

Assessment on the Safety of an Extension of Use of DHA-rich Oil From *Schizochytrium* sp. Strain FCC-3204 for Use in All Protein Products (RP2316)

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FSA Research and Evidence

FermentaIq, France ("the applicant") submitted a novel food application for a change in conditions of use of *Schizochytrium* sp. strain (FCC-3204) oil as a novel food to each nation of Great Britain (GB) in June 2025.

The novel food is an oil rich in docosahexaenoic acid (DHA) produced by the microalga *Schizochytrium* sp. strain (FCC-3204), which is already authorised for use in a range of food categories and supplements in GB. The applicant is seeking authorisation of a change in conditions of use to extend the permitted uses to protein products, at a proposed maximum level of 1 g DHA per 100 g of product.

The application for a change in the conditions of use for this novel food was assessed by the European Food Safety Authority (EFSA), which published its scientific opinion in 2024. The Food Standards Agency (FSA) and Food Standards Scotland (FSS) have reviewed the information available, including the EFSA opinion, and confirmed that the proposed change in conditions of use for *Schizochytrium* sp. strain (FCC-3204) was safe. The anticipated intake levels and proposed uses were not considered to be nutritionally disadvantageous.

This assessment represents the opinion of the FSA and FSS.

This is a joint FSA and FSS publication.

1. Introduction

In accordance with assimilated Regulation (EU) 2015/2283 on novel foods, an application (RP2316) was submitted in each nation of Great Britain (GB), requesting a change to the conditions of use for *Schizochytrium* sp. (strain FCC-3204) oil to extend use to protein products.

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 novel food 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

The applicant, Fermentalg (France), is seeking authorisation for a change in conditions of use to extend the use of *Schizochytrium* sp. strain (FCC-3204) oil, in protein products.

Docosahexaenoic acid (DHA)-rich *Schizochytrium* sp. oil, produced using any strain, has been authorised as a novel food for inclusion in several specified food categories in the UK (and the EU) since 2003, under assimilated Commission Decision (EU) 2003/427 (EC, 2003).

In 2021, the EFSA published two favourable opinions on the safety of oil from *S. limacinum* (strain FCC-3204) for use in food supplements (EFSA NDA Panel, 2021a) and for use in infant formula and follow-on formula (EFSA NDA Panel, 2021b). Both opinions were reviewed by the FSA and FSS in 2021 and considered appropriate for risk assessment in the UK (FSA and FSS 2021). This resulted in authorisations in GB to include the novel food in infant formula and follow-on formula, as well as its inclusion at a higher level in supplements (NOVEL-157). It was authorised in Great Britain under

'The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) Regulations 2022' (England 2022; Scotland 2022; Wales 2022) and in the European Union under Commission Implementing Regulation (EU) 2021/1326 (EC, 2021).

Schizochytrium sp. FCC-3204 oil is authorised in the USA under the Generally Recognised As Safe (GRAS) framework for use as an ingredient in various foods and infant formula (FDA, 2018, 2019).

In 2024, the EFSA published an opinion on the safety of an extension of use of oil from *S. limacinum* (strain FCC-3204) for use in protein products (EFSA NDA Panel, 2024). Following the EFSA opinion, the novel food has been authorised for use in protein products (excluding dairy analogues) in the EU, following Commission Implementing Regulation 2025/688 (EC, 2025). The EFSA opinion has been reviewed by FSA and FSS assessors to inform the view on this application received by countries in GB.

2.1. Methodology applied in the EFSA Opinion

The 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, 2017a).

Under Article 3(4) of Commission Implementing Regulation (EU) 2017/2469 (EC, 2017a), it may not be necessary for the applicant to provide all the data required under Article 5 of this Regulation when a novel food application seeks to modify the conditions of use, the specifications, additional specific labelling requirements or post-market monitoring requirements of an authorised novel food. Verifiable justification explaining that the intended changes do not affect the results of the existing safety assessment is provided by the applicant. Given that the novel food is identical to the one reviewed in the previous assessment, this new safety assessment has focused on the impact of the intended changes of use for novel food.

The novel food has already been assessed and authorised under assimilated Commission Implementing Decision (EU) 2003/427 (EC, 2003), and DHA-rich oil from *Schizochytrium* sp. strain (strain FCC-3204) is on the permitted list of novel foods in GB (NOVEL-157) and the EU. As the identity of the novel food and its production process remain unchanged, the conclusions drawn from the information provided in the original application on identity of the novel food, the production process, the compositional information, stability, specification, Absorption, Distribution,

Metabolism and Excretion (ADME), toxicity and allergenicity, would not be affected by the proposed change in condition of use. Therefore, this information was not provided or reviewed as part of the assessment.

The FSA and FSS agree with the view that the proposed change in the conditions of use does not alter the previous assessment of the novel food composition and specification or the conclusion that no safety concerns have been identified. As such, the focus of this review has been the impact of the changes to the conditions of use to extend exposure to the additional food category of protein products.

2.1.1. Identity of the novel food

The novel food is an oil rich in docosahexaenoic acid (DHA) obtained from the unicellular microalga *Schizochytrium* sp. strain (FCC-3204). The EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) concluded in previous opinions that the strain belongs to the species *Schizochytrium limacinum* (EFSA NDA Panel, 2021a, 2021b).

The FSA and FSS agree with EFSA that the identity of the novel food is unchanged since the previous authorisation and therefore no further assessment on the identity of the novel food is necessary.

2.1.2. Production Process

The novel food is produced by fermentation under controlled conditions. The production strain, *S. limacinum* strain (FCC-3204), is cultured in a liquid medium enriched with essential nutrients. The crude oil is extracted following enzymatic hydrolysis of the algal biomass and centrifugation. The crude oil is then refined following production processes that are commonly used in the edible oil industry, and EU-authorised antioxidants are added at various stages to maintain stability. The resulting refined oil is stored in airtight and lightproof containers at -20 °C.

The EFSA NDA Panel noted that the production process has been assessed in previous opinions with no concerns.

The applicant confirmed to the FSA and FSS that the production process has not changed since the last authorisation, and that all food additives used throughout the production process are also authorised in GB. Therefore, the FSA and FSS agree with the EFSA that no further assessment on the production process is necessary.

2.1.3. Compositional information and stability

The oil consists of a mix of triglycerides, made up from polyunsaturated fatty acids. DHA is the predominant fatty acid, constituting >55% of the total fatty acid content. The composition of five independent batches was

reviewed by the NDA Panel in previous opinions; the Panel concluded that the composition of the novel food was sufficiently characterised (EFSA NDA Panel, 2021a, 2021b).

The FSA and FSS note that the 2021 EFSA opinions were accepted by the FSA and FSS (FSA and FSS 2021) and therefore are also applicable to GB. The FSA and FSS agree with the conclusions of the NDA Panel; therefore, no further assessment of the composition of the novel food is necessary.

The shelf-life stability of the novel food was evaluated by the EFSA NDA Panel in previous opinions; the Panel concluded that the oil was stable for 2 years when stored at or below the proposed storage temperature of -15 °C in the absence of light, moisture, heat and oxygen.

In the current application, the applicant provided a study examining the stability of the novel food in a food matrix. In line with the intended extension of use for inclusion in protein products, the stability of the novel food in a plant-based fish analogue was examined. The effect of processing (extrusion) on stability of the novel food was considered, as the high temperature and moist conditions of extrusion are expected to be detrimental to DHA-rich oils.

The novel food was included in a soy concentrate, produced using an extrusion-based process, at an inclusion rate of 0% (control), 5% and 10% of the total oil. Oxidative parameters, including peroxide value and p-anisidine values, were measured immediately after extrusion; the fish analogues containing the novel food had lower peroxide and p-anisidine values (relative to the control), indicating less oxidation. The NDA Panel noted that continued stability in the food matrix was not evaluated. However, it has been previously demonstrated that the novel food is stable for 113 weeks at 25°C/60% relative humidity (EFSA NDA Panel, 2021b); the Panel therefore concluded that the novel food is expected to be stable under the intended conditions of use.

The FSA and FSS agree with the conclusions of the NDA panel on stability and therefore no further assessment on the stability of the novel food as an ingredient in different food categories is considered necessary.

2.1.4. Specification

The EFSA NDA Panel outlined the specification, as described in the Union list, and concluded that sufficient information had been provided relating to the specification of the novel food. The Panel also evaluated a request from the applicant to amend the specification but concluded that there was no safety-related need for the proposed amendment.

The FSA and FSS note that the specification reported in the EFSA opinion is the same as the specification listed in assimilated Regulation 2017/2470 (EC, 2017b) for *Schizochytrium* sp. strain (FCC-3204) oil ([Table 1](#)). This is also the specification in the GB list of authorised novel foods.

The applicant confirmed that they are not seeking to amend the specification in GB; therefore, the FSA and FSS agree with the EFSA and conclude that no further assessment of the specification is required.

Table 1. Specification of DHA-rich oil from *Schizochytrium* sp. strain (FCC-3204).

Parameter	Specification
Acid value	≤0.5 mg KOH (potassium hydroxide)/g
Peroxide value (PV)	≤5.0 meq (milliequivalent)/kg oil
Moisture and volatiles	≤0.05 %
Unsaponifiables	≤4.5 %
Trans-fatty acids	≤1.0 %
Docosahexaenoic acid (DHA)	≥32.0 %
P-anisidine value	≤10

2.1.5. History of Use of the novel food and its source

The novel food is a DHA-rich oil obtained from *Schizochytrium* sp*. strain (FCC-3204). DHA-rich oil from the genus *Schizochytrium* has been authorised and widely used as a novel food for inclusion in a large number of specified food categories in the EU since 2003 ([Table 2](#)). The first authorisation was based on *Schizochytrium* sp. strain ATCC 20888; following that, strains FCC-1324 and FCC-3204 (the subject of this novel food application) were considered substantially equivalent to strain ATCC 20888 (ANSES, 2018), and therefore a suitable source of DHA-rich oil.

Table 2. Authorised uses of DHA-rich *Schizochytrium* sp. oil in the EU

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

Specified food category	Maximum level DHA
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 ^a
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

^aValue in Union list (differs to value reported in EFSA opinion)

In addition to the generic authorisation, DHA-rich oil from *Schizochytrium* sp. strain (FCC-3204), the subject of this novel food application, was authorised separately to generic DHA-rich *Schizochytrium* sp. oil in 2021, to allow for its inclusion in infant formula (IF) and follow-on formula (FOF), as well as its inclusion at a higher level in supplements ([Table 3](#)). There are also several other *Schizochytrium* sp. strains that have been authorised separately for use specifically in IF and FOF. Furthermore, *Schizochytrium* sp. oil rich in DHA and eicosapentaenoic acid (EPA) is also authorised for use as a novel food in various food categories.

Table 3. Authorised uses of DHA-rich oil from *Schizochytrium* sp. strain (FCC-3204) in the EU

Specified food category	Maximum level DHA
Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No. 609/2013
Food supplement as defined in Directive 2002/46/EC for the general population above 3 years	1 g/day

The FSA and FSS accept the EFSA conclusions and agree that DHA-rich oil produced by *Schizochytrium* sp. has a long history of safe use as a novel food. The FSA and FSS note that the novel food is also authorised in GB for all the food categories listed in [Table 2](#) and [Table 3](#), at the same inclusion level.

Since the 2024 EFSA opinion, DHA-rich oil obtained from *Schizochytrium* sp. strain (FCC-3204) has additionally been authorised for inclusion in protein products (excluding dairy analogues) in the EU.

2.1.6. Proposed Use and Intake

The target population is the general population.

The novel food is already authorised for inclusion in a large number of specified food categories. The applicant is proposing a change in conditions of use to extend use to protein products, excluding dairy analogues ([Table 4](#)). This corresponds with the specified food category 12.9 'Protein products, excluding dairy analogues', as laid out in assimilated Regulation (EC) No 1333/2008 (EC, 2008). The applicant indicated that the most likely use is in seafood analogues.

Table 4. Proposed uses.

Specified food category	Maximum levels of DHA
Protein products, excluding dairy analogues	1 g DHA/100 g

The EFSA NDA Panel reported the anticipated daily intake of DHA from the new intended use alone, from all authorised uses (excluding supplements), and from the combined intake of the new intended use and all other authorised uses (excluding supplements). Anticipated daily intake was estimated using the EFSA Food Additives Intake Model (FAIM) tool, which uses data from the EFSA Comprehensive European Food Consumption Database (EFSA, 2011), and is reported separately for each population group. The age range and default bodyweight for each population group is reported in [Table 5](#). The default bodyweights are those set by the EFSA Scientific Committee (EFSA Scientific Committee, 2012).

Table 5. Population groups as defined by age. The default bodyweight is reported for each population group.

Population group	Age (years)	Default body weight (kg)
Infants	<1	5
Young children/toddlers	1-<3	12
Other children	3-<10	23
Adolescents	10-<18	61
Adults ^a	≥18	70

^aThis population group also includes the elderly and very elderly.

The EFSA NDA Panel calculated the anticipated daily intake of DHA from the new intended use of the novel food only, based on the new intended use in the food category 'protein products, excluding dairy analogues'. The estimated mean and 95th percentile (P95) intake levels of DHA from the new intended use of the novel food for each population group is presented in [Table 6](#). The results are reported on both a mg/kg bodyweight (bw) per day basis and a mg/day basis, as calculated using the default bodyweight

in [Table 5](#). A range is given for each value, to reflect the highest and lowest value observed across all the EU surveys. P95 values based on less than 60 individuals were not considered in the assessment.

Table 6. Anticipated intake of DHA from the new intended use of the novel food alone

Population group	Mean intake (mg/kg bw per day)	P95 intake (mg/kg bw per day)	Mean intake (mg/day)	P95 intake (mg/day)
Infants	0 - 0.1	0 - 0.4	0 - 0.5	0 - 2
Young children/toddlers	0 - 0.6	0 - 0.7	0 - 7.2	0 - 8.4
Other children	0 - 0.6	0 - 1.1	0 - 13.8	0 - 25.3
Adolescents	0 - 1.0	0 - 6.3	0 - 61	0 - 384.3
Adults	0 - 0.4	0 - 1.9	0 - 28	0 - 133

The novel food is already authorised for inclusion in a number of food categories in the EU ([Table 2](#) and [3](#)). To estimate daily intake of DHA from all authorised uses, excluding food supplements, the authorised uses were translated into FAIM tool categories. However, there were a number of considerations that the Panel made in their assessment, as the authorised uses do not always translate easily to a corresponding FAIM tool category. For instance, the authorised uses of 600 mg DHA/100g in 'spreadable fats and dressings' and 360 mg DHA/100g in 'cooking fats' were translated to the FAIM tool category 'fats and oils', with a set value of 600 mg DHA/100g. Furthermore, because of the lack of a corresponding FAIM tool category, the following authorised uses were not considered in the intake assessment:

- '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', as there is no equivalent FAIM tool category for these authorised uses.
- 'Total diet replacement for weight control, as defined in Regulation (EU) No 609/2013 and Meal replacements for weight control', as there is no maximum use level expressed per gram that can be inputted into the FAIM tool.
- 'Foods for special medical purposes as defined in Regulation (EU) No 609/2013' as there is no maximum use level that can be inputted into the FAIM tool.

The anticipated intake assessment also includes intake of DHA from IF and FOF. For these food categories, DHA addition is mandatory under Commission Delegated Regulation (EU) 2016/127. The Panel used the maximum limit of 50 mg DHA/ 100 kcal and standard energy content of maximum 70 kcal/100 mL for both IF and FOF.

The estimated mean and 95th percentile intake levels of DHA from the current authorised uses of the novel food (excluding supplements and the exceptions listed above) for each population group is presented in [Table 7](#).

Table 7. Anticipated intake of DHA from the existing authorised uses of the novel food

Population group	Mean intake (mg/kg bw per day)	P95 intake (mg/kg bw per day)	Mean intake (mg/day)	P95 intake (mg/day)
Infants	24.6 – 77.2	61.6 – 172.5	123 – 386	308 – 863
Young children/toddlers	56.3 – 109.9	112.7 – 192.5	676 – 1319	1352 – 2310
Other children	41.9 – 88.5	80.1 – 137.5	964 – 2036	1842 – 3163
Adolescents	16.2 – 39.7	35.3 – 71.0	988 – 2422	2153 – 4331
Adults	11.1 – 22.8	22.8 – 45.4	777 – 1596	1596 – 3178

The combined intake of DHA from both the new intended use and the existing authorised uses was also estimated ([Table 8](#)).

Table 8. Anticipated intake of DHA intake from the new intended use and all existing authorised uses of the novel food combined

Population group	Mean intake (mg/kg bw per day)	P95 intake (mg/kg bw per day)	Mean intake (mg/day)	P95 intake (mg/day)
Infants	24.6 – 77.2	61.6 – 172.5	123 – 386	308 – 863
Young children/toddlers	56.3 – 110.2	112.8 – 192.5	676 – 1322	1354 – 2310
Other children	42.0 – 88.8	80.1 – 138.4	966 – 2042	1842 – 3183
Adolescents	16.3 – 40.0	35.3 – 71.0	994 – 2440	2153 – 4331
Adults	11.2 – 22.9	22.8 – 45.4	784 – 1603	1596 – 3178

The EFSA NDA Panel observe that exposure to DHA from the new intended use is very low when compared with the exposure from authorised uses.

Based on the compositional data provided and the intake assessment, the new intended use is not expected to increase exposure to undesirable substances. Furthermore, there are no specific precautions or restrictions of use associated with the new intended use.

The FSA and FSS reviewed the EFSA NDA Panel opinion and the data provided by the applicant. In addition, the FSA and FSS reviewed the intake assessment performed by EFSA that is available as supplementary information on the EFSA website.

The applicant provided a new intake assessment for DHA from the new intended use and authorised uses, using a more recent version of the FAIM tool. The FSA and FSS evaluated both the intake assessment performed by EFSA and the intake assessment provided by the applicant. The FSA and FSS deemed the intake assessment performed by EFSA as part of their risk assessment to be sufficient; therefore, the applicant's intake assessment using the FAIM tool was not considered further as part of this assessment.

Consideration was given to the relevance of the dataset used in the EFSA intake assessment to the GB population. No evidence was identified to suggest that the EFSA assessment would not be applicable to GB consumption patterns, and there is no indication that intake of the new use differs substantially between the EU and GB. Furthermore, the NDA Panel noted that exposure to DHA from the new intended use is very low compared to exposure from the existing authorised uses. Considering all this information together, the FSA and FSS conclude that further intake assessment based on GB-specific consumption data is not necessary. It should, however, be noted that an intake assessment using GB consumption data has not been performed. Furthermore, no formal comparison of consumption data for the food category 'protein products, excluding dairy analogues' between the EU and GB has been performed. These exist as uncertainties in the FSA and FSS risk assessment.

In summary, the FSA and FSS accept the intake assessment performed by EFSA and agree with the conclusions of the EFSA NDA Panel. The FSA and FSS determine that these conclusions are relevant to the GB population without the need for further data or risk assessment. No concerns were raised with extending the use of the novel food to the additional category.

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

No new ADME studies were provided as part of this application. The NDA Panel agreed that further ADME studies were not necessary for the safety assessment, as the ADME of DHA (the key component of the novel food) has been well characterised in a previous EFSA opinion (EFSA NDA Panel, 2012).

The 2012 EFSA opinion was published when the UK was still part of the EU and therefore the FSA and FSS agree with the conclusions and agree that no further ADME studies are necessary.

2.1.8. Nutritional Information

The NDA Panel concluded that consumption of the novel food in line with the proposed conditions of use was not expected to be nutritionally disadvantageous to the consumer.

The FSA and FSS agree with this conclusion and no further assessment on the nutritional information of the novel food was considered necessary.

2.1.9. Toxicological Information

The Panel noted that no new toxicological data were provided as part of the application, but toxicological information for the novel food has been considered in previous EFSA opinions (EFSA NDA Panel, 2021a, 2021b). The 2021 opinions concluded that there were no toxicological concerns for DHA oil from *S. limacinum* (strain FCC-3204), based on the Qualified Presumption of Safety (QPS) status of the production strain, the absence of viable cells in the novel food, the production process, the composition and the available toxicological data from other strains within the *Schizochytrium* genus.

The FSA and FSS agree with the conclusions of the EFSA NDA Panel and consider that no further toxicological studies on the novel food are necessary.

2.1.10. Allergenicity

The EFSA NDA Panel reiterated the conclusions of the 2021 opinions, namely that the novel food is unlikely to pose allergenicity risk to consumers, due to very low concentration of protein (i.e. below the LoQ of 0.25%).

The FSA and FSS agree with the conclusions of the EFSA NDA Panel; no further assessment of allergenicity is required.

3. Other Regulators Opinions and Conclusions

The EFSA NDA Panel concluded that DHA-rich oil from *S. limacinum* strain FCC-3204 is safe under the proposed change in condition of use to extend to additional food categories. The anticipated intake levels and the proposed use in protein products were not considered to be nutritionally disadvantageous.

4. Uncertainties and Limitations

No specific uncertainties were flagged in the assessment by the EFSA.

The FSA and FSS note that the intake assessments have not been specifically calculated using GB consumption data, and that no formal comparison of consumption patterns between the EU and GB population has been performed. However, the FSA and FSS note that the EFSA NDA Panel determined that consumption of the proposed new use was very low compared to consumption of existing authorised uses. Furthermore, no evidence has been identified that would suggest intake of the additional uses differs substantially between the EU and GB.

5. FSA-FSS conclusion for GB assessment

The application has been evaluated in line with 'Guidance on the preparation and submission of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283' (EFSA NDA Panel, 2016) and assimilated Commission Implementing Regulation (EU) 2017/2469, for purposes of the GB assessment.

The conclusions of the EFSA opinion (EFSA NDA Panel, 2024), which have 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.

6. Outcome of the assessment

The FSA and FSS have reviewed the applicant's dossier, supporting documentation, and most notably the EFSA opinion (EFSA NDA Panel, 2024), and consider that there is sufficient evidence to conclude the assessment for the extension of use of DHA-rich oil from *Schizochytrium* sp. strain (FCC-3204) for use in all protein products without obtaining further information or conducting a further risk assessment.

The FSA and FSS conclude DHA-rich oil from *Schizochytrium* sp. strain (FCC-3204) is safe under the proposed conditions of use. The anticipated intake levels and the proposed use in food is not considered to be nutritionally disadvantageous.

In making this assessment, the FSA and FSS were able to rely on sufficient scientific evidence 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 which 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.

Abbreviations

ADME	Absorption, distribution, metabolism and excretion
ANSES	French Agency for Food, Environmental and Occupational Health & Safety
ATCC	American Type Culture Collection
Bw	Body weight
DHA	Docosahexaenoic acid
EC	European Commission
EFSA	European Food Safety Authority
EPA	Eicosapentaenoic acid
EU	European Union
FAIM	Food Additives Intake Model
FDA	US Food and Drug Administration
FOF	Follow-on formula
FSA	Food Standards Agency
FSS	Food Standards Scotland
GB	Great Britain
GRAS	Generally recognised as safe
IF	Infant formula
LoQ	Limit of Quantitation
meq	milliequivalent
NDA Panel	Panel on Nutrition, Novel Foods and Food Allergens
P95	95th percentile
PV	Peroxide value
QPS	Qualified Presumption of Safety
UK	United Kingdom

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