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SCIENTIFIC OPINION

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Safety of an extension of use of oil from *Schizochytrium limacinum* (strain FCC-3204) as a novel food pursuant to Regulation (EU) 2015/2283

EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) | Dominique Turck | Torsten Bohn | Montaña Cámara | Jacqueline Castenmiller | Stefaan De Henauw | Karen Ildico Hirsch-Ernst | Ángeles Jos | Alexandre Maciuk | Inge Mangelsdorf | Breige McNulty | Harry J. McArdle | Androniki Naska | Kristina Pentieva | Alfonso Siani | Frank Thies | Margarita Aguilera-Gómez | Francesco Cubadda | Thomas Frenzel | Marina Heinonen | Monika Neuhäuser-Berthold | Morten Poulsen | Miguel Prieto Maradona | Josef Rudolf Schlatter | Alexandros Siskos | Henk van Loveren | Irene Nuin Garciarena | Emanuela Turla | Silvia Valtueña Martínez | Helle Katrine Knutsen

Correspondence: nif@efsa.europa.eu

Abstract

Following a request from the European Commission, the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) was asked to deliver an opinion on the safety of an extension of use of oil from *Schizochytrium limacinum* (strain FCC-3204) as a novel food (NF) pursuant to Regulation (EU) 2015/2283. The extension of use pertains to the use of the NF as a food ingredient in protein products at a maximum use level of 1 g of docosahexaenoic acid (DHA) in 100 g of product. The Panel considers that the information provided on the composition and the production process is sufficiently described and does not raise safety concerns. *S. limacinum* was attributed the qualified presumption of safety (QPS) status with the qualification 'for production purposes only'. Data provided demonstrated the absence of viable cells in the NF. Under the proposed extension of use, the highest intake estimate (at the 95th percentile) of DHA from the NF in protein products is 6.3 mg DHA/kg bw per day for adolescents. The Panel notes that the exposure to DHA from the new intended use of the NF in protein products is very low compared to the exposure to DHA from the already authorised food categories (excluding food supplements). The Panel concludes that the NF (oil from *S. limacinum* (FCC-3204)) is safe under the new intended use.

KEYWORDS

alga, DHA, docosahexaenoic acid, extension of use, novel food, safety, *Schizochytrium*

CONTENTS

1 | INTRODUCTION

1.1 | Background and Terms of Reference as provided by the requestor

On 22 June 2023, the company Fermentalg submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 for an amendment of the conditions of use of the novel food *Schizochytrium* sp. (FCC-3204) oil.

The applicant requests to authorise the use of the novel food *Schizochytrium* sp. (FCC-3204) oil in protein products at levels of 1000 mg DHA/100 g of product, intended for the general population.

The applicant also requests data protection under Article 26 of Regulation (EU) 2015/2283. In accordance with Article 29(I)(a) of Regulation (EC) No 178/2002, the European Commission asks EFSA to provide a scientific opinion on an amendment of the conditions of use of the novel food *Schizochytrium* sp. (FCC-3204) oil in accordance with Article 10(3) of Regulation (EU) 2015/2283.

The Commission also asks EFSA to evaluate and inform the Commission as to whether and if so, to what extent, the requirements of Article 26(2)(c) of Regulation (EU) 2015/2283 are fulfilled in elaborating its opinion on an amendment of the conditions of use of the novel food *Schizochytrium* sp. (FCC-3204) oil regarding the proprietary data for which the applicant is requesting data protection.

1.2 | Additional information

In 2012, the EFSA NDA Panel adopted a Scientific Opinion on the tolerable upper intake level of eicosapentaenoic acid (EPA), DHA and docosapentaenoic acid (DPA) (EFSA NDA Panel, 2012). The Panel concluded that a tolerable upper intake level for DHA could not be established. However, the Panel noted that supplemental intakes of EPA and DHA combined at doses up to 5 g/day, and supplemental intakes of EPA alone up to 1.8 g/day, do not raise safety concerns for the adult population. The Panel also considered that supplemental intakes of DHA alone up to about 1 g/day do not raise safety concerns for the general population. Limited data were available on the effects of long-term supplementation with DHA alone at higher doses. The Panel noted that specific dietary recommendations for DHA for European adults and children were well below this amount.

In 2021, the EFSA NDA Panel adopted two scientific opinions on the safety of the NF, which is the subject of this extension of use [oil from *S. limacinum* (strain FCC-3204)] for use in food supplements and infant formulae (IF) and follow-on formulae (FOF) (EFSA NDA Panel, 2021a, 2021b). The Panel concluded that the oil from *S. limacinum* (strain FCC-3204) is safe for the use in food supplements at the maximum intake level of 1 g DHA/day for the target population (adults, excluding pregnant and lactating women) (EFSA NDA Panel, 2021a). The Panel concluded that oil from *S. limacinum* (strain FCC-3204) is safe for the use in IF and FOF (EFSA NDA Panel, 2021b).

2 | DATA AND METHODOLOGIES

2.1 | Data

The safety assessment of this NF is based on data supplied in the application. In addition, information provided by the EFSA Panel on Biological Hazards has also been considered (EFSA BIOHAZ Panel, 2020).

Administrative and scientific requirements for NF applications referred to in Article 10 of Regulation (EU) 2015/2283 are listed in Commission Implementing Regulation (EU) 2017/2469.[1]

A common and structured format on the presentation of NF applications is described in the EFSA guidance on the preparation and presentation of a NF application (EFSA NDA Panel, 2021c). As indicated in this guidance, it is the duty of the applicant to provide all the available (proprietary, confidential and published) scientific data, (including both data in favour and not in favour) that are pertinent to the safety of the NF.

The applicant has submitted a confidential and a non-confidential version of a dossier following the 'Guidance on the preparation and submission of an application for authorisation of a NF in the context of Regulation (EU) 2015/2283 (Revision 1)' (EFSA NDA Panel, 2021c) and the 'Administrative guidance for the preparation of applications on NF pursuant to Article 10 of Regulation (EU) 2015/2283' (EFSA, 2021).

In accordance with Art. 38 of Regulation (EC) No 178/2002[2] 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,[3] the non-confidential version of the dossier has been published on Open.EFSA.[4]

[1]Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods. OJ L 351, 30.12.2017, pp. 64–71.

[2]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.

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

[4]The non-confidential version of the dossier has been published on Open.EFSA and is available at the following link: https://open.efsa.europa.eu/consultations/a0cTk000004GjV9IAK?search=schizochytrium.

According to Art. 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,[2] EFSA carried out a public consultation on the non-confidential version of the technical dossier from 17 July 2024 to 7 August 2024 for which no comments were received.

This NF application includes a request for protection of proprietary data in accordance with Article 26 of Regulation (EU) 2015/2283. The data requested by the applicant to be protected comprise: taxonomic analysis (Annex 3 – under Section 3.2 'Identity of the NF'), viable cell analysis (Annex 35 – under Section 3.3 'Production process'), certificate of analyses of protein products to which the NF was added (Annex 51 – under Section 3.4 'Compositional data').

2.2 | Methodologies

The assessment follows the methodology set out in the EFSA guidance on NF applications (EFSA NDA Panel, 2021c) and the principles described in the relevant existing guidance documents from the EFSA Scientific Committee. The legal provisions for the assessment are laid down in Article 11 of Regulation (EU) 2015/2283 and in Article 7 of Commission Implementing Regulation (EU) 2017/2469.

This assessment concerns only the risks that might be associated with consumption of the NF under the proposed conditions of use, and is not an assessment of the efficacy of the NF with regard to any claimed benefit.

3 | ASSESSMENT

3.1 | Introduction

The NF, which is the subject of this request for extension of use, is the oil produced by the microalga *S. limacinum* (strain FCC-3204). The production process involves the controlled growth of these microalgae followed by extraction and refinement of the oil produced by the microalgae. The oil is a mixture of triglycerides composed of polyunsaturated fatty acids (PUFA), in which DHA represents more than 55%.

In 2021, the EFSA NDA Panel assessed the safety of this NF [oil from *S. limacinum* (strain FCC-3204)]. The Panel concluded that the NF was safe for the use in food supplements at the maximum intake level of 1 g DHA/day for the target population (adults, excluding pregnant and lactating women) and for the use in IF and FOF (EFSA NDA Panel, 2021a, 2021b). These uses were authorised by Commission Implementing Regulation (EU) 2021/1326.[5]

Several other uses for oils obtained from *Schizochytrium* sp. have been authorised in the Union list (e.g. dairy products, fats, fruit and vegetables puree, breakfast cereals, bakery products, non-alcoholic beverages).

This opinion addresses the applicant's request to extend the use of the oil from *S. limacinum* (strain FCC-3204) as an ingredient in protein products, at a maximum use level of 1 g DHA/100 g of product.

3.2 | Identity of the NF

The NF under assessment in the present application is an oil containing DHA which is obtained from the microalga *Schizochytrium* sp. FCC-3204.

In 2021, the Panel concluded that the *Schizochytrium* strain FCC-3204 used for the production of the NF is a member of the species *S. limacinum* (EFSA NDA Panel, 2021a, 2021b).

3.3 | Production process

The unicellular microalgae *S. limacinum* (FCC-3204) are grown under controlled conditions (time, temperature, pH and aeration) in a liquid culture medium containing the necessary nutrients. After lysing microalgal biomass via an enzymatic hydrolysis, the crude oil is recovered by centrifugation. The crude oil is subsequently refined using standard techniques (neutralisation, decolouration and deodorisation at high temperature). At different steps of the process, EU authorised antioxidants are added to ensure stability. The NF is finally packaged in airtight and light-proof containers and stored at a temperature of –20°C.

The production process has already been assessed by the Panel and did not raise safety concerns (EFSA NDA Panel, 2021a, 2021b).

3.4 | Compositional data

The NF consists of triglycerides composed of PUFA in which DHA is the predominant one (more than 55%), making up together with DPA and palmitic acid more than 92% of the total fatty acids (FAs).

[5]Commission Implementing Regulation (EU) 2021/1326 of 10 August 2021 authorising the placing on the market of *Schizochytrium* sp. (FCC-3204) oil as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470. https://eur-lex.europa.eu/eli/reg_impl/2021/1326/oj.

The batch-to-batch analysis was evaluated by the Panel in 2021. The Panel concluded that the information provided on the composition was sufficient for characterising the NF and did not raise a safety concern (EFSA NDA Panel, 2021a, 2021b).

3.4.1 | Stability

Stability of the NF

Based on the stability studies provided and evaluated by the Panel in 2021, the applicant proposed a shelf life for the NF of 2 years from the date of manufacture, to be stored at a temperature at or below –15°C (frozen conditions), away from light, moisture, heat and oxygen.

The Panel considers that the data provided sufficient information with respect to the stability of the NF at the proposed conditions of storage for 2 years.

Stability of the NF under the intended conditions of use

The applicant assessed the behaviour of the NF in matrices used for the production of protein products such as fish analogues. An extrusion-based process using a soy concentrate was used to produce two protein products added respectively with 5% and 10% of the NF. Extrusion-based processes, due to the use of high temperatures in combination with moist conditions, are likely to damage algal oils. The applicant presented data on markers of oxidation (peroxide and p-anisidine values) for the control (extruded soy mass only) and the two extruded soy mass products to which the NF was added. Compared to the control, the protein products with the NF showed reduced values of the markers of oxidation. The Panel notes that the data provided related only to the time point after adding the NF to protein products and did not cover a longer time span. However, considering the stability data of the NF at 25°C/60% relative humidity up to 113 weeks, the Panel expects the NF to be stable under the intended conditions of use.

3.5 | Specifications

Parameters and corresponding values of the current specifications presented in the Union list for the NF are reported in Table 1.

TABLE 1 Specifications of the NF (as currently reported in the Union list).

Parameter	Specifications in the union list
Acid value (mg KOH/g)	≤ 0.5
Peroxide value (PV) (meq/kg)	≤ 5.0
Moisture and volatiles (%)	≤ 0.05
Unsaponifiables (%)	≤ 4.5
Trans-fatty acids (%)	≤ 1.0
DHA content (%)	≥ 32.0
p-Anisidine value	≤10

Abbreviation: DHA, docosahexaenoic acid.

The applicant proposed to amend the current specifications of the Union list by increasing the DHA content from 32% to 55% and reducing the percentage of unsaponifiables from 4.5% to 3.5%. The Panel considers that the proposed changes in the specifications are not deemed necessary from a safety point of view.

The Panel considers that the information provided on the specifications of the NF is sufficient and does not raise safety concerns.

3.6 | History of use of the NF and/or of its source

3.6.1 | History of use of the source

The source of the NF is a microalga belonging to the genus *Schizochytrium*. Table 2 presents the different entries referring to oils from microalgae of the genus *Schizochytrium* which are authorised in the Union list. This genus has been used as a source of DHA-oils since 2003, the year of the first authorisation of DHA-oil from *Schizochytrium* sp. as NF. The first assessment of DHA-oil from *Schizochytrium* sp. involved the strain ATCC 20888 (United Kingdom, 2002). Following two substantial equivalence assessments (Anses, 2018; FSAI, 2014), two other strains (FCC-1324 and FCC-3204) were recognised as valid

sources to produce DHA-oils equivalent to the original NF. On the Union list, the DHA-oils produced from these strains are commonly referred to as '*Schizochytrium* sp. oil'. The following strains belonging to the genus *Schizochytrium* have been authorised for the production of DHA-oils to be used in IF and FOF: *Schizochytrium* sp. ATCC PTA-9695, *Schizochytrium* sp. T18, *S. limacinum* WZU477 (EFSA NDA Panel, 2020) and *S. limacinum* FCC-3204 (EFSA NDA Panel, 2021a, 2021b).

TABLE 2 Overview of the entries referring to oils from the genus *Schizochytrium* which are authorised in the Union list.

Novel food	Year of 1st authorisation	Decisions	Remarks
Schizochytrium sp. Oil	2003	Decision 2003/427/EC[6]	Authorised to be added to foods but not in IF and FOF
Schizochytrium sp. oil rich in DHA and EPA	2012	Assessed by UK and authorised under Regulation (EC) No 258/97[7]	Authorised to be added to foods but not in IF and FOF
Schizochytrium sp. (ATCC PTA-9695) oil	2015	Decision (EU) 2015/545[8]	Authorised use in IF and FOF
Schizochytrium sp. (T18) oil	2017	Assessed by UK and authorised under Regulation (EC) No. 258/97	Authorised use in IF and FOF
Schizochytrium limacinum (WZU477) oil	2021	Regulation (EU) 2021/670[9]	Authorised use in IF and FOF
Schizochytrium limacinum (FCC-3204) oil	2021	Regulation (EU) 2021/1326[10]	Authorised use in IF and FOF

Abbreviations: DHA, docosahexaenoic acid; EPA, eicosapentaenoic acid; FOF, follow-on formulae; IF, infant formulae; UK, United Kingdom.

3.6.2 | History of use of the NF

The NF application under assessment is an extension of use for the oil referred to as *Schizochytrium* sp. oil which has been authorised in 2003.[11] The entry *Schizochytrium* sp. oil has been authorised to be added to several foods (e.g. dairy products, fats, fruit and vegetables puree, breakfast cereals, bakery products, non-alcoholic beverages). Furthermore, the oil obtained from the strain *S. limacinum* FCC-3204 has been recently subject to an extension of use in food supplements and in IF and FOF, which were positively assessed by EFSA (EFSA NDA Panel, 2021a, 2021b). Appendix A presents the authorised uses for the oils obtained from *Schizochytrium* sp. and from the strain FCC-3204 as listed in the Union list.

3.7 | Proposed uses and use levels and anticipated intake

3.7.1 | Target population

The target population proposed by the applicant is the general population.

3.7.2 | Proposed uses and use levels

With the current application, the applicant proposed to extend the use of the NF as an ingredient in protein products, such as fish analogues and seafood analogues. The new intended use corresponds to category 12.9 'Protein products, excluding dairy analogues' as defined by Regulation (EC) No 1333/2008 on food additives. The maximum use level proposed by the applicant is 1 g DHA/100 g of protein products.

[6]Commission Decision 2003/427/EC: Commission Decision of 5 June 2003 authorising the placing on the market of oil rich in DHA (docosahexaenoic acid) from the microalgae *Schizochytrium* sp. as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council; OJ L 144, 16.6.2003, p. 13–14.

[7]Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients.

[8]Commission Implementing Decision (EU) 2015/545 of 31 March 2015 authorising the placing on the market of oil from the microalgae *Schizochytrium* sp. (ATCC PTA-9695) as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council; OJ L 90, 2.4.2015, p. 7–10.

[9]Commission Implementing Regulation (EU) 2021/670 of 23 April 2021 authorising the placing on the market of *Schizochytrium* sp. (WZU477) oil as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470; OJ L 141, 26.4.2021, p. 14–18.

[10]Commission Implementing Regulation (EU) 2021/1326 of 10 August 2021 authorising the placing on the market of *Schizochytrium* sp. (FCC-3204) oil as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470. OJ L 288, 11.8.2021, p. 24–27.

[11]Commission Decision 2003/427/EC: Commission Decision of 5 June 2003 authorising the placing on the market of oil rich in DHA (docosahexaenoic acid) from the microalgae *Schizochytrium* sp. as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council. OJ L 144, 16.6.2003, p. 13–14.

3.7.3 | Anticipated intake of DHA from the new intended use of the NF

The anticipated daily intake of DHA from the NF from the new intended use in 'Protein products, excluding dairy analogues' has been estimated using the EFSA Food Additives Intake Model (FAIM) tool,[12] which is based on data from the EFSA Comprehensive European Food Consumption Database (EFSA, 2011). The lowest and highest means and 95th percentiles anticipated daily intakes of DHA from the new intended use of the NF among the EU dietary surveys are presented in Tables 3, 4 (on a mg/kg bw per day and on a mg/day basis, respectively). The estimated daily intakes of DHA from the new intended use of the NF for each population group from each EU dietary survey are available in the excel file annexed to this scientific opinion (see Annex A under 'Supporting Information').

TABLE 3 Intake estimates of DHA from the new intended use (on a mg/kg bw per day basis).

Population group	Age (years)	Mean intake (mg/kg bw per day)		P95 intake (mg/kg bw per day)	
		Lowest[a]	Highest[a]	Lowest[b]	Highest[b]
Infants	< 1	0	0.1	0	0.4
Young children[c]	1–< 3	0	0.6	0	0.7
Other children	3–< 10	0	0.6	0	1.1
Adolescents	10–< 18	0	1.0	0	6.3
Adults[d]	≥ 18	0	0.4	0	1.9

Abbreviations: bw, body weight; P95, 95th percentile.

[a]Intakes are assessed for all EU dietary surveys available in the food comprehensive database on 24/4/2024. The lowest and the highest averages observed among all EU surveys are reported in these columns.

[b]Intakes are assessed for all EU dietary surveys available in the food comprehensive database on 24/4/2024. The lowest and the highest P95 observed among all EU surveys are reported in these columns (P95 based on less than 60 individuals are not considered).

[c]Referred to as 'toddlers' in the EFSA food consumption comprehensive database (EFSA, 2011).

[d]This population group also includes elderly and very elderly.

TABLE 4 Intake estimates of DHA from the new intended use (on a mg/day basis).

Population group	Age (years)	Default body weights (kg)[a]	Mean intake (mg/day)		P95 intake (mg/day)	
			Lowest[b]	Highest[b]	Lowest[c]	Highest[c]
Infants	< 1	5	0	0.5	0	2
Young children[d]	1–< 3	12	0	7.2	0	8.4
Other children	3–< 10	23	0	13.8	0	25.3
Adolescents	10–< 18	61	0	61	0	384.3
Adults[e]	≥ 18	70	0	28	0	133

Abbreviation: P95, 95th percentile.

[a]Default body weights as set by the EFSA Scientific Committee (2012), which were used to calculate the intake estimates in this table.

[b]Intakes are assessed for all EU dietary surveys available in the food comprehensive database on 24/4/2024. The lowest and the highest averages observed among all EU surveys are reported in these columns.

[c]Intakes are assessed for all EU dietary surveys available in the food comprehensive database on 24/4/2024. The lowest and the highest P95 observed among all EU surveys are reported in these columns (P95 based on less than 60 individuals are not considered).

[d]Referred to as 'toddlers' in the EFSA food consumption comprehensive database (EFSA, 2011).

[e]This population group also includes elderly and very elderly.

3.7.3.1 | *Intake estimates of DHA from the NF from the authorised uses (excluding food supplements)*

The NF is currently authorised to be marketed as a food ingredient in several foods (e.g. dairy products, fats, fruit and vegetables puree, breakfast cereals, bakery products, non-alcoholic beverages) at maximum levels of DHA (Appendix A). The authorised uses have been translated into FAIM tool food categories to estimate the intake of DHA from the NF from the currently authorised uses (excluding food supplements) (Appendix B). Regarding the matching of the authorised uses of the NF with FAIM tool food categories, the following considerations should be noted:

- the authorised use in 'Spreadable fats and dressings' (600 mg DHA/100 g) has been matched with the FAIM tool entry 'Fats and oils'. The authorised use in 'Cooking fats' (360 mg DHA/100 g) has been considered to be covered by the FAIM tool entries 'Fats and oils', which was selected in the FAIM tool with a maximum level of 600 mg DHA/100 g;

[12]https://www.efsa.europa.eu/en/applications/food-improvement-agents/tools.

- the maximum uses in IF and FOF have been calculated based on the mandatory addition of DHA to IF and FOF as stated in Commission Delegated Regulation (EU) 2016/127 (i.e. maximum limit for DHA of 50 mg/100 kcal and standard energy content of maximum 70 kcal/100 mL for both IF and FOF);
- the authorised uses 'Foods bearing statements on the absence or reduced presence of gluten' in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014' and 'Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen' are not present in the FAIM tool and these authorised uses were not considered in the intake estimate calculation;
- the authorised use in 'Total diet replacement for weight control' as defined in Regulation (EU) No 609/2013 and 'Meal replacements for weight control' have not been included in the intake estimate since there is no maximum use level expressed per g that can be entered in the FAIM tool;
- the authorised use in 'Foods for special medical purposes' as defined in Regulation (EU) No 609/2013 has not been included in the intake estimate since there is no maximum use level that can be entered in the FAIM tool.

Tables 5, 6 present the intake estimates of DHA (on a mg/kg bw per day and on a mg/day basis, respectively) resulting from the use of the NF as ingredient in currently authorised uses (excluding food supplements). According to the intake estimates, milk, fermented milk and bread and rolls represent the main food contributors. The estimated daily intakes of DHA from the NF for each population group from each EU dietary survey are available in the excel file annexed to this scientific opinion (see Annex B under 'Supporting Information').

TABLE 5 Intake estimates of DHA from the authorised uses in the Union list* (on a mg/kg bw per day basis).

		Mean intake (mg/kg bw per day)		P95 intake (mg/kg bw per day)	
Population group	**Age (years)**	**Lowest[a]**	**Highest[a]**	**Lowest[b]**	**Highest[b]**
Infants	< 1	24.6	77.2	61.6	172.5
Young children[c]	1–< 3	56.3	109.9	112.7	192.5
Other children	3–< 10	41.9	88.5	80.1	137.5
Adolescents	10–< 18	16.2	39.7	35.3	71.0
Adults[d]	≥ 18	11.1	22.8	22.8	45.4

Abbreviations: bw, body weight; P95, 95th percentile.

*Excluding the authorised uses in food supplements, foods for special medical purposes, total diet replacement and meal replacements for weight control, foods bearing statements on the absence or reduced presence of gluten, foods intended to meet the expenditure of intense muscular effort, especially for sportsmen.

[a]Intakes are assessed for all EU dietary surveys available in the food comprehensive database on 24/4/2024. The lowest and the highest averages observed among all EU surveys are reported in these columns.

[b]Intakes are assessed for all EU dietary surveys available in the food comprehensive database on 24/4/2024. The lowest and the highest P95 observed among all EU surveys are reported in these columns (P95 based on less than 60 individuals are not considered).

[c]Referred to as 'toddlers' in the EFSA food consumption comprehensive database (EFSA, 2011).

[d]This population group also includes elderly and very elderly.

TABLE 6 Intake estimates of DHA from the authorised uses in the Union list* (on a mg/day basis).

			Mean intake (mg/day)		P95 intake (mg/day)	
Population group	**Age (years)**	**Default body weights (kg)[a]**	**Lowest[b]**	**Highest[b]**	**Lowest[c]**	**Highest[c]**
Infants	< 1	5	123	386	308	863
Young children[d]	1–< 3	12	676	1319	1352	2310
Other children	3–< 10	23	964	2036	1842	3163
Adolescents	10–< 18	61	988	2422	2153	4331
Adults[e]	≥ 18	70	777	1596	1596	3178

Abbreviation: P95, 95th percentile.

*Excluding the authorised uses in food supplements, foods for special medical purposes, total diet replacement and meal replacements for weight control, foods bearing statements on the absence or reduced presence of gluten, foods intended to meet the expenditure of intense muscular effort, especially for sportsmen.

[a]Default body weights as set by the EFSA Scientific Committee (2012), which were used to calculate the intake estimates in this table.

[b]Intakes are assessed for all EU dietary surveys available in the food comprehensive database on 24/4/2024. The lowest and the highest averages observed among all EU surveys are reported in these columns.

[c]Intakes are assessed for all EU dietary surveys available in the food comprehensive database on 24/4/2024. The lowest and the highest P95 observed among all EU surveys are reported in these columns (P95 based on less than 60 individuals are not considered).

[d]Referred to as 'toddlers' in the EFSA food consumption comprehensive database (EFSA, 2011).

[e]This population group also includes elderly and very elderly.

3.7.3.2 | *Combined intake estimates of DHA from the NF from the extended proposed use and the already authorised uses (excluding food supplements)*

Tables 7, 8 present the combined intake estimates of DHA from the NF from the new intended use in protein products (1 g DHA/100 g of product) and the already authorised uses (excluding food supplements). Add a sentence on the highest dietary surveys The estimated daily intakes of DHA from the NF for each population group from each EU dietary survey are available in the excel file annexed to this scientific opinion (see Annex C under 'Supporting Information').

The Panel notes that the exposure to DHA from the NF from the new intended use in protein products is very low compared to the exposure to DHA from the already authorised food categories.

TABLE 7 Combined intake estimates of DHA from the new intended use and the authorised uses in the Union list* (on a mg/kg bw per day basis).

		Mean intake (mg/kg bw per day)		P95 intake (mg/kg bw per day)	
Population group	**Age (years)**	**Lowest[a]**	**Highest[a]**	**Lowest[b]**	**Highest[b]**
Infants	< 1	24.6	77.2	61.6	172.5
Young children[c]	1–< 3	56.3	110.2	112.8	192.5
Other children	3–< 10	42.0	88.8	80.1	138.4
Adolescents	10–< 18	16.3	40.0	35.3	71.0
Adults[d]	≥ 18	11.2	22.9	22.8	45.4

Abbreviations: bw, body weight; P95, 95th percentile.

*Excluding the authorised uses in food supplements, foods for special medical purposes, total diet replacement and meal replacements for weight control, foods bearing statements on the absence or reduced presence of gluten, foods intended to meet the expenditure of intense muscular effort, especially for sportsmen.

[a]Intakes are assessed for all EU dietary surveys available in the food comprehensive database on 24/4/2024. The lowest and the highest averages observed among all EU surveys are reported in these columns.

[b]Intakes are assessed for all EU dietary surveys available in the food comprehensive database on 24/4/2024. The lowest and the highest P95 observed among all EU surveys are reported in these columns (P95 based on less than 60 individuals are not considered).

[c]Referred to as 'toddlers' in the EFSA food consumption comprehensive database (EFSA, 2011).

[d]This population group also includes elderly and very elderly.

TABLE 8 Combined intake estimates of DHA from the new intended use and the authorised uses in the Union list* (on a mg/day basis).

			Mean intake (mg/day)		P95 intake (mg/day)	
Population group	**Age (years)**	**Default body weights (kg)[a]**	**Lowest[b]**	**Highest[b]**	**Lowest[c]**	**Highest[c]**
Infants	< 1	5	123	386	308	863
Young children[d]	1–< 3	12	676	1322	1354	2310
Other children	3–< 10	23	966	2042	1842	3183
Adolescents	10–< 18	61	994	2440	2153	4331
Adults[e]	≥ 18	70	784	1603	1596	3178

Abbreviation: P95, 95th percentile.

*Excluding the authorised uses in food supplements, foods for special medical purposes, total diet replacement and meal replacements for weight control, foods bearing statements on the absence or reduced presence of gluten, foods intended to meet the expenditure of intense muscular effort, especially for sportsmen.

[a]Default body weights as set by the EFSA Scientific Committee (2012), which were used to calculate the intake estimates in this table.

[b]Intakes are assessed for all EU dietary surveys available in the food comprehensive database on 24/4/2024. The lowest and the highest averages observed among all EU surveys are reported in these columns.

[c]Intakes are assessed for all EU dietary surveys available in the food comprehensive database on 24/4/2024. The lowest and the highest P95 observed among all EU surveys are reported in these columns (P95 based on less than 60 individuals are not considered).

[d]Referred to as 'toddlers' in the EFSA food consumption comprehensive database (EFSA, 2011).

[e]This population group also includes elderly and very elderly.

3.7.4 | Estimate of exposure to undesirable substances

Considering the compositional data and that the exposure does not change significantly as compared to the authorised uses, the new proposed use and use level are not associated with an increased exposure to undesirable substances.

3.7.5 | Precautions and restrictions of use

The new proposed use of the NF is not associated with specific precaution of use.

3.8 | Absorption, distribution, metabolism and excretion (ADME)

No new ADME data for the NF have been submitted. Digestion, absorption and metabolism of DHA have been extensively documented in the EFSA Scientific Opinion on Tolerable Upper Intake Level of EPA, DHA and DPA (EFSA NDA Panel, 2012).

3.9 | Nutritional information

The Panel considers that taking into account the composition of the NF and the proposed conditions of use, consumption of the NF is not nutritionally disadvantageous.

3.10 | Toxicological information

No new toxicological data have been submitted in the context of this extension of use. The applicant referred to the toxicological information assessed in the context of the recently adopted scientific opinions on the safety of oil from *S. limacinum* (strain FCC-3204) for use in food supplements and in IF and FOF (EFSA NDA Panel, 2021a, 2021b).

Even though toxicological tests were not conducted with the NF under assessment, taking into account the results on toxicity in studies performed with various forms of DHA-oils derived from strains belonging to the genus *Schizochytrium* sp., the QPS status of the source of the NF (*S. limacinum*), the data on the production process, on the composition of the NF and the absence of viable cells, the Panel considers that there are no concerns with regard to toxicity of the NF.

3.11 | Allergenicity

As assessed in 2021 (EFSA NDA Panel, 2021a, 2021b), based on the data on proteins in the NF (i.e. concentrations below the LOQ of 0.25%), the Panel considers that the NF is unlikely to trigger adverse allergic reactions in the general population.

4 | DISCUSSION

The NF application under assessment is an extension of use for *Schizochytrium* sp. oil, which has been authorised since 2003 to be added to several foods (e.g. dairy products, fats, fruit and vegetables puree, breakfast cereals, bakery products, non-alcoholic beverages). The source organism which is assessed in this application is *S. limacinum* (strain FCC-3204) and not the generic *Schizochytrium* sp.

In 2021, the oil from the strain *S. limacinum* (strain FCC-3204) was positively assessed by EFSA to be used in food supplements and in IF and FOF (EFSA NDA Panel, 2021a, 2021b). The available evidence indicated that the source organism (*Schizochytrium* sp., strain FCC3204) belongs to the species *S. limacinum* (EFSA NDA Panel, 2021a, 2021b).

In 2020, *S. limacinum* was assessed by the EFSA BIOHAZ Panel and attributed the QPS status with the qualification 'for production purposes', which implies the absence of viable *Schizochytrium* cells in the final product (EFSA BIOHAZ Panel, 2020). Data provided by the applicant demonstrated the absence of viable cells in the NF.

The Panel considers that the information provided on the composition and the production process is sufficiently described and does not raise safety concerns (EFSA NDA Panel, 2021a, 2021b).

In this application, the applicant requests to extend the use of the oil from *S. limacinum* (strain FCC-3204) as an ingredient in protein products, at a maximum use level of 1 g DHA/100 g of product. After considering the intake estimates of DHA from the authorised uses (Tables 5, 6) and the combined intake estimates of DHA from the new intended use and the authorised uses (Tables 7, 8), the Panel notes that the exposure to DHA from the new intended use of the NF in protein products is very low compared to the exposure to DHA from the already authorised food categories (excluding food supplements).

5 | CONCLUSIONS

The Panel concludes that the NF (oil from *S. limacinum* (FCC-3204)) is safe under the new intended use.

5.1 | Protection of proprietary data in accordance with article 26 of regulation (EU) 2015/2283

The data requested by the applicant to be protected comprise: taxonomic analysis (Annex 3 – under Section 3.2 'Identity of the NF'), viable cell analysis (Annex 35 – under Section 3.3 'Production process'), certificate of analyses of protein products added with the NF (Annex 51 – under Section 3.4 'Compositional data'). The Panel notes that the taxonomic analysis and

the viable cell analysis were also submitted in the applications already assessed by EFSA (NF 2019/0825 and NF 2019/1046) and that at that time they were not claimed proprietary.

The Panel could have reached the conclusion on the safety of the NF under the proposed conditions of use without the data claimed as proprietary by the applicant.

6 | STEPS TAKEN BY EFSA

1. On 15/02/2024, EFSA received a letter from the European Commission with the request for a scientific opinion on an amendment of the conditions of use of the NF *Schizochytrium* sp. (FCC-3204) oil. Ref. Ares (2024)1160079–15/02/2024.
2. On 15/02/2024, a valid application on an amendment of the conditions of use of the NF *Schizochytrium* sp. (FCC-3204) oil, which was submitted by Fermentalg (France), was made available to EFSA by the European Commission through the Commission e-submission portal (NF-2023-17070) and the scientific evaluation procedure was initiated.
3. During its meeting on 24 September 2024, the NDA Panel, having evaluated the data, adopted a scientific opinion on the Safety of an extension of use of oil from Schizochytrium limacinum (strain FCC-3204) as a NF pursuant to Regulation (EU) 2015/2283.

ABBREVIATIONS

ADME	Absorption, distribution, metabolism and excretion
Anses	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (French Agency for Food, Environmental and Occupational Health and Safety)
ATCC	American type culture collection
BIOHAZ	Panel on Biological Hazards
bw	body weight
DHA	docosahexaenoic acid
DPA	docosapentaenoic
EPA	eicosapentaenoic acid
FA	fatty acids
FAIM	Food Additive Intake Model
FOF	follow-on formula
FSAI	Food Safety Authority of Ireland
IF	infant formula
LOQ	limit of quantification
NDA	Panel on Nutrition, Novel Foods and Food Allergens
NF	novel food
P95	95th percentile
PUFA	polyunsaturated fatty acids
PV	peroxide value
QPS	qualified presumption of safety
TOTOX	total oxidation value
UHT	ultra high temperature
w/w	weight per weight

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.

REQUESTOR

European Commission

QUESTION NUMBER

EFSA-Q-2024-00003

PANEL MEMBERS

Dominique Turck, Torsten Bohn, Montaña Cámara, Jacqueline Castenmiller, Stefaan de Henauw, Karen-Ildico Hirsch-Ernst, Ángeles Jos, Alexandre Maciuk, Inge Mangelsdorf, Breige McNulty, Androniki Naska, Kristina Pentieva, Alfonso Siani and Frank Thies.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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APPENDIX A

Authorised uses of the NF as listed in the Union list

Authorised uses for *Schizochytrium* sp. oil		
Specified food category	**Maximum level of DHA**	**Additional specific labelling requirements**
Dairy products except milk-based drinks	200 mg/100 g or for cheese products 600 mg/100 g	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Oil from the microalgae *Schizochytrium* sp.'
Dairy analogues except drinks	200 mg/100 g or for analogues to cheese products 600 mg/100 g	
Spreadable fats and dressings	600 mg/100 g	
Cooking fats	360 mg/100 g	
Fruit/vegetable puree	100 mg/100 g	
Breakfast cereals	500 mg/100 g	
Cereal bars	500 mg/100 g	
Bakery products (breads, rolls and sweet biscuits)	200 mg/100 g	
Processed cereal-based foods and baby foods for infants and young children as defined in Regulation (EU) No 609/2013	200 mg/100 g	
Milk-based drinks and similar products intended for young children	200 mg/100 g	
Non-alcoholic beverages (including dairy analogue and milk-based drinks)	80 mg/mL	
Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen	200 mg/100 g	
Foods bearing statements on the absence or reduced presence of gluten in Accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014	200 mg/100 g	
Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control	250 mg/meal	
Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended	
Food supplements as defined in Directive 2022/46/EC	250 mg/day for the general population 450 mg/day for pregnant and lactating women	

Authorised uses for oil from *Schizochytrium*, strain ATCC-3204		
Specified food category	**Maximum level of DHA**	**Additional specific labelling requirements**
Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Oil from the microalgae 'Oil from the microalgae *Schizochytrium* sp.' The labelling of food supplements containing *Schizochytrium* sp. (FCC-3204) oil shall bear a statement that they should not be consumed by infants and children under 3 years of age'
Food supplement as defined in Directive 2002/46/EC for the general population above 3 years	1 g/day	

APPENDIX B

Authorised uses of the NF translated into FAIM tool food categories

Authorised food categories in the union list for *Schizochytrium* sp. oil		FAIM tool food categories		
Specified food category in the Union list	**Maximum level of DHA in the Union list**	**Food category**	**Denomination**	**Occurrence level of DHA (mg/kg)**
Dairy products except milk-based drinks	200 mg/100 g or for cheese products 600 mg/100 g	01.1	Unflavoured pasteurised and sterilised (including UHT) milk	2000
		01.2	Unflavoured fermented milk products, including natural unflavoured buttermilk (excluding sterilised buttermilk) non heat-treated after fermentation	2000
		01.4	Flavoured fermented milk products including heat-treated products	2000
		01.6.1	Unflavoured pasteurised cream (excluding reduced fat creams)	2000
		01.6.2	Unflavoured live fermented cream products and substitute products with a fat content of less than 20%	2000
		01.6.3	Other creams	2000
		01.7	Cheese and cheese products	6000
		01.7.1	Unripened cheese excluding products falling in category 16	6000
		01.7.2	Ripened cheese	6000
		01.7.4	Whey cheese	6000
		01.7.5	Processed cheese	6000
		01.7.6	Cheese products (excluding products falling in category 16)	6000
Dairy analogues except drinks	200 mg/100 g or for analogues to cheese products 600 mg/100 g	01.8	Dairy analogues, including beverage whiteners	2000
Spreadable fats and dressings	600 mg/100 g	02.1	Fats and oils essentially free from water (excluding anhydrous milkfat)	6000
Cooking fats	360 mg/100 g	02.2	Fat and oil emulsions mainly of type water-in-oil	6000
		02.2.1	Butter and concentrated butter and butter oil and anhydrous milkfat	6000
		02.2.2	Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions	6000
Fruit/vegetable puree	100 mg/100 g	04.2	Processed fruit and vegetables	1000
		04.2.4.1	Fruit and vegetable preparations excluding compote	1000
		04.2.4.2	Compote, excluding products covered by category 16	1000
Breakfast cereals	500 mg/100 g	06.3	Breakfast cereals	5000
Cereal bars	500 mg/100 g	15.1	Potato-, cereal-, flour- or starch-based snacks	5000
Bakery products (breads, rolls and sweet biscuits)	200 mg/100 g	07.1	Bread and rolls	2000
		07.2	Fine bakery wares	2000

(Continued)

Authorised food categories in the union list for *Schizochytrium* sp. oil		**FAIM tool food categories**		
Specified food category in the Union list	**Maximum level of DHA in the Union list**	**Food category**	**Denomination**	**Occurrence level of DHA (mg/kg)**
Infant and follow-on formulae as defined by Regulation (EU) No 609/2013	In accordance with Regulation EU) No 609/2013	13.1.1	Infant formulae as defined by Commission Directive 2006/141/EC	350
		13.1.2	Follow-on formulae as defined by Directive 2006/141/EC	350
Processed cereal-based foods and baby foods for infants and young children as defined in Regulation (EU) No 609/2013	200 mg/100 g	13.1.3	Processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC	2000
Milk-based drinks and similar products intended for young children	200 mg/100 g			
Non-alcoholic beverages (including dairy analogues and milk-based drinks)	80 mg/mL	14.1.2	Fruit and vegetable juices	800
		14.1.2.1	Fruit juices as defined by Directive 2001/112/EC	800
		14.1.2.2	Vegetable juices	800
		14.1.3	Fruit nectars as defined by Directive 2001/112/EC and vegetable nectars and similar products	800
		14.1.4	Flavoured drinks	800
		14.1.4.1	Flavoured drinks with sugar	800
		14.1.4.2	Flavoured drinks with sweetener	800
Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen	200 mg/100 g	Food category not available in the FAIM tool		
Foods bearing statements on the absence or reduced presence of gluten in Accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014	200 mg/100 g	Food category not available in the FAIM tool		
Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control	250 mg/meal	Food category not available in the FAIM tool		
Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended	Food category not available in the FAIM tool		

ANNEXES

Annex A - Intake estimates of DHA from the new intended use

Annex B - Intake estimates of DHA from the NF from the authorised uses

Annex C - Combined intake estimates of DHA from the NF from the new intended use and the authorised uses

Information provided in the Annexes above are available under 'Supporting Information'.