 2021/Annex_03 and Annex_04.
[15]Technical dossier/Supplementary Information January 2021/Annex_05.
[16]Technical dossier/Supplementary Information January 2021/Annex_03.

TABLE 1 Carotenoid profile (g/kg) of red carotenoid-rich *Paracoccus carotinifaciens* NITE SD 00017.

	Specification	Average	Range
Astaxanthin	20–23	21.68	21.2–22.0
Adonirubin	7–15	8.5	7.6–9.4
Canthaxanthin	1–5	2.04	1.8–2.3
Adonixanthin		2.74	2.2–3.5
Echinenone		0.68	0.5–0.9
beta-Carotene		0.44	0.2–0.6
Asteroidenone		0.42	0.3–0.5
3-Hydroxyechinenone		0.24	0.1–0.4
Others		0.1	< 0.1–0.1
Total carotenoids (TC)		36.8	35.1–38.0

Three of the above batches were analysed to provide information on the proximate composition (Table 2).

TABLE 2 Proximate composition (% as is) of red carotenoid-rich *Paracoccus carotinifaciens* NITE SD 00017.

	Average	Range
Crude protein	41.1	37.1–43.4
Crude ash	21.9	20.1–24.5
Crude fat	2.9	2.7–3.2
Crude fibre	< 0.1	< 0.1
Carbohydrates	5.6	5.0–5.9
Moisture	2.8	2.5–2.9

In the same three batches, lead concentration ranged from 0.08 to 0.17 mg/kg, cadmium ranged from 0.02 to 0.03 mg/kg while arsenic and mercury were below their limit of quantification (LOQ)[17] as well as mycotoxins[18] (aflatoxins B1, B2, G1 and G2, fumonisins B1 and B2, nivalenol, deoxynivalenol, zearalenone, patulin, ochratoxin A, citrinin, sterigmatocystin, penicillic acid).[19]

Polychlorinated dibenzodioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and coplanar dioxin-like polychlorinated biphenyls (Co-planar PCBs) were analysed in three other batches. The calculated (lower bound) levels of the sum of dioxins and dioxin-like-PCBs ranged from 0.028 to 0.062 pg WHO-PCDD/F-PCB-TEQ/kg.[20]

The FEEDAP Panel considers that the amounts of the detected impurities do not raise safety concerns.

Five other batches were assessed for microbiological contamination. Total aerobic count was between 2.40×10^4 and 2.90×10^5 CFU/g, coliform bacteria was absent in 10 g samples and *Salmonella* spp. was not detected in 25 g samples.[21] The FEEDAP Panel notes that the values found regarding the total aerobic count are high and may deserve attention/monitoring during the production process.

Lipopolysaccharides (LPS) are present in most Gram-negative bacteria's outer membrane and are typically recognised by Toll-like receptor 4 (TLR4) present on the surface of phagocytic cells. The applicant provided analytical data for the determination of LPS content in five batches of the additive.[22] The results of the chromogenic Limulus Amebocyte Lysate (LAL) assay averaged 1.50×10^6 EU/g[23] (range 0.76×10^6–2.90×10^6 EU/g). Moreover, the LPS of *P. carotinifaciens* NITE SD 00017 pure culture were extracted, purified and characterised (in terms of composition and potential for cytokines induction).[24] Based on the results of silver-staining SDS-PAGE, GS-MS and MALDI-TOF-MS, it was determined that the strain's LPS have low molecular weight and that its Lipid A is penta-acylated.[25] The strain's LPS and their Lipid A potential to induce

[17]LOQs were for arsenic 0.1 mg/kg and for mercury 0.01 mg/kg.

[18]Technical dossier/Section II/Annex 2.5.

[19]0.005 mg/kg for Aflatoxins B1, B2, G1, G2; 0.05 mg/kg for Fumonisins B1, B2, Nivalenol, Deoxynivalenol, Zearalenone, Patulin, Citrinin, Sterigmatocystin; 0.2 mg/kg for Penicillic acid and 5 µg/kg for Ochratoxin A.

[20]Technical dossier/Supplementary information January 2021/Annex 17. TEQ = toxic equivalency factors for PCDD/Fs and DL-PCBs established by WHO in 2005 (van den Berg et al., 2006).

[21]Technical dossier/Section II/Annex 2.6.

[22]Technical dossier/Supplementary information January 2021/Annex_20.

[23]Endotoxin Unit. One EU is equal to one International Unit (IU) of endotoxin.

[24]Technical dossier/Supplementary Information January 2021/Annex_09, Annex_10, Annex_11, Annex_12 and Annex_13.

[25]Technical dossier/Supplementary Information January 2021/Annex_09, Annex_10, Annex_11 and Annex_12.

inflammatory cytokines was investigated in two different cell lines and the results showed lower cytokine induction activity compared with the *Escherichia coli* O55 LPS and comparable to a TLR4 antagonist (ultrapure commercial extract of LPS from *Rhodobacter sphaeroides*).[26,27] Based on the biological activity data, it is concluded that the LPS of the *P. carotinifaciens* NITE SD 00017 LPS trigger low TLR4-mediated cytokine release.

The presence of viable cells of the production strain was investigated in three batches, in triplicate. One gram of product per batch was diluted in 50 mL saline and 50 μL of this suspension was spread in solid media and incubated at 28°C for 10 days (positive controls were incubated for 5 days). The production strain was not detected.[28] Due to the low amount of the additive tested, the presence of viable cells cannot be excluded. However, the FEEDAP Panel considers that based on the inactivation steps in the manufacturing process, the presence of *P. carotinifaciens* NITE SD 00017 is unlikely. Based on the data provided to characterise *P. carotinifaciens* NITE SD 00017, the potential presence of viable cells in the additive would not represent a safety concern.

The Chemical Abstracts Service (CAS) number, molecular formula and molecular weight of astaxanthin, canthaxanthin and adonirubin are reported in Table 3.

TABLE 3 Description of the main carotenoids in red carotenoid-rich *Paracoccus carotinifaciens* NITE SD 00017.

	Chemical abstracts service (CAS) number	Molecular formula	Molecular weight (g/mol)
Astaxanthin (3,3′-dihydroxy-β,β-carotene-4,4′-dione)	472–61-7	$C_{40}H_{52}O_4$	597
Canthaxanthin (β-carotene-4,4′-dione)	514–78-3	$C_{40}H_{52}O_2$	565
Adonirubin (3-hydroxy-ββ-carotene-4,4′-dione)	4418-72-8	$C_{40}H_{52}O_3$	581

Due to the presence of the long hydrocarbon chain, these substances are insoluble in water but soluble in fats and most organic solvents.

3.1.4 | Physico-chemical and technological properties of the additive

The additive is a dark red granular powder with an average bulk density of 473 kg/m^3 and tapped density of 623 kg/m^3.

In order to establish the impact of the changes implemented in the manufacturing process on the physico-chemical properties of the additive, the applicant provided new data regarding the dusting potential and particle size, which are described below.

The particle size distribution was determined by laser diffraction analysis in three batches of the additive. The fractions of particles below 10, 50 and 100 μm were in the range of 3–4, 12–15 and 29–35%(V/V), respectively. Dusting potential, measured in the same batches (Stauber-Heubach method) showed values of 1.9, 3.1 and 2.6 g/m^3. The dusting potential was also measured in five additional batches (Stauber-Heubach method) showing values of 2.6, 2.3, 3.1, 4.8 and 5.1 g/m^3.[29] In this experiment, the concentration of astaxanthin, adonirubin and cantaxanthin was also determined. The following mean concentrations were measured before and after dust generation, respectively: 21.7 and 20.1 mg/g astaxanthin; 9.0 and 8.4 mg/g adonirubin; 2.2 and 1.9 mg/g canthaxanthin. Particle size distribution of the dust was not analysed.

No new data were submitted on stability and homogeneity. The Panel considers that the small changes introduced in the manufacturing process would not have an impact on the stability and the homogeneous distribution of the additive in feed, and therefore, the previous assessment is still considered valid (EFSA, 2007).

The applicant reported the potential incompatibility between carotenoids and blood meal based on customer feedback and scientific literature data. Hatlen et al. (2012) observed lower muscle colour score and lower astaxanthin concentrations when the diet of salmons was supplemented with porcine blood meal, possibly due to degradation of astaxanthin catalysed by iron from haemoglobin present in blood meal. The FEEDAP Panel recommends avoiding the simultaneous use of the additive and blood meal in the diet of salmon and trout.

3.1.5 | Conditions of use

The additive is currently authorised for use in feed for salmon and trout with a maximum content of 100 mg/kg complete feed where the maximum content is expressed as the sum of astaxanthin, adonirubin and canthaxanthin.

The authorisation under other provisions foresees:

[26]Technical dossier/Supplementary Information January 2021/Annex_13.

[27]Technical dossier/Spontaneous submission March 2024/240326 New data LPS Paracoccus carotinifaciens.

[28]Technical dossier/Supplementary information January 2021/Annex_08.

[29]Technical dossier/Supplementary information January 2021/Annex 19.

1. The maximum content is expressed as the sum of astaxanthin, adonirubin and canthaxanthin.
2. Use permitted from the age of 6 months onwards or weight of 50 g.
3. The mixture of the additive with astaxanthin or canthaxanthin is allowed provided that the total concentration of the sum of astaxanthin, adonirubin and canthaxanthin from other sources does not exceed 100 mg/kg in complete feedingstuff.

Maximum residue limits are also set in the authorising regulation as follows:

For salmon: 10 mg/kg for the sum of adonirubin and canthaxanthin/kg muscle (wet tissue).
For trout: 8 mg/kg for the sum of adonirubin and canthaxanthin/kg muscle (wet tissue).

The applicant is requesting to delete the provision limiting the use from the age of 6 months onwards or weight of 50 g (point 2 under other provisions).

The applicant is requesting the modification of provision 3 as follows: '*The mixture of the additive with astaxanthin is allowed provided that the total concentration of the sum of astaxanthin, adonirubin and canthaxanthin from other sources does not exceed 100 mg/kg in complete feedingstuff*' considering that as of today, there is no authorisation in force for canthaxanthin in feed for salmonids.

Lastly, the applicant is requesting to lower the MRLs for salmon to 5 mg for the sum of adonirubin and canthaxanthin/kg muscle (wet tissue).

In addition, the applicant is asking to add the following provisions:

- For safety: breathing protection, safety glasses and gloves shall be worn during handling.
- Red carotenoid-rich *Paracoccus carotinifaciens* may be placed on the market and used as an additive consisting of a preparation.

3.2 | Safety

The safety of the additive red carotenoid-rich *Paracoccus carotinifaciens* NITE SD 00017 for the target species, consumer, user and environment was established in previous FEEDAP opinions (EFSA, 2007; EFSA FEEDAP Panel, 2010).

The applicant provided the following information to support that, under the approved conditions of use, the additive remains safe for the target species, consumer, user and environment: (i) a company report on adverse events (see Section 3.2.4), (ii) an extensive literature search and (iii) a report on residue monitoring.

The extensive literature search[30,31] (ELS) covered the period June 2005 until March 2024 and the search terms and search strategy were provided.[32] The main search terms regarded the additive, the active substances and included terms concerning the safety and the toxicity for the target species, consumers, users and the environment. A total of 78 publications were considered relevant by the applicant. The FEEDAP Panel reviewed the papers and mentioned them in the assessment when considered relevant.

3.2.1 | Absorption, distribution, metabolism, excretion and residues

The metabolism of the three main carotenoids (astaxanthin, adonirubin and canthaxanthin) was described in the former opinion of the FEEDAP Panel (EFSA, 2007). No new studies have been submitted in the current application. No relevant publications were identified in the ELS by the Panel for the assessment of the renewal of the authorisation.

The applicant submitted a report on residue monitoring.[33] Samples of salmon and trout were collected at the end of the production cycle of fish fed red carotenoid-rich *Paracoccus carotinifaciens* NITE SD 00017 in one European country. The samples originated from three fish producers using the additive under assessment. The inclusion rate of the additive was variable depending on the growth rate of the fish and was not always reaching the highest authorised use level. In all three cases, the highest supplementation level was calculated to be ~ 100 mg of the sum of astaxanthin, canthaxanthin and adonirubin. The carotenoids were extracted from the fish flesh, separated and quantified using a validated HPLC method. The results (125 samples analysed) indicated 0.3 ± 0.1 mg canthaxanthin/kg muscle, 1.3 ± 0.2 mg adonirubin/kg muscle and 3.8 ± 0.6 mg astaxanthin/kg muscle. A similar analysis was performed in trout from four producers. Also in this case, the inclusion level varied based on the growing stage of the trout; the highest inclusion level was calculated to be ~ 100 mg of the sum of astaxanthin, canthaxanthin and adonirubin. The results (32 samples analysed) indicated 0.3 ± 0.1 mg canthaxanthin/kg muscle, 1.7 ± 0.8 mg adonirubin/kg muscle and 5.2 ± 2.3 mg astaxanthin/kg muscle.

The FEEDAP Panel considers that the data provided might reflect current fish farming practices (adapting use levels according to the growth phase of the fish). However, considering that the additive was not administered up to the highest

[30]Technical dossier/Section III/Annex 3.1.
[31]Technical dossier/Supplementary information/March 2024/Annex_Literature search.
[32](Livivo, Ovid, PubMed, ToxNET, ECHA, IPS INCHEM, ScienceDirect, ETH Knowledge Portal (including Web of Science), Google Scholar, AGRICOLA and AGRIS).
[33]Technical dossier/Section III/Annex 3.3.

authorised use level continuously during the production cycle of the fish, the data cannot be used for the calculation of consumer exposure.

Residue data derived from studies with animals exposed to the highest proposed use level of the additive were assessed in the former opinion (EFSA, 2007). The FEEDAP Panel reviewed the studies in salmon and trout and considered that the dose–response study performed with the additive under assessment in rainbow trout (*Oncorhynchus mykiss*) can be retained for the consumer safety assessment. The treatment group with 100 mg of the sum of astaxanthin, adonirubin and canthaxanthin will be considered to derive residue data. The residue values are reported in Table 4.

TABLE 4 Concentration of astaxanthin, canthaxanthin and adonirubin in muscle of rainbow trout fed the additive for 12 weeks.

	Astaxanthin	Canthaxanthin	Adonirubin
Average (mg/kg) ± SD	3.30 ± 1.95	0.43 ± 0.21	1.87 ± 1.02
Average + 2SD	7.20	0.85	3.91

3.2.2 | Toxicology

The toxicity of red carotenoid-rich *Paracoccus carotinifaciens* NITE SD 00017 was assessed by the FEEDAP Panel in 2007 and it was concluded that 'Panaferd®-AX is non genotoxic and exhibits very low acute and sub-chronic toxicity. Therefore, the FEEDAP Panel considers that no specific risk for the consumer related to compounds arising from the fermentation process (other than red carotenoids) is likely to occur' (EFSA, 2007).

No new studies were submitted. The toxicology of ATX was re-evaluated by the FEEDAP Panel in 2019 (EFSA FEEDAP Panel, 2019a). In this opinion, an acceptable daily intake (ADI) of 0.2 mg astaxanthin/kg body weight (bw) per day was established based on a lowest observed adverse effect level (LOAEL) of 40 mg ATX/kg bw per day (end point: increased incidence of multinucleated hepatocytes in a 2-year rat study). Similarly, the toxicology of CTX was re-evaluated by the FEEDAP Panel in 2013 (EFSA FEEDAP Panel, 2013). In this opinion, the ADI of 0.03 mg CTX/kg bw, already agreed by JECFA (JECFA, 1995), the EU Scientific Committee for Food (European Commission, 2000), and by EFSA ANS Panel (EFSA ANS Panel, 2010), was confirmed.[34] The ELS did not identify relevant studies that would lead the Panel to modify these conclusions.

In its previous opinion (EFSA, 2007), the FEEDAP Panel noted that the safety of adonirubin was not established. However, it was stated that 'adonirubin has an intermediary chemical structure between canthaxanthin and astaxanthin, which suggests that the toxicological profiles of the three compounds are similar.' Therefore, the Panel stated that the ADI for canthaxanthin should be applied to the sum of canthaxanthin plus adonirubin on a precautionary basis. In the absence of any new evidence, the FEEDAP Panel considers that the same conclusions should be retained for the present assessment.

Conclusions on the absence of a genotoxic potential of the additive were reached in the previous opinion (EFSA, 2007) based on a negative Ames test, a negative mouse lymphoma assay and a negative in vivo micronucleus test in bone marrow erythrocytes. However, the FEEDAP Panel noted that the available data set did not comply with the current requirements on genotoxicity testing strategy (EFSA FEEDAP Panel, 2017a; EFSA Scientific Committee, 2017) since the negative results observed in the in vivo micronucleus test were not associated with evidence of target tissue exposure and did not allow to evaluate the aneugenic potential of the test item. To this aim, the applicant provided an in vitro micronucleus test performed in Chinese hamster ovary (CHO) cells following the OECD Guideline 487 and claimed to be GLP-compliant. Based on the results of a preliminary cytotoxicity test, four concentrations were selected for the analysis of micronucleus frequency in binucleated cells. Panaferd®-AX was tested at (i) 100, 300, 600, 1250 μg/mL applying a short treatment (3 + 21 h of recovery) in the presence of metabolic activation; (ii) 100, 200, 700, 1250 μg/mL after a short treatment in the absence of metabolic activation; (iii) 40, 60, 80, 100 μg/mL following a continuous treatment (24 + 0 h of recovery) without metabolic activation. Cytotoxicity up to 54% was recorded at the highest concentrations tested. The frequencies of micronuclei observed after treatment with Panaferd®-AX were comparable to the values detected in the vehicle control cultures. Therefore, the FEEDAP Panel concluded that Panaferd®-AX did not induce structural and numerical chromosomal damage in cultured Chinese Hamster Ovary (CHO) cells under the experimental conditions applied in this study.

Conclusions on toxicology

The FEEDAP Panel concludes that Panaferd®-AX does not raise safety concern for genotoxicity.

The ADI of 0.2 and 0.03 mg/kg bw can be retained for the consumer safety assessment of astaxanthin and of the sum of canthaxanthin and adonirubin, respectively.

[34] By applying an uncertainty factor of 10 to a no observed adverse effect level (NOAEL) of 0.25 mg/kg bw per day for scotopic b-wave changes (without impairment of vision) in humans and a lower benchmark dose (BMDL05) of 0.2–0.33 mg/kg bw per day for crystal incidence in a meta-analysis of findings of crystals in the retina of humans exposed to canthaxanthin.

3.2.3 | Safety for the target species

In its previous opinion (EFSA, 2007), the FEEDAP Panel concluded that the additive is safe for salmonids at the inclusion level of 0.4% based on a tolerance study in rainbow trout in which Panaferd®-AX was tolerated at dietary incorporation rate of 12.5-fold greater than the maximum incorporation rate of 0.4%. Considering the carotenoid levels in the additive, the Panel recommended to set the maximum use level for the sum of astaxanthin, canthaxanthin and adonirubin and to apply 100 mg/kg feed for this sum.

No new studies have been provided in the present application. No relevant publications were identified by the Panel in the ELS.

The measured levels of endotoxins in the additive 2.9×10^6 EU/g are of the same order of magnitude as those commonly found in feedingstuffs (ca. 1,000,000 IU/g, Cort et al., 1990). Therefore, at the usual conditions of use of the additive in feed, the endotoxins potentially added by the additive would be around 7300 EU/kg complete feed. The Panel also notes that the characterisation of the LPS showed that those originating from the production strain under assessment are of low concern.

Considering that no adverse effects have been reported, and no relevant information was found in the ELS with regard to the safety of the product and taking into account that the manufacturing/composition of the additive has not been substantially changed, the Panel considers that the conclusions reached in the previous opinion are still valid. The FEEDAP Panel concludes that the use of the additive remains safe for the target species under the conditions of the authorisation.

The applicant requested to remove the restriction of use of the additive from the age of 6 months onwards or weight of 50 g. As already expressed by the FEEDAP Panel in 2005 (EFSA, 2005), there is no reason to restrict the use of ATX to any particular physiological developmental stage of fish. In addition, the Panel notes that the tolerance studies in rainbow trout considered in the original opinion was done in juvenile animals (6–7.5 g). Therefore, the Panel concludes that there is no need to restrict the use of the additive from the age of 6 months onwards or weight of 50 g.

3.2.4 | Safety for the consumer

In its former opinion, the FEEDAP Panel concluded that 'As consumer exposure to astaxanthin and canthaxanthin after administration of Panaferd-AX at the maximum dose proposed would be at the most equal or less than that resulting from the use of other astaxanthin or canthaxanthin sources, there is no additional risk for the consumer. [...] The calculated consumer exposure to adonirubin plus canthaxanthin derived from the use of Panaferd-AX in salmon and trout complies with the ADI for canthaxanthin (37 %). Therefore, no additional risk due to adonirubin exposure resulting from the use of Panaferd-AX is likely to occur.' (EFSA, 2007).

The applicant provided a company report on adverse events[35] [redacted] could not be related to the use of the additive and are not considered relevant for the current assessment.

The consumer exposure to residues of astaxanthin, canthaxanthin and adonirubin has been assessed following the methodology detailed in the guidance on consumer safety (EFSA FEEDAP Panel, 2017b). The input values used in the calculation are included in Table 5. The outcome of the calculation is shown in Table 6 (for detailed results per age class, country and survey, see Appendix A, Table A.1).

TABLE 5 Input values used to calculate consumer exposure to carotenoid residues from red carotenoid-rich *Paracoccus carotinifaciens* NITE SD 00017.

	Astaxanthin (mg/kg tissue)	Canthaxanthin + adonirubin (mg/kg tissue)
Fish (meat)	7.20	4.76

TABLE 6 Chronic dietary exposure to carotenoid residues from red carotenoid-rich *Paracoccus carotinifaciens* NITE SD 00017 calculated based on residue data in trout.

	Astaxanthin		Canthaxanthin + adonirubin	
Population class	Highest exposure estimate[a] (mg/kg bw per day)	% ADI[b]	Highest exposure estimate[a] (mg/kg bw per day)	% ADI[c]
Infants	0.0153	8	0.0101	34
Toddlers	0.0413	21	0.0273	91
Other children	0.0286	14	0.0189	63
Adolescents	0.0203	10	0.0134	45

(Continues)

[35]Technical dossier/Section III/Annex 3.4.

TABLE 6 (Continued)

Population class	Astaxanthin: Highest exposure estimate[a] (mg/kg bw per day)	Astaxanthin: % ADI[b]	Canthaxanthin + adonirubin: Highest exposure estimate[a] (mg/kg bw per day)	Canthaxanthin + adonirubin: % ADI[c]
Adults	0.0170	9	0.0112	37
Elderly	0.0158	8	0.0104	35
Very elderly	0.0120	6	0.0079	26

[a]Expressed as maximum highest reliable percentile (HRP).
[b]ADI astaxanthin: 0.2 mg/kg bw.
[c]ADI canthaxanthin: 0.03 mg/kg bw.

Following the exposure calculation, it appears that the exposure to astaxanthin is well below the ADI (6%–21%), and that of canthaxanthin plus adonirubin ranges between 26% and 91% of the respective ADI.

MRLs exists for the sum of canthaxanthin and adonirubin for salmon (10 mg/kg muscle (wet tissue)) and trout (8 mg/kg muscle (wet tissue)). For astaxanthin, the setting of MRLs was not considered necessary (EFSA FEEDAP Panel, 2014).

When assessing consumer exposure to canthaxanthin and adonirubin at the level of the existing MRLs, the exposure of consumers exceeds the ADI in the population classes toddlers and other children for both salmon and trout (Table 7) (for detailed results per age class, country and survey, see Appendix A, Table A.2 and A.3).

TABLE 7 Chronic dietary exposure to canthaxanthin + adonirubin residues from red carotenoid-rich *Paracoccus carotinifaciens* NITE SD 00017 calculated based on existing MRLs in trout (8 mg/kg muscle) and salmon (10 mg/kg muscle).

Population class	Input value: 8 mg/kg muscle: Highest exposure estimate[a] (mg/kg bw per day)	Input value: 8 mg/kg muscle: % ADI[b]	Input value: 10 mg/kg muscle: Highest exposure estimate[a] (mg/kg bw per day)	Input value: 10 mg/kg muscle: % ADI[b]
Infants	0.0170	56.7	0.0213	70.9
Toddlers	0.0459	152.9	0.0573	191.1
Other children	0.0318	106.1	0.0398	132.6
Adolescents	0.0226	75.2	0.0282	94.0
Adults	0.0188	62.8	0.0235	78.5
Elderly	0.0175	58.4	0.0219	73.0
Very elderly	0.0133	44.4	0.0166	55.4

[a]Expressed as maximum HRP.
[b]ADI canthaxanthin: 0.03 mg/kg bw.

The applicant proposes to reduce the MRLs for salmon from 10 mg to 5 mg/kg muscle while keeping that of trout at 8 mg/kg muscle. When calculating the consumer exposure at the MRL of 5 mg/kg muscle, the exposure is below the ADI for all population classes (Table 8) (for detailed results per age class, country and survey, see Appendix A, Table A.4).

TABLE 8 Chronic dietary exposure to canthaxanthin + adonirubin residues from red carotenoid-rich *Paracoccus carotinifaciens* NITE SD 00017 calculated based on proposed MRL for trout/salmon.

Population class	Input value: 5 mg/kg muscle: Highest exposure estimate[a] (mg/kg bw per day)	Input value: 5 mg/kg muscle: % ADI[b]
Infants	0.0106	35.5
Toddlers	0.0287	95.5
Other children	0.0199	66.3
Adolescents	0.0141	47.0
Adults	0.0118	39.2
Elderly	0.0109	36.5
Very elderly	0.0083	27.7

[a]Expressed as maximum HRP.
[b]ADI canthaxanthin: 0.03 mg/kg bw.

The FEEDAP Panel considers that the MRL of 5 mg/kg muscle would ensure compliance with the ADI for the sum of canthaxanthin and adonirubin, and could be applied to both salmon and trout. The existing data on residues (see Table 4), also confirmed by the data from the recent residue monitoring performed by the applicant, show that the residues would comply with this proposed MRL of 5 mg/kg for muscle of salmon and trout.

Consumer exposure needs to take into consideration all potential dietary sources. Astaxanthin is currently authorised only in salmon and trout, while canthaxanthin is also authorised for use in chickens for fattening, minor poultry species for fattening, laying poultry, poultry reared for laying and the following MRLs are in force: 2.5 mg/kg skin/fat, 15 mg/kg liver, 30 mg/kg egg yolk (8.1 mg/kg whole egg containing 27% of yolk).[36] Consumer exposure considering the combined exposure from salmonids and poultry was done using the proposed MRL of 5 mg/kg muscle as input data together with existing MRLs in poultry (Table 9). The outcome of the calculation is shown in Table 10 (for detailed results per age class, country and survey, see Appendix A, Table A.5).

TABLE 9 Input values used to calculate consumer exposure to canthaxanthin + adonirubin from all sources (fish and poultry).

	Canthaxanthin + adonirubin (mg/kg tissue)
Fish (meat)	5
Birds fat/skin tissue	2.5
Birds liver	15
Whole eggs	8.1

TABLE 10 Chronic dietary exposure to canthaxanthin + adonirubin residues calculated based on proposed MRL in trout/salmon and existing MRLs in poultry.

Population class	Highest exposure estimate[a] (mg/kg bw per day)	% ADI[b]
Infants	0.0295	98
Toddlers	0.0385	128
Other children	0.0426	142
Adolescents	0.0248	83
Adults	0.0176	59
Elderly	0.0175	58
Very elderly	0.0186	62

[a]Expressed as maximum HRP.
[b]ADI canthaxanthin: 0.03 mg/kg bw.

When assessing consumer exposure to canthaxanthin and adonirubin at the level of the existing MRLs for poultry and the proposed MRL for trout/salmon, the exposure of consumers exceeds the ADI in the population classes toddlers and other children. The main contributors to the consumer exposure are eggs and fish.

3.2.5 | Safety for user

In 2007, based on the results of an acute inhalation study in rats and a skin and eye irritation study in rabbits, the FEEDAP Panel concluded that: 'Panaferd-AX shows very low acute inhalation toxicity and no potential for skin irritation. However, Panaferd-AX is considered an eye irritant. Considering the nature of the product, it should also be considered a respiratory sensitiser' (EFSA, 2007).

No additional studies were submitted in the present application, and no relevant data were found in the ELS performed by the applicant.

The highest dusting potential measured was 5.1 g/m^3, indicating that exposure of users by inhalation is likely.

The additive consists of inactivated cells of *P. carotinifaciens*, and therefore, it should be considered as a skin and respiratory sensitiser. In addition, considering the high content of LPS, albeit its low TLR4 mediated cytokine release, the Panel considers that any exposure via inhalation is a risk.

Therefore, considering the above, the Panel concludes that the additive is not irritant to the skin, but is irritant to the eyes. It is considered a dermal and respiratory sensitiser and any exposure via skin or the respiratory tract is a risk.

[36]Commission Implementing Regulation (EU) 2015/1486 of 2 September 2015 concerning the authorisation of canthaxanthin as feed additive for certain categories of poultry, ornamental fish and ornamental birds, OJ L 229, 3.9.2015, p. 5–8.

3.2.6 | Safety for the environment

In 2007, the FEEDAP Panel concluded that astaxanthin, adonirubin and canthaxanthin, the major red carotenoids contained in the additive, are not expected to pose a risk for the environment (EFSA, 2007).

In the current dossier, no new studies were provided, and the ELS did not identify any relevant papers on the safety of the additive or its main components for the environment.

Considering that the major carotenoids contained in the additive are naturally occurring in the marine environment (Mapelli-Brahm et al., 2023), in line with the provisions of the guidance on the assessment of feed additive for the environment (EFSA FEEDAP Panel, 2019b), the FEEDAP Panel concludes that the use of red carotenoid-rich *Paracoccus carotinifaciens* NITE SD 00017 as source of astaxanthin, canthaxanthin and adonirubin for salmon and trout is not expected to pose additional risk to the environment in comparison with their naturally occurring forms.

Therefore, the FEEDAP Panel concludes that the use of the additive in salmon and trout remains safe for the environment under the conditions of the authorisation.

3.3 | Efficacy

The present application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the authorisation that would have an impact on the efficacy of the additive. Therefore, there is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

4 | CONCLUSIONS

The applicant provided evidence that the additive currently in the market complies with the existing conditions of the authorisation.

The Panel concludes that the use of the additive in salmon and trout remains safe for the target species, the consumer and the environment under the authorised conditions. The Panel considers that there is no need to restrict the use of the additive to fish older than 6 months or of more than 50 g.

When assessing consumer exposure to canthaxanthin and adonirubin at the level of the existing MRLs for poultry and the proposed MRL for trout/salmon (5 mg/kg muscle), the exposure of consumers exceeds the ADI in the population classes toddlers and other children. The main contributors to the consumer exposure are eggs and fish.

Red carotenoid-rich *Paracoccus carotinifaciens* NITE SD 00017 is not irritant to the skin but is considered an eye irritant, and a skin and respiratory sensitiser. Any exposure though skin and inhalation is considered a risk for the user.

There is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

5 | RECOMMENDATIONS

The Panel recommends reducing the MRLs for the sum of canthaxanthin and adonirubin for both salmon and trout to 5 mg/kg muscle. The Panel also notes that a revision of the MRL for canthaxanthin when used in poultry might be needed.

The applicant is requesting the modification of provision 3 as follows: '*The mixture of the additive with astaxanthin is allowed provided that the total concentration of the sum of astaxanthin, adonirubin and canthaxanthin from other sources does not exceed 100 mg/kg in complete feedingstuff*' considering that as of today, there is no authorisation in force for canthaxanthin in feed for salmonids. However, the Panel notes that such a provision should be independent from other authorisations. Therefore, the Panel recommends the following wording for provision 3: 'the mixture of the additive with other authorised feed additives containing astaxanthin, adonirubin and/or canthaxanthin is allowed provided that the total concentration of the sum of astaxanthin, adonirubin and canthaxanthin in the diet does not exceed 100 mg/kg complete feed'.

The FEEDAP Panel notes that the values found regarding the total aerobic count are high and may deserve attention/monitoring during the production process.

The FEEDAP Panel recommends avoiding the simultaneous use of the additive and blood meal in the feed of salmon and trout.

ABBREVIATIONS

ADI	average daily intake
ANS	EFSA Scientific Panel on Additives and Nutrient Sources added to Food
BW	body weight
CAS	Chemical Abstracts Service
CFU	colony forming unit
ECHA	European Chemicals Agency
EURL	European Union Reference Laboratory
FAO	Food Agricultural Organisation

JECFA	The Joint FAO/WHO Expert Committee on Food Additives
LOD	limit of detection
LOQ	limit of quantification
MIC	minimum inhibitory concentration
MRL	maximum residue limit
NOAEL	no observed adverse effect level
TLR4	Toll-like receptor 4
WHO	World Health Organization

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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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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 carotenoid residues from red carotenoid-rich *Paracoccus carotinifaciens* NITE SD 00017 calculated based on residue data in trout.

Population class	Survey's country	Number of subjects	HRP[a]	HRP description
Infants	Bulgaria	523	0.0000000000	95th
Infants	Germany	142	0.0029559317	95th
Infants	Denmark	799	0.0077157853	95th
Infants	Finland	427	0.0036363622	95th
Infants	Italy	9	0.0000000000	50th
Infants	United Kingdom	1251	0.0101243870	95th
Toddlers	Belgium	36	0.0056855556	90th
Toddlers	Bulgaria	428	0.0145921048	95th
Toddlers	Germany	348	0.0068889419	95th
Toddlers	Denmark	917	0.0068965060	95th
Toddlers	Spain	17	0.0000000000	75th
Toddlers	Finland	500	0.0129741912	95th
Toddlers	Italy	36	0.0272874933	90th
Toddlers	Netherlands	322	0.0065954276	95th
Toddlers	United Kingdom	1314	0.0116716291	95th
Toddlers	United Kingdom	185	0.0113715804	95th
Other children	Austria	128	0.0117113962	95th
Other children	Belgium	625	0.0111474667	95th
Other children	Bulgaria	433	0.0154518368	95th
Other children	Germany	293	0.0061458337	95th
Other children	Germany	835	0.0070677736	95th
Other children	Denmark	298	0.0072481150	95th
Other children	Spain	399	0.0189301929	95th
Other children	Spain	156	0.0186426809	95th
Other children	Finland	750	0.0110503166	95th
Other children	France	482	0.0090069371	95th
Other children	Greece	838	0.0123067824	95th
Other children	Italy	193	0.0161838740	95th
Other children	Latvia	187	0.0056355860	95th
Other children	Netherlands	957	0.0069203857	95th
Other children	Netherlands	447	0.0051069872	95th
Other children	Sweden	1473	0.0092019583	95th
Other children	Czechia	389	0.0142800000	95th
Other children	United Kingdom	651	0.0098818535	95th
Adolescents	Austria	237	0.0070973372	95th
Adolescents	Belgium	576	0.0055768640	95th
Adolescents	Cyprus	303	0.0058013599	95th
Adolescents	Germany	393	0.0062010913	95th
Adolescents	Germany	1011	0.0036293080	95th
Adolescents	Denmark	377	0.0032538857	95th
Adolescents	Spain	651	0.0123959402	95th
Adolescents	Spain	209	0.0134188661	95th
Adolescents	Spain	86	0.0078876794	95th
Adolescents	Finland	306	0.0057278142	95th
Adolescents	France	973	0.0052963799	95th
Adolescents	Italy	247	0.0086180723	95th

(Continues)

TABLE A.1 (Continued)

Population class	Survey's country	Number of subjects	HRP[a]	HRP description
Adolescents	Latvia	453	0.0053702564	95th
Adolescents	Netherlands	1142	0.0039414618	95th
Adolescents	Sweden	1018	0.0061347714	95th
Adolescents	Czechia	298	0.0102450000	95th
Adolescents	United Kingdom	666	0.0048347955	95th
Adults	Austria	308	0.0066763944	95th
Adults	Belgium	1292	0.0064297215	95th
Adults	Germany	10,419	0.0060720513	95th
Adults	Denmark	1739	0.0031674570	95th
Adults	Spain	981	0.0112070886	95th
Adults	Spain	410	0.0109408802	95th
Adults	Finland	1295	0.0082308617	95th
Adults	France	2276	0.0049364499	95th
Adults	Hungary	1074	0.0042881410	95th
Adults	Ireland	1274	0.0053214015	95th
Adults	Italy	2313	0.0073546215	95th
Adults	Latvia	1271	0.0067462935	95th
Adults	Netherlands	2055	0.0052789365	95th
Adults	Romania	1254	0.0051694167	95th
Adults	Sweden	1430	0.0085898584	95th
Adults	Czechia	1666	0.0068417109	95th
Adults	United Kingdom	1265	0.0054537924	95th
Elderly	Austria	67	0.0065826934	95th
Elderly	Belgium	511	0.0067216905	95th
Elderly	Germany	2006	0.0069406535	95th
Elderly	Denmark	274	0.0035665458	95th
Elderly	Finland	413	0.0086504675	95th
Elderly	France	264	0.0053049130	95th
Elderly	Hungary	206	0.0027647849	95th
Elderly	Ireland	149	0.0064539234	95th
Elderly	Italy	289	0.0078837387	95th
Elderly	Netherlands	173	0.0076905019	95th
Elderly	Netherlands	289	0.0067622862	95th
Elderly	Romania	83	0.0063917123	95th
Elderly	Sweden	295	0.0104221110	95th
Elderly	United Kingdom	166	0.0060098262	95th
Very elderly	Austria	25	0.0000000000	75th
Very elderly	Belgium	704	0.0071588823	95th
Very elderly	Germany	490	0.0070466667	95th
Very elderly	Denmark	12	0.0028655477	75th
Very elderly	France	84	0.0053826988	95th
Very elderly	Hungary	80	0.0025079570	95th
Very elderly	Ireland	77	0.0055575139	95th
Very elderly	Italy	228	0.0057559903	95th
Very elderly	Netherlands	450	0.0067874889	95th
Very elderly	Romania	45	0.0039666667	90th
Very elderly	Sweden	72	0.0079179395	95th
Very elderly	United Kingdom	139	0.0063528194	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 canthaxanthin + adonirubin residues from red carotenoid-rich *Paracoccus carotinifaciens* NITE SD 00017 calculated based on existing MRL in trout (8 mg/kg muscle).

Population class	Survey's country	Number of subjects	HRP[a]	HRP description
Infants	Bulgaria	523	0.0000000000	95th
Infants	Germany	142	0.0049679524	95th
Infants	Denmark	799	0.0129677064	95th
Infants	Finland	427	0.0061115331	95th
Infants	Italy	9	0.0000000000	50th
Infants	United Kingdom	1251	0.0170157764	95th
Toddlers	Belgium	36	0.0095555556	90th
Toddlers	Bulgaria	428	0.0245245459	95th
Toddlers	Germany	348	0.0115780536	95th
Toddlers	Denmark	917	0.0115907664	95th
Toddlers	Spain	17	0.0000000000	75th
Toddlers	Finland	500	0.0218053634	95th
Toddlers	Italy	36	0.0458613333	90th
Toddlers	Netherlands	322	0.0110847523	95th
Toddlers	United Kingdom	1314	0.0196161833	95th
Toddlers	United Kingdom	185	0.0191118998	95th
Other children	Austria	128	0.0196830189	95th
Other children	Belgium	625	0.0187352381	95th
Other children	Bulgaria	433	0.0259694737	95th
Other children	Germany	293	0.0103291323	95th
Other children	Germany	835	0.0118786111	95th
Other children	Denmark	298	0.0121817059	95th
Other children	Spain	399	0.0318154502	95th
Other children	Spain	156	0.0313322368	95th
Other children	Finland	750	0.0185719606	95th
Other children	France	482	0.0151377094	95th
Other children	Greece	838	0.0206836679	95th
Other children	Italy	193	0.0271997882	95th
Other children	Latvia	187	0.0094715732	95th
Other children	Netherlands	957	0.0116309003	95th
Other children	Netherlands	447	0.0085831718	95th
Other children	Sweden	1473	0.0154654762	95th
Other children	Czechia	389	0.0240000000	95th
Other children	United Kingdom	651	0.0166081571	95th
Adolescents	Austria	237	0.0119282978	95th
Adolescents	Belgium	576	0.0093728807	95th
Adolescents	Cyprus	303	0.0097501848	95th
Adolescents	Germany	393	0.0104220022	95th
Adolescents	Germany	1011	0.0060996773	95th
Adolescents	Denmark	377	0.0054687155	95th
Adolescents	Spain	651	0.0208335129	95th
Adolescents	Spain	209	0.0225527161	95th
Adolescents	Spain	86	0.0132566040	95th
Adolescents	Finland	306	0.0096265785	95th
Adolescents	France	973	0.0089014788	95th
Adolescents	Italy	247	0.0144841551	95th
Adolescents	Latvia	453	0.0090256410	95th
Adolescents	Netherlands	1142	0.0066243056	95th

(Continues)

TABLE A.2 (Continued)

Population class	Survey's country	Number of subjects	HRP[a]	HRP description
Adolescents	Sweden	1018	0.0103105402	95th
Adolescents	Czechia	298	0.0172184874	95th
Adolescents	United Kingdom	666	0.0081257067	95th
Adults	Austria	308	0.0112208310	95th
Adults	Belgium	1292	0.0108062547	95th
Adults	Germany	10,419	0.0102051282	95th
Adults	Denmark	1739	0.0053234571	95th
Adults	Spain	981	0.0188354430	95th
Adults	Spain	410	0.0183880339	95th
Adults	Finland	1295	0.0138333811	95th
Adults	France	2276	0.0082965544	95th
Adults	Hungary	1074	0.0072069597	95th
Adults	Ireland	1274	0.0089435319	95th
Adults	Italy	2313	0.0123607083	95th
Adults	Latvia	1271	0.0113383085	95th
Adults	Netherlands	2055	0.0088721622	95th
Adults	Romania	1254	0.0086880952	95th
Adults	Sweden	1430	0.0144367368	95th
Adults	Czechia	1666	0.0114986737	95th
Adults	United Kingdom	1265	0.0091660376	95th
Elderly	Austria	67	0.0110633502	95th
Elderly	Belgium	511	0.0112969589	95th
Elderly	Germany	2006	0.0116649639	95th
Elderly	Denmark	274	0.0059941947	95th
Elderly	Finland	413	0.0145386008	95th
Elderly	France	264	0.0089158201	95th
Elderly	Hungary	206	0.0046466974	95th
Elderly	Ireland	149	0.0108469302	95th
Elderly	Italy	289	0.0132499810	95th
Elderly	Netherlands	173	0.0129252132	95th
Elderly	Netherlands	289	0.0113651869	95th
Elderly	Romania	83	0.0107423736	95th
Elderly	Sweden	295	0.0175161529	95th
Elderly	United Kingdom	166	0.0101005482	95th
Very elderly	Austria	25	0.0000000000	75th
Very elderly	Belgium	704	0.0120317349	95th
Very elderly	Germany	490	0.0118431373	95th
Very elderly	Denmark	12	0.0048160466	75th
Very elderly	France	84	0.0090465526	95th
Very elderly	Hungary	80	0.0042150538	95th
Very elderly	Ireland	77	0.0093403595	95th
Very elderly	Italy	228	0.0096739333	95th
Very elderly	Netherlands	450	0.0114075444	95th
Very elderly	Romania	45	0.0066666667	90th
Very elderly	Sweden	72	0.0133074614	95th
Very elderly	United Kingdom	139	0.0106770074	95th

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

TABLE A.3 Chronic dietary exposure per population class, country and survey of consumers (mg/kg bw per day) to canthaxanthin + adonirubin residues from red carotenoid-rich *Paracoccus carotinifaciens* NITE SD 00017 calculated based on existing MRL in salmon (10 mg/kg muscle).

Population class	Survey's country	Number of subjects	HRP[a]	HRP description
Infants	Bulgaria	523	0.0000000000	95th
Infants	Germany	142	0.0062099405	95th
Infants	Denmark	799	0.0162096330	95th
Infants	Finland	427	0.0076394164	95th
Infants	Italy	9	0.0000000000	50th
Infants	United Kingdom	1251	0.0212697205	95th
Toddlers	Belgium	36	0.0119444444	90th
Toddlers	Bulgaria	428	0.0306556824	95th
Toddlers	Germany	348	0.0144725670	95th
Toddlers	Denmark	917	0.0144884580	95th
Toddlers	Spain	17	0.0000000000	75th
Toddlers	Finland	500	0.0272567042	95th
Toddlers	Italy	36	0.0573266667	90th
Toddlers	Netherlands	322	0.0138559404	95th
Toddlers	United Kingdom	1314	0.0245202292	95th
Toddlers	United Kingdom	185	0.0238898747	95th
Other children	Austria	128	0.0246037736	95th
Other children	Belgium	625	0.0234190476	95th
Other children	Bulgaria	433	0.0324618421	95th
Other children	Germany	293	0.0129114154	95th
Other children	Germany	835	0.0148482639	95th
Other children	Denmark	298	0.0152271324	95th
Other children	Spain	399	0.0397693127	95th
Other children	Spain	156	0.0391652961	95th
Other children	Finland	750	0.0232149508	95th
Other children	France	482	0.0189221368	95th
Other children	Greece	838	0.0258545849	95th
Other children	Italy	193	0.0339997353	95th
Other children	Latvia	187	0.0118394665	95th
Other children	Netherlands	957	0.0145386254	95th
Other children	Netherlands	447	0.0107289648	95th
Other children	Sweden	1473	0.0193318452	95th
Other children	Czechia	389	0.0300000000	95th
Other children	United Kingdom	651	0.0207601964	95th
Adolescents	Austria	237	0.0149103722	95th
Adolescents	Belgium	576	0.0117161009	95th
Adolescents	Cyprus	303	0.0121877310	95th
Adolescents	Germany	393	0.0130275028	95th
Adolescents	Germany	1011	0.0076245967	95th
Adolescents	Denmark	377	0.0068358944	95th
Adolescents	Spain	651	0.0260418911	95th
Adolescents	Spain	209	0.0281908951	95th
Adolescents	Spain	86	0.0165707550	95th
Adolescents	Finland	306	0.0120332231	95th
Adolescents	France	973	0.0111268485	95th
Adolescents	Italy	247	0.0181051939	95th
Adolescents	Latvia	453	0.0112820513	95th
Adolescents	Netherlands	1142	0.0082803819	95th

(Continues)

TABLE A.3 (Continued)

Population class	Survey's country	Number of subjects	HRP[a]	HRP description
Adolescents	Sweden	1018	0.0128881752	95th
Adolescents	Czechia	298	0.0215231092	95th
Adolescents	United Kingdom	666	0.0101571333	95th
Adults	Austria	308	0.0140260387	95th
Adults	Belgium	1292	0.0135078184	95th
Adults	Germany	10,419	0.0127564103	95th
Adults	Denmark	1739	0.0066543213	95th
Adults	Spain	981	0.0235443038	95th
Adults	Spain	410	0.0229850424	95th
Adults	Finland	1295	0.0172917263	95th
Adults	France	2276	0.0103706931	95th
Adults	Hungary	1074	0.0090086996	95th
Adults	Ireland	1274	0.0111794148	95th
Adults	Italy	2313	0.0154508854	95th
Adults	Latvia	1271	0.0141728856	95th
Adults	Netherlands	2055	0.0110902028	95th
Adults	Romania	1254	0.0108601190	95th
Adults	Sweden	1430	0.0180459209	95th
Adults	Czechia	1666	0.0143733422	95th
Adults	United Kingdom	1265	0.0114575471	95th
Elderly	Austria	67	0.0138291878	95th
Elderly	Belgium	511	0.0141211986	95th
Elderly	Germany	2006	0.0145812049	95th
Elderly	Denmark	274	0.0074927433	95th
Elderly	Finland	413	0.0181732510	95th
Elderly	France	264	0.0111447751	95th
Elderly	Hungary	206	0.0058083717	95th
Elderly	Ireland	149	0.0135586627	95th
Elderly	Italy	289	0.0165624762	95th
Elderly	Netherlands	173	0.0161565165	95th
Elderly	Netherlands	289	0.0142064836	95th
Elderly	Romania	83	0.0134279670	95th
Elderly	Sweden	295	0.0218951911	95th
Elderly	United Kingdom	166	0.0126256852	95th
Very elderly	Austria	25	0.0000000000	75th
Very elderly	Belgium	704	0.0150396687	95th
Very elderly	Germany	490	0.0148039216	95th
Very elderly	Denmark	12	0.0060200582	75th
Very elderly	France	84	0.0113081907	95th
Very elderly	Hungary	80	0.0052688172	95th
Very elderly	Ireland	77	0.0116754494	95th
Very elderly	Italy	228	0.0120924167	95th
Very elderly	Netherlands	450	0.0142594305	95th
Very elderly	Romania	45	0.0083333333	90th
Very elderly	Sweden	72	0.0166343267	95th
Very elderly	United Kingdom	139	0.0133462593	95th

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

TABLE A.4 Chronic dietary exposure per population class, country and survey of consumers (mg/kg bw per day) to canthaxanthin + adonirubin residues from red carotenoid-rich *Paracoccus carotinifaciens* NITE SD 00017 calculated based on proposed MRL in trout/salmon (5 mg/kg muscle).

Population class	Survey's country	Number of subjects	HRP[a]	HRP description
Infants	Bulgaria	523	0.0000000000	95th
Infants	Germany	142	0.0031049702	95th
Infants	Denmark	799	0.0081048165	95th
Infants	Finland	427	0.0038197082	95th
Infants	Italy	9	0.0000000000	50th
Infants	United Kingdom	1251	0.0106348602	95th
Toddlers	Belgium	36	0.0059722222	90th
Toddlers	Bulgaria	428	0.0153278412	95th
Toddlers	Germany	348	0.0072362835	95th
Toddlers	Denmark	917	0.0072442290	95th
Toddlers	Spain	17	0.0000000000	75th
Toddlers	Finland	500	0.0136283521	95th
Toddlers	Italy	36	0.0286633333	90th
Toddlers	Netherlands	322	0.0069279702	95th
Toddlers	United Kingdom	1314	0.0122601146	95th
Toddlers	United Kingdom	185	0.0119449374	95th
Other children	Austria	128	0.0123018868	95th
Other children	Belgium	625	0.0117095238	95th
Other children	Bulgaria	433	0.0162309211	95th
Other children	Germany	293	0.0064557077	95th
Other children	Germany	835	0.0074241320	95th
Other children	Denmark	298	0.0076135662	95th
Other children	Spain	399	0.0198846564	95th
Other children	Spain	156	0.0195826480	95th
Other children	Finland	750	0.0116074754	95th
Other children	France	482	0.0094610684	95th
Other children	Greece	838	0.0129272925	95th
Other children	Italy	193	0.0169998676	95th
Other children	Latvia	187	0.0059197332	95th
Other children	Netherlands	957	0.0072693127	95th
Other children	Netherlands	447	0.0053644824	95th
Other children	Sweden	1473	0.0096659226	95th
Other children	Czechia	389	0.0150000000	95th
Other children	United Kingdom	651	0.0103800982	95th
Adolescents	Austria	237	0.0074551861	95th
Adolescents	Belgium	576	0.0058580504	95th
Adolescents	Cyprus	303	0.0060938655	95th
Adolescents	Germany	393	0.0065137514	95th
Adolescents	Germany	1011	0.0038122983	95th
Adolescents	Denmark	377	0.0034179472	95th
Adolescents	Spain	651	0.0130209456	95th
Adolescents	Spain	209	0.0140954476	95th
Adolescents	Spain	86	0.0082853775	95th
Adolescents	Finland	306	0.0060166116	95th
Adolescents	France	973	0.0055634243	95th
Adolescents	Italy	247	0.0090525970	95th
Adolescents	Latvia	453	0.0056410256	95th
Adolescents	Netherlands	1142	0.0041401910	95th

(Continues)

TABLE A.4 (Continued)

Population class	Survey's country	Number of subjects	HRP[a]	HRP description
Adolescents	Sweden	1018	0.0064440876	95th
Adolescents	Czechia	298	0.0107615546	95th
Adolescents	United Kingdom	666	0.0050785667	95th
Adults	Austria	308	0.0070130193	95th
Adults	Belgium	1292	0.0067539092	95th
Adults	Germany	10,419	0.0063782051	95th
Adults	Denmark	1739	0.0033271607	95th
Adults	Spain	981	0.0117721519	95th
Adults	Spain	410	0.0114925212	95th
Adults	Finland	1295	0.0086458632	95th
Adults	France	2276	0.0051853465	95th
Adults	Hungary	1074	0.0045043498	95th
Adults	Ireland	1274	0.0055897074	95th
Adults	Italy	2313	0.0077254427	95th
Adults	Latvia	1271	0.0070864428	95th
Adults	Netherlands	2055	0.0055451014	95th
Adults	Romania	1254	0.0054300595	95th
Adults	Sweden	1430	0.0090229605	95th
Adults	Czechia	1666	0.0071866711	95th
Adults	United Kingdom	1265	0.0057287735	95th
Elderly	Austria	67	0.0069145939	95th
Elderly	Belgium	511	0.0070605993	95th
Elderly	Germany	2006	0.0072906025	95th
Elderly	Denmark	274	0.0037463717	95th
Elderly	Finland	413	0.0090866255	95th
Elderly	France	264	0.0055723876	95th
Elderly	Hungary	206	0.0029041859	95th
Elderly	Ireland	149	0.0067793314	95th
Elderly	Italy	289	0.0082812381	95th
Elderly	Netherlands	173	0.0080782583	95th
Elderly	Netherlands	289	0.0071032418	95th
Elderly	Romania	83	0.0067139835	95th
Elderly	Sweden	295	0.0109475956	95th
Elderly	United Kingdom	166	0.0063128426	95th
Very elderly	Austria	25	0.0000000000	75th
Very elderly	Belgium	704	0.0075198343	95th
Very elderly	Germany	490	0.0074019608	95th
Very elderly	Denmark	12	0.0030100291	75th
Very elderly	France	84	0.0056540954	95th
Very elderly	Hungary	80	0.0026344086	95th
Very elderly	Ireland	77	0.0058377247	95th
Very elderly	Italy	228	0.0060462083	95th
Very elderly	Netherlands	450	0.0071297152	95th
Very elderly	Romania	45	0.0041666667	90th
Very elderly	Sweden	72	0.0083171634	95th
Very elderly	United Kingdom	139	0.0066731296	95th

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

TABLE A.5 Chronic dietary exposure per population class, country and survey of consumers (mg/kg bw per day) to canthaxanthin + adonirubin residues from red carotenoid-rich *Paracoccus carotinifaciens* NITE SD 00017 calculated based on proposed MRL in trout/salmon (5 mg/kg muscle) and existing MRLs in poultry (2.5 mg/kg skin/fat, 15 mg/kg liver, 8.1 mg/kg whole egg).

Population class	Survey's country	Number of subjects	HRP[a]	HRP description
Infants	Bulgaria	523	0.0295425218	95th
Infants	Germany	142	0.0071013211	95th
Infants	Denmark	799	0.0126831412	95th
Infants	Finland	427	0.0046619796	95th
Infants	Italy	9	0.0000000000	50th
Infants	United Kingdom	1251	0.0221930993	95th
Toddlers	Belgium	36	0.0183966594	90th
Toddlers	Bulgaria	428	0.0385329845	95th
Toddlers	Germany	348	0.0226049313	95th
Toddlers	Denmark	917	0.0180122437	95th
Toddlers	Spain	17	0.0329787844	75th
Toddlers	Finland	500	0.0171376984	95th
Toddlers	Italy	36	0.0376773699	90th
Toddlers	Netherlands	322	0.0247201657	95th
Toddlers	United Kingdom	1314	0.0307526485	95th
Toddlers	United Kingdom	185	0.0274996860	95th
Other children	Austria	128	0.0231133609	95th
Other children	Belgium	625	0.0215155028	95th
Other children	Bulgaria	433	0.0380361724	95th
Other children	Germany	293	0.0224972095	95th
Other children	Germany	835	0.0232480974	95th
Other children	Denmark	298	0.0182667992	95th
Other children	Spain	399	0.0346943531	95th
Other children	Spain	156	0.0425867801	95th
Other children	Finland	750	0.0204681918	95th
Other children	France	482	0.0268136075	95th
Other children	Greece	838	0.0326378847	95th
Other children	Italy	193	0.0311447529	95th
Other children	Latvia	187	0.0200220170	95th
Other children	Netherlands	957	0.0227084231	95th
Other children	Netherlands	447	0.0197769173	95th
Other children	Sweden	1473	0.0189405524	95th
Other children	Czechia	389	0.0267404243	95th
Other children	United Kingdom	651	0.0212877672	95th
Adolescents	Austria	237	0.0144073775	95th
Adolescents	Belgium	576	0.0109846479	95th
Adolescents	Cyprus	303	0.0115588716	95th
Adolescents	Germany	393	0.0187298095	95th
Adolescents	Germany	1011	0.0096067721	95th
Adolescents	Denmark	377	0.0085276849	95th
Adolescents	Spain	651	0.0220150298	95th
Adolescents	Spain	209	0.0248407149	95th
Adolescents	Spain	86	0.0146678501	95th
Adolescents	Finland	306	0.0090255836	95th
Adolescents	France	973	0.0140350384	95th
Adolescents	Italy	247	0.0160495718	95th
Adolescents	Latvia	453	0.0155985999	95th
Adolescents	Netherlands	1142	0.0122253500	95th

(Continues)

TABLE A.5 (Continued)

Population class	Survey's country	Number of subjects	HRP[a]	HRP description
Adolescents	Sweden	1018	0.0125638201	95th
Adolescents	Czechia	298	0.0195888480	95th
Adolescents	United Kingdom	666	0.0112887366	95th
Adults	Austria	308	0.0116144563	95th
Adults	Belgium	1292	0.0107307774	95th
Adults	Germany	10,419	0.0109307402	95th
Adults	Denmark	1739	0.0075375787	95th
Adults	Spain	981	0.0175754124	95th
Adults	Spain	410	0.0169648178	95th
Adults	Finland	1295	0.0137165716	95th
Adults	France	2276	0.0104962006	95th
Adults	Hungary	1074	0.0125170878	95th
Adults	Ireland	1274	0.0105116610	95th
Adults	Italy	2313	0.0126736930	95th
Adults	Latvia	1271	0.0146564547	95th
Adults	Netherlands	2055	0.0104692288	95th
Adults	Romania	1254	0.0151611125	95th
Adults	Sweden	1430	0.0161737693	95th
Adults	Czechia	1666	0.0119670902	95th
Adults	United Kingdom	1265	0.0105546939	95th
Elderly	Austria	67	0.0148730274	95th
Elderly	Belgium	511	0.0104632476	95th
Elderly	Germany	2006	0.0106927589	95th
Elderly	Denmark	274	0.0087101570	95th
Elderly	Finland	413	0.0124664943	95th
Elderly	France	264	0.0108186600	95th
Elderly	Hungary	206	0.0098739020	95th
Elderly	Ireland	149	0.0131396483	95th
Elderly	Italy	289	0.0122267132	95th
Elderly	Netherlands	173	0.0104713904	95th
Elderly	Netherlands	289	0.0115192457	95th
Elderly	Romania	83	0.0153391266	95th
Elderly	Sweden	295	0.0175284436	95th
Elderly	United Kingdom	166	0.0109637065	95th
Very elderly	Austria	25	0.0070351759	75th
Very elderly	Belgium	704	0.0113161930	95th
Very elderly	Germany	490	0.0108696817	95th
Very elderly	Denmark	12	0.0060964295	75th
Very elderly	France	84	0.0104695165	95th
Very elderly	Hungary	80	0.0101788342	95th
Very elderly	Ireland	77	0.0116206972	95th
Very elderly	Italy	228	0.0108682818	95th
Very elderly	Netherlands	450	0.0108584144	95th
Very elderly	Romania	45	0.0128392514	90th
Very elderly	Sweden	72	0.0186499053	95th
Very elderly	United Kingdom	139	0.0104998682	95th

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