

REGULATED PRODUCTS SAFETY ASSESSMENT

Assessment on the Safety of DHA-rich Algal Oil From *Schizochytrium Limacinum* Strain ATCC 20889 for Use in Infant Formula and Follow-On Formula (RP2358)

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FSA Research and Evidence

BioPlus Life Sciences (“the applicant”) submitted a novel food application for the authorisation of DHA-rich algal oil produced by *Schizochytrium limacinum* (strain ATCC 20889) as a novel food to each nation of Great Britain in November 2025.

The new application is seeking authorisation for DHA-rich algal oil produced by *Schizochytrium limacinum* (strain ATCC 20889) for use in infant formula and follow-on formula.

The application for authorisation of this novel food was assessed by the European Food Safety Authority (EFSA), and its opinion was published in January 2025. The Food Standards Agency (FSA) and Food Standards Scotland (FSS) have reviewed the information available, including the EFSA opinion, and confirmed that DHA-rich algal oil produced by *Schizochytrium limacinum* strain ATCC 20889 was safe under the proposed conditions of use. The anticipated intake levels and proposed use in infant and follow-on formula was not considered to be nutritionally disadvantageous.

This assessment represents the opinion of the FSA and FSS.

1. Introduction

In accordance with assimilated Regulation (EU) 2015/2283 (EC, 2017) on novel foods, an application (RP2358) for DHA-rich algal oil from *Schizochytrium limacinum* (strain ATCC 20889) as a novel food has been submitted for authorisation in each nation of Great Britain (GB). The novel

food (NF) is an algal oil rich in docosahexaenoic acid (DHA), obtained from the microalgae *Schizochytrium limacinum* strain ATCC 20889. The applicant is seeking authorisation for this new strain for uses in infant formula (IF) and follow-on formula (FOF).

Whilst it was a Member State of the EU, the UK accepted the risk assessments of the European Food Safety Authority (EFSA) in respect of authorisations for regulated food and feed products. Since the end of the transition period, FSA and FSS have adopted equivalent technical guidance and quality assurance processes to be able to undertake GB risk assessments for regulated product applications.

To ensure our regulatory systems are risk proportionate, and resources are used effectively, the FSA and FSS have used the evidence submitted by the applicant and other information in the public domain, including the EFSA risk assessment opinion, to inform this assessment.

The FSA and FSS have evaluated the published EFSA risk assessment on the NF (EFSA NDA Panel, 2025) and confirmed that this is appropriate for GB risk analysis. Consideration has been given to the processes undertaken to ensure the EFSA opinion is robust and whether there are any aspects that would require further review, such as specific issues for the countries of GB. The result of the assessment is that there is sufficient evidence of safety to conclude without requiring further risk assessment at this time.

This assessment represents the opinion of the FSA and FSS.

2. Details of other Regulators Opinions

In 2025, the safety of a change in the conditions of use of DHA-rich algal oil from *Schizochytrium limacinum* strain ATCC 20889 from BioPlus Life Sciences, for inclusion in IF and FOF, was assessed by EFSA and received a positive opinion (EFSA NDA Panel, 2025). This opinion has been reviewed by FSA and FSS to inform the assessment on this application.

DHA-rich algal oils derived from *Schizochytrium* sp. have been authorised as novel foods in the UK and EU since 2003 for use across a range of food categories (Commission Decision (EU) 2003/427 (EC, 2003)). Over the past two decades, multiple *Schizochytrium*-derived DHA-rich algal oils have been assessed and approved. Accordingly, six DHA-rich *Schizochytrium* sp. algal oils are currently authorised for use in the GB, four of which are specifically permitted for use in IF and FOF. These include algal oils from strains ATCC PTA-9695 (NOVEL-126), T18 (NOVEL-127), FCC-3204 (NOVEL-157), and WZU477 (NOVEL-158), each of which has undergone a detailed risk assessment.

The NF under assessment, DHA-rich algal oil from *Schizochytrium limacinum* strain ATCC 20889 (commercially BioDHA), is produced via a fermentation and refining process comparable to that used for other authorised *Schizochytrium*-derived DHA-rich algal oils and edible vegetable oils. As detailed in the dossier, whole genome sequencing confirms that strain ATCC 20889 belongs to the species *Schizochytrium limacinum* and is genetically highly similar (average nucleotide identity (ANI) of 99.97%) to strain MYA-1381, which holds qualified presumption of safety (QPS) status.

The NF meets the general specifications for *Schizochytrium* sp. algal oils set out in assimilated Regulation (EU) 2017/2470, including limits for DHA content, acid value, peroxide value, unsaponifiables, trans-fatty acids, and moisture. Therefore, DHA-rich algal oil from *Schizochytrium limacinum* ATCC 20889 may already be lawfully placed on the GB market for use in food products covered by the generic *Schizochytrium* sp. algal oil entry, provided it meets these existing specifications and conditions of use.

This application seeks a new authorisation for DHA-rich algal oil from *Schizochytrium limacinum* strain ATCC 20889 for use in IF and FOF. This use is already permitted for several DHA-rich algal oils derived from other strains of *Schizochytrium* sp.

2.1. Methodology applied in the EFSA Opinion

EFSA conducted the assessment of the novel food in accordance with the procedure as outlined in the EFSA scientific opinion 'Guidance on the preparation and submission of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283 (Revision 1)' (EFSA NDA Panel, 2021) and Commission Implementing Regulation (EU) 2017/2469 (EC, 2017).

2.1.1. Identity of the novel food

The novel food under assessment is an algal oil extracted and refined from the wild-type marine microalgae *Schizochytrium limacinum* strain ATCC 20889. This algal oil consists of a mixture of triglycerides in which docosahexaenoic acid (DHA) comprises approximately 42% of the total fatty acids.

Whole genome sequencing (WGS) analyses were conducted by the applicant to verify the identity of the ATCC 20889 strain. These analyses were performed in accordance with EFSA requirements for WGS analysis of microorganisms intentionally used in the food chain (EFSA, 2021). Illumina sequencing was carried out for both ATCC 20889 and the reference strain MYA-1381, which has previously been used as a comparator in other *Schizochytrium* sp. algal oil authorisations for IF and FOF, and for which a

QPS status has been established. The sequencing data demonstrated that ATCC 20889 and MYA-1381 share an ANI of 99.97%, confirming that the two strains belong to the same species.

In line with EFSA guidelines, the 18S rRNA sequence of ATCC 20889 was compared with the NCBI reference sequence for MYA-1381, showing 99.43% identity and high collinearity across the sequence, further supporting their placement within the same species (EFSA, 2021). Lastly, phylogenetic analyses based on 18S rRNA, ITS regions, and 28S rRNA sequences confirmed that ATCC 20889 clusters with MYA-1381 and other related strains within *Aurantiochytrium limacinum*, a currently accepted synonym of *Schizochytrium limacinum*.

Based on these data, the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) concluded that strain ATCC 20889 is a member of the species *Schizochytrium limacinum*. The FSA and FSS concur with this conclusion and agree that no further assessment of the identity of the novel food is required.

2.1.2. Production Process

The novel food is produced by fermentation in accordance with Good Manufacturing Practices (GMP) and Hazard Analysis and Critical Control Point (HACCP) principles. The marine microalgae *Schizochytrium limacinum* ATCC 20889 is grown under controlled conditions (temperature, dissolved oxygen, pH, and aeration) in an optimised sterile fermentation medium. The cultures are subject to fermentation to increase biomass then lysed and the algal oil is collected and purified. It is subject to processing to support the stability of the oil. The final product, BioDHA, is packaged in food-grade epoxy-lined containers under nitrogen to prevent oxidation.

Based on the production process described by the applicant and the accompanying data, the EFSA NDA Panel concluded that the process is sufficiently described. The FSA and FSS concur with this conclusion and agree that no further assessment of the production process of the NF is required.

2.1.3. Compositional Information and Stability

The NF consists of a mixture of triglycerides primarily composed of polyunsaturated fatty acids (PUFAs), of which DHA is the predominant component, comprising approximately 42% of the total fatty-acid content. The composition of five independent batches of the NF was assessed by the applicant after the addition of high-oleic sunflower oil and deodorisation.

The physico-chemical properties of the novel food and the proximate analysis were analysed and are detailed in [Table 1](#).

Table 1. Physico-chemical properties of the NF (after the addition of high oleic sunflower oil and after deodorisation)

Parameter	Specification	LOQ	Batch 1	Batch 2	Batch 3	Batch 4	Batch 5
Free Fatty Acids (g/100g)	≤ 0.25	0.02	0.07	0.07	0.07	0.05	0.07
Trans Fatty Acids (%) ^a	≤ 1	36.3(ppm)	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected
Moisture & Volatiles (%)	≤ 0.05	0.005	0.02	0.02	0.03	0.02	0.02
Unsaponifiable Matter (%)	≤ 4.5	0.5	1.57	1.61	1.68	1.63	1.65
Acid Values (mg KOH/g)	≤ 0.5	0.03	0.13	0.13	0.14	0.10	0.14
Peroxide Value (meq/kg)	≤ 5	0.03	0.54	0.52	0.81	0.49	0.62
p-Anisidine	≤ 10	0.91	19.66	11.23	14.19	14.67	12.11
DHA Content (mg/g) ^b	≥ 320	6(ppm)	422.9	401.5	410.3	411.1	419.2

^a Trans Fatty Acids LOQ, 36.3 ppm = 36.3 mg/kg = 0.0363 mg/g = 0.00363%

^b DHA LOQ, 6 ppm = 6 mg/kg = 0.006 mg/g = 0.0006%

A custom British Pharmacopoeia/European Pharmacopoeia-compliant protocol was used to quantify p-anisidine in the NF; this protocol was validated at EFSA's request. Results of this analysis are provided in [Table 2](#).

Table 2. p-Anisidine analysis of the NF

Parameter	Specification	Batch 1	Batch 2	Batch 3	Batch 4	Batch 5
Before the addition of high-oleic sunflower oil and before deodorisation						
Acid Values (mg KOH/g)	≤ 0.5	0.12	0.11	0.12	0.18	0.12
Peroxide Value (meq/kg)	≤ 5	0.58	0.54	0.86	0.55	0.68
p-Anisidine	≤ 10	10.48	10.51	11.86	9.83	10.98
DHA Content (%)	NA	45.32	43.06	42.75	44.22	43.61
pH	NA	6.6	6.6	6.5	6.5	6.6
After the addition of high-oleic sunflower oil and after deodorisation						
Acid Values (mg KOH/g)	≤ 0.5	0.13	0.13	0.14	0.10	0.14
Peroxide Value (meq/kg)	≤ 5	0.54	0.52	0.81	0.49	0.62
p-Anisidine	≤ 10	19.66	11.23	14.19	14.67	12.11
DHA Content (%)	NA	42.29	40.15	41.03	41.11	41.92

The results show an increase in p-anisidine levels following the addition of high-oleic sunflower oil and after deodorisation, prompting further assessment as requested by EFSA. Subsequently, p-anisidine levels in the NF were quantified in five additional independent batches before and after deodorisation ([Table 3](#)), demonstrating lower p-anisidine levels after deodorisation, with values closer to 10 (See 2.14 Specifications).

Table 3. p-Anisidine analysis of the NF before and after deodorisation

	p-Anisidine Levels (before deodorisation)	p-Anisidine Levels (after deodorisation)
Batch 6	12.60	12.50
Batch 7	10.75	9.07
Batch 8	12.56	12.27
Batch 9	9.48	9.40
Batch 10	9.92	9.85

An analysis of the fatty acid composition of the product was undertaken for five batches of the NF to allow full characterisation ([Table 4](#)).

Table 4. Fatty acid profile of the NF (after the addition of high oleic sunflower oil and after deodorisation)

Fatty Acids (FA) (% of Total Fatty Acids)	FA Structure (Carbons: Double Bonds)	Batch 1	Batch 2	Batch 3	Batch 4	Batch 5
Myristic acid	14:0	1.87	1.83	1.77	1.53	1.95
Pentadecanoic acid	15:0	0.57	0.73	0.55	0.6	0.71

Fatty Acids (FA) (% of Total Fatty Acids)	FA Structure (Carbons: Double Bonds)	Batch 1	Batch 2	Batch 3	Batch 4	Batch 5
Palmitic acid	16:0	27.43	29.17	30.96	29.55	32.38
Heptadecanoic acid	17:0	0.27	0.34	0.32	0.2	0.34
Stearic acid	18:0	1.48	1.62	1.86	1.56	1.52
Oleic acid	18:1	9.24	8.34	4.8	8.56	4.58
Linoleic acid	18:2 (n-6)	1.43	1.3	0.91	1.17	0.77
Arachidic acid	20:0	0.36	0.43	0.49	0.37	0.23
Eicosadienoic acid	20:1	0.26	0.23	0.23	0.23	0.22
Eicosatrenoic acid	20:3	0.71	0.75	0.72	0.19	0.66
Arachidonic acid	20:4 (n-6)	0.36	0.75	0.29	0.64	0.66
Eicosapentaenoic acid	20:5 (n-3)	1.26	1.01	1.08	1.14	1.11
Erucic acid	22:1	0.44	0.49	0.52	0.2	0.2
Docosapentaenoic acid	22:5 (n-6)	8.71	10.05	10.97	9.86	9.78
Docosahexaenoic acid	22:6 (n-3)	43.18	40.74	42.05	41.69	43.0
Lignoceric acid	24:0	0.67	0.68	0.75	0.68	0.67
Nervonic acid	24:1	0.45	0.46	0.24	0.34	0.17
Total		98.69	98.92	98.51	98.51	98.95

DHA is the predominant fatty acid in all batches. Values across the five batches showed only minor variation, with a mean of 42.13% and a range of 40.74–43.18%, indicating strong batch-to-batch consistency.

Sterol content was also measured. The results of this analysis for the five batches are presented in [Table 5](#).

Table 5. Sterol content of the NF (after the addition of high oleic sunflower oil and after deodorisation)

Sterols (mg/100g)	Batch 1	Batch 2	Batch 3	Batch 4	Batch 5
Cholesterol	285.57	181.13	296.63	349.69	326.13
Sitosterol	36.68	35.45	63.95	82.14	64.03
Stigmasterol	48.93	35.98	52.09	51.09	47.25
Campesterol	2.44	1.85	9.53	5.43	4.78
Brassicasterol	28.94	53.25	20.22	9.1	19.75
Total	402.56	307.66	442.42	497.45	442.19

The total sterol content across batches spans a wide range (307.6–497.4 mg/100 g), with cholesterol consistently present at the highest concentration among the sterols measured. Sitosterol, stigmasterol, campesterol, and brassicasterol were also detected in all batches, with notable variation in their absolute amounts. No concerns were raised by the EFSA on the cholesterol content of the novel food.

Pesticide residues and polycyclic aromatic hydrocarbons were not detected. Microbial contamination was below acceptable limits in the NF and the NF ingredient under the intended conditions of use (i.e. microencapsulated for incorporation into IF and FOF). Organic volatile impurities, heavy metals, polychlorinated biphenyls, dioxins, process contaminants, and marine toxins were below the limit of quantification. Importantly, *Schizochytrium* sp. are not listed in a comprehensive UNESCO review of toxin-producing marine microalgae (Lassus et al., 2016), nor have they been identified as toxin producers in major reviews of toxic microalgal species to date (Hinder et al., 2011; Katircioğlu et al., 2004; Zaccaroni & Scaravelli, 2008). Accordingly, *Schizochytrium* sp. ATCC 20889 is not considered a toxin-producing strain and is not expected to produce marine toxins.

The EFSA NDA Panel concluded that the information provided is sufficient to characterise the NF and that no safety concerns were identified. The FSA and FSS concur with this conclusion and agree that no further assessment of the composition of the NF is required.

The stability of the final NF (after deodorisation and after addition of high oleic sunflower oil and antioxidants) and the NF ingredient under the intended conditions of use (i.e. microencapsulated for incorporation into IF and FOF) was assessed by the applicant.

Stability of the Final NF

Stability of the final NF was assessed under the following conditions: (i) $-20 \pm 1^\circ\text{C}$ for 36 months, (ii) $4 \pm 1^\circ\text{C}$ for 18 months, and (iii) $25 \pm 2^\circ\text{C}$ for 6 months. The first condition represents the proposed storage temperature and covers the intended 24-month shelf-life. The NF remained stable for up to 2 years at -20°C , up to 12 months at 4°C , and up to 6 months at 25°C . These results demonstrate that the NF complies with the required product specifications throughout the duration of the stability studies.

Stability of the NF Ingredient Under the Intended Conditions of Use

Two microencapsulated powders (10% DHA and 17% DHA) were prepared by the applicant. Stability was assessed under the following conditions: (i) $5 \pm 1^\circ\text{C}$ for 36 months and (ii) $25 \pm 2^\circ\text{C}$ for 6 months. Both microencapsulated powders remained stable for up to 3 years at $5 \pm 1^\circ\text{C}$ and up to 6 months at 25°C . These results demonstrate that the NF ingredient complies with the required product specifications throughout the duration of the stability studies.

The EFSA NDA Panel concluded that the data provided is sufficient regarding the stability of the NF. The FSA and FSS concur with this conclusion and agree that no further assessment of the stability of the NF is required.

2.1.4. Specification

The specifications of the NF are presented in [Table 6](#) and are consistent with those of other *Schizochytrium* sp. algal oils currently authorised in the Union list.

Table 6. Specification of DHA-rich algal oil from *Schizochytrium limacinum* strain ATCC 20889

Parameter (unit)	Specification
Acid Value (mg KOH/g)	≤ 0.5
Peroxide Value (meq/kg)	≤ 5
Moisture & Volatiles (%)	≤ 0.05
Unsaponifiables (%)	≤ 4.5
Trans-Fatty Acids (%)	≤ 1
DHA (%)	≥ 32
p-Anisidine	≤ 10

To address the EFSA NDA Panel's view that secondary oxidation products may pose a safety concern (Kanner, 2007; Vieira et al., 2017), a p-anisidine value has been added to the NF specification. Accordingly, the Panel recommended a maximum p-anisidine value of 10 for *Schizochytrium* sp. algal oils, aligned with the European Pharmacopoeia limit for salmon oils and informed by the NF's composition data. Notably, the applicant applied a different specification (p-anisidine ≤20) in the early analyses, and p-anisidine values in five batches exceeded the upper limits set by the EFSA NDA Panel. At EFSA's request, the applicant subsequently analysed p-anisidine levels in five additional batches (Section 2.1.3, [Table 3](#)) before and after deodorisation. After deodorisation, p-anisidine values were below or close to 10, meeting the NDA Panel's requirements.

The EFSA NDA Panel considered a formal request by the applicant to amend the Union List specification by increasing the minimum DHA content from 32% (320 mg/g) to 35% (350 mg/g). However, the Panel concluded that such an amendment was not necessary from a safety perspective. The applicant did not seek to amend the specification in GB: the dossier retains DHA ≥32%, which is the same parameter listed in the EFSA opinion and in assimilated Regulation 2017/2470 for *Schizochytrium* sp. algal oil.

The EFSA NDA Panel further concluded that the information provided on the NF specifications is sufficient and raises no safety concerns. The FSA and FSS concur with this conclusion and agree that no further assessment is required.

2.1.5. History of Use of the Novel Food and Its Source

The NF is a DHA-rich algal oil extracted from *Schizochytrium limacinum* strain ATCC 20889 strain. DHA-rich algal oils derived from the *Schizochytrium* genus have been authorised in the EU since 2003 (EC, 2003) and have an established history of use across a range of specified food categories. These are detailed in [Table 7](#).

Table 7. Conditions under which *Schizochytrium* sp. algal oil rich in DHA may be used.

Specified food category	Maximum level DHA
Dairy products except milk-based drinks	200 mg/100 g or for cheese products 600 mg/100 g
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/100 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 2002/46/EC	250 mg/day for the general population 450 mg/day for pregnant and lactating women

Following the first authorisation for *Schizochytrium* sp. strain ATCC20888 (EC, 2003), additional strains have subsequently been evaluated and authorised as acceptable sources of DHA-rich algal oil. Of the seven *Schizochytrium*-derived algal oils currently authorised for use in IF and FOF in the EU under assimilated Regulation (EU) No 609/2013, four are authorised for use in IF and FOF in GB, as listed in [Table 8](#).

Table 8. *Schizochytrium* sp. algal oils authorised for use in IF and FOF in GB and the EU

Novel Food	Year	Authorisation/ Decision
Authorisations in Great Britain		
<i>Schizochytrium</i> sp. (ATCC PTA-9695) algal oil	2020	NOVEL-126
<i>Schizochytrium</i> sp. (T18) algal oil	2020	NOVEL-127
<i>Schizochytrium limacinum</i> (FCC-3204) algal oil	2022	NOVEL-157
<i>Schizochytrium limacinum</i> (WZU477) algal oil	2022	NOVEL-158
Authorisation in the European Union		
<i>Schizochytrium</i> sp. (ATCC PTA-9695) algal oil	2015	Decision (EU) 2015/545
<i>Schizochytrium</i> sp. (T18) algal oil	2017	Assessed in the UK and authorised under Regulation (EC) No. 258/97
<i>Schizochytrium limacinum</i> (WZU477) algal oil	2021	Regulation (EU) 2021/670
<i>Schizochytrium limacinum</i> (FCC-3204) algal oil	2021	Regulation (EU) 2021/1326
<i>Schizochytrium limacinum</i> (TKD-1) algal oil	2024	Regulation (EU) 2024/2049
<i>Schizochytrium</i> sp. (CABIO-A-2) algal oil	2024	Regulation (EU) 2024/2101
<i>Schizochytrium limacinum</i> (ATCC 20889) algal oil	2025	Regulation (EU) 2025/1515

2.1.6. Proposed Use and Intake

The target population for the NF is infants and young children.

Proposed Uses and Use Levels

The NF is intended for use in IF and FOF in accordance with assimilated Regulation (EU) No 609/2013 and its supplementary Regulation (EU) 2016/127, which require the mandatory addition of DHA at 20 – 50 mg/100 kcal (4.8–12 mg/100 kJ). It is noted that the proposed use calculations present in both the applicant's dossier and the EFSA assessment are based on a DHA content of $\geq 35\%$ (≥ 350 mg/g), reflecting the applicant's originally proposed specification to EFSA (Section 2.1.4). Accordingly, based on a DHA concentration of 350 mg DHA/g in the NF, the amount of *Schizochytrium*

limacinum (ATCC 20889) algal oil required to meet these DHA levels is 285 – 714 mg of the NF per 100 g of dried formula powder. The proposed uses are detailed in [Table 9](#).

Table 9. Detailing the proposed uses of the novel food

Specified food category	Maximum levels of DHA
Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013

Anticipated Intake

The NF is proposed as an alternative, not an additional, source of DHA. Other DHA-rich algal oils from *Schizochytrium* sp. are already authorised for use in IF and FOF at comparable levels. Therefore, the introduction of this NF is not expected to modify the overall daily intake of DHA in infants and young children.

2.1.7. Absorption, Distribution, Metabolism and Excretion (ADME)

The applicant did not submit an ADME study as part of the dossier. However, the digestion, absorption, and metabolism of DHA is well established in the scientific literature, as previously described by the EFSA NDA Panel (2012). On this basis, EFSA concluded that additional ADME studies were not required for the safety assessment of the NF. FSA and FSS concur with this conclusion and agree that no further ADME studies are required.

2.1.8. Nutritional Information

The nutritional profile of five independent batches of the NF was assessed by the applicant ([Table 10](#)).

Table 10. Nutritional profile of the NF.

	Batch 1	Batch 2	Batch 3	Batch 4	Batch 5
Proximate Composition					
Protein (g/100 g)	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected
Fat (g/100 g)	99.6	99.7	99.6	99.8	99.5
Carbohydrates (g/100 g)	Nil	Nil	Nil	Nil	Nil
Moisture & Volatiles (%)	0.02	0.02	0.03	0.02	0.02
Energy (kcal/100 g)	896	897	896	898	895
Lipids					
Free Fatty Acids (g/	0.07	0.07	0.07	0.05	0.07

	Batch 1	Batch 2	Batch 3	Batch 4	Batch 5
100g)					
Trans Fatty Acids (%)	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected
Sterols					
Cholesterol (mg/100g)	285.57	181.13	296.63	349.69	326.13
Sitosterol (mg/100g)	36.68	35.45	63.95	82.14	64.03
Stigmasterol (mg/100g)	48.93	35.98	52.09	51.09	47.25
Campesterol (mg/100g)	2.44	1.85	9.53	5.43	4.78
Brassicasterol (mg/100g)	28.94	53.25	20.22	9.1	19.75

The analyses showed that the NF consists almost entirely of fat, with no detectable protein or carbohydrates and a moisture and volatile content between 0.02–0.03%. Free fatty acids were low across all batches (0.05–0.07 g/100 g), remaining below the specification limit of <0.25 g/100 g, and trans-fatty acids were not detected in any batch. Collectively, these data ([Table 9](#)) show that the NF is a concentrated lipid source with negligible contributions from protein, carbohydrate, or other macronutrients.

The EFSA NDA Panel noted that the fatty acid profile ([Table 4](#)) indicates the presence of other components that may influence the overall fatty-acid ratios in IF and FOF. However, the Panel emphasised that it is ultimately the responsibility of IF/FOF manufacturers to ensure that the final fatty-acid composition of their products complies with the regulatory requirements.

Based on the composition of the NF and its intended conditions of use, the EFSA NDA Panel concluded that consumption of the NF is not nutritionally disadvantageous. The FSA and FSS concur with this conclusion and agree that no further assessment of the nutritional content is required.

2.1.9. Toxicological Information

The applicant did not submit toxicity studies as part of the dossier. However, the toxicity of DHA-rich algal oil extracted from a variety of *Schizochytrium* spp. strains has been extensively investigated. Past studies, which no longer have data protection, have included genotoxicity, subchronic toxicity, and developmental and reproductive toxicity studies. These evaluations, conducted with algal oils derived from strains such as ATCC PTA-9695 (Fedorova-Dahms et al., 2011), T18 (Schmitt, Tran, Peach, Bauter, et al., 2012; Schmitt, Tran, Peach, Edwards, et al., 2012), and other *Schizochytrium* sp. (Falk et al., 2017; Lewis et al., 2016), have previously supported authorisations in IF and FOF extension of use applications. Assessments by competent authorities, including ANSES (ANSES, 2012),

consistently report no concerns regarding genotoxicity or subchronic toxicity. Additional published studies on other *Schizochytrium*-derived DHA-rich algal oils have reached the same conclusions.

Based on the QPS status of the source organism *Schizochytrium limacinum* MYA-1381, which shares 99.97% sequence identity with the ATCC 20889 strain, together with the available toxicological data, the production process, compositional information, and the demonstrated absence of marine toxins and viable cells, the EFSA NDA Panel concluded that there are no concerns regarding the toxicity of the NF. The FSA and FSS concur with this conclusion and agree that no further toxicity studies are required.

2.1.10. Allergenicity

The NF primarily comprises lipids (99.5–99.8%), and proximate composition analyses provided by the applicant show that protein levels are below the limit of quantification (LOQ) (0.625 g/100 g). Based on these data, the EFSA NDA Panel concluded that the NF is unlikely to trigger allergic reactions in the target population under the intended conditions of use. The FSA and FSS concur with this conclusion and agree that no further allergenicity studies are required.

3. Other Regulators Opinions and Conclusions

Under Assimilated Regulation (EU) 2016/127, DHA is a mandatory constituent of IF and FOF. Several DHA sources are already authorised for use in these products in both the EU and the UK (Section 2.1.5, [Table 8](#)). EFSA has concluded that DHA-rich algal oil from *Schizochytrium limacinum* strain ATCC 20889 is safe under the proposed conditions of use in IF and FOF (EFSA NDA Panel, 2025). EFSA further concluded that the anticipated intake levels and the proposed use in IF and FOF are not nutritionally disadvantageous. As the composition and use of IF and FOF do not differ substantially between the UK and the EU, the FSA and FSS concur with EFSA's conclusion.

4. Uncertainties and Limitations

No specific uncertainties were flagged in the assessment by EFSA. The FSA and FSS did not identify further uncertainties to be considered for this assessment.

5. FSA-FSS conclusion for GB assessment

The application has been evaluated in line with 'Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of assimilated Regulation (EU) 2015/2283' (EFSA NDA Panel, 2012), and assimilated Commission Implementing Regulation (EU) 2017/2469, for purposes of the GB assessment.

The conclusions of the EFSA opinion (EFSA NDA Panel, 2025), which has been reviewed in detail by the FSA and FSS for the purposes of the GB assessment, are considered appropriate and consistent within the uncertainties and limitations identified by EFSA.

The FSA and FSS could not have completed the assessment of the novel food under the proposed conditions of use without the following data claimed as proprietary by the applicant:

- Part 1 Administrative data: Personal Data (name, signature, function in company)
- Section 2.1 Identity (Page 17)
 - Section 2.1.2 (First paragraph)
- Section 2.2 Production Process:
 - Sections 2.2.1 and 2.2.2 (Pages 24 to 29)
 - Section 2.2.4 (Page 30) from "All materials in contact with the food ..." to "... Neutralisation is done if the value is over the limit."
- Annex A (Full document)
- Annex 1.1 – 1.7 (Full documents)
- Annex 2.1 – 2.17 (Full documents)
- Annex 3.10 – 3.30 (Full documents)

6. Outcome of the assessment

The FSA and FSS has reviewed the applicant's dossier, supporting documentation, and most notably the EFSA opinion (EFSA NDA Panel, 2025), and consider that there is sufficient evidence to conclude the

assessment for the use of DHA-rich algal oil from *Schizochytrium limacinum* strain ATCC 20889 for use in IF and FOF without obtaining further information or conducting a further risk assessment.

The FSA and FSS conclude that, under the proposed conditions of use, the DHA-rich algal oil extracted from the *Schizochytrium* sp. strain ATCC 20889 is as safe as alternatives that have already been authorised for use in IF and FOF and that consumption is not considered to be nutritionally disadvantageous.

In making this assessment, the FSA and FSS were able to rely on sufficient scientific evidence provided by the EFSA Opinion and by the applicant to make a conclusion on safety with no further questions to the applicant, and therefore no further risk assessment activities are necessary.

Sufficient evidence was available in the literature to give the FSA and FSS confidence about the safety of this novel food, for example, where other national food safety authorities had positively assessed the application using the same risk assessment guidance and core legal requirements that apply in GB.

The applicant provided sufficient relevant information as requested by the FSA and FSS.

The FSA and FSS review did not find any issues of divergence from the EFSA guidance (EFSA NDA Panel, 2021) or mutual approaches or new scientific issues for consideration.

There were no other specific issues that would require an assessment for the UK or the nations of the UK.

Abbreviations

ANI	Average Nucleotide Identity
ATCC	American Type Culture Collection
DHA	Docosahexaenoic Acid
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
FOF	Follow-On Formula
FSA	Food Standards Agency
FSS	Food Standards Scotland
g	Gram
GB	Great Britain
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis and Critical Control Points
IF	Infant Formula
kcal	Kilocalorie
KOH	Potassium Hydroxide

ANI	Average Nucleotide Identity
LOQ	Limit of Quantification
meq	Milli-equivalents
mg	Milligram
NDA	Nutrition, Novel Foods and Food Allergens
NF	Novel Food
No	Number
PUFA	Polyunsaturated Fatty Acids
QPS	Qualified Presumption of Safety
rRNA	Ribosomal RNA
UK	United Kingdom
WGS	Whole Genome Sequencing

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