REGULATED PRODUCTS SAFETY ASSESSMENT

Safety Assessment of an Extension of Use of the Novel Food Schizochytrium sp. (ATCC PTA-9695) Oil (RP2328)

Food Standards Agency[1], Food Standards Scotland[2]

[1] Regulated Products Risk Assessment, Food Standards Agency, UK, [2] Risk Assessment, Food Standards Scotland, UK

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FSA Research and Evidence

The Food Standards Agency (FSA) and Food Standards Scotland (FSS) received an application, in July 2025 from DSM Nutritional Products Europe Ltd., Switzerland ("the applicant"). The application is seeking to change the conditions of use of an authorised novel food *Schizochytrium* sp. (ATCC PTA-9695) oil, to increase the daily intake of the novel food in food supplements to 1 g DHA/day for those 3 years of age and above including pregnant and lactating women, whilst maintaining 250 mg DHA/day in food supplements for the general population below 3 years of age. The purpose of the proposed change is to align with similar authorisations for high-DHA *Schizochytrium* sp. oils.

The FSA and FSS in their evaluation of the application reviewed the safety dossier and supplementary information provided by the applicant. The FSA and FSS did not consider any potential health benefits or claims arising from consuming the food, as the focus of the novel food assessment is to ensure the food is safe and not putting consumers at a nutritional disadvantage.

The FSA and FSS concluded that the applicant had provided sufficient information to assure that the change in the conditions of use of *Schizochytrium* sp. (ATCC PTA-9695) oil did not raise any safety concerns for the target populations. The anticipated intake levels and the intended use was not considered to be nutritionally disadvantageous.

The assessment represents the opinion of the FSA and FSS.

This is a joint FSA and FSS publication.

1. Introduction

Schizochytrium sp. (ATCC PTA-9695) oil is an authorised novel food in the UK. The novel food is an oil high in docosahexaenoic acid (DHA) produced by fermentation using the microalgae *Schizochytrium* sp. (ATCC PTA-9695). The novel food is an alternative source of DHA, an omega-3 long-chain polyunsaturated fatty acid (n-3 LCPUFA) in the diet.

High-DHA *Schizochytrium* sp. oil has been authorised as a novel food in the EU and UK since 2003 (assimilated Implementing Decision (EU) 2003/427). The original authorisation was addressed to Martek Biosceinces. In 2015, high-DHA oil from *Schizochytrium* sp. (ATCC PTA-9695), the subject of this novel food application, was authorised separately to generic high-DHA *Schizochytrium* sp. oil (EC, 2015, 2017).

In July 2025, DSM Nutritional Products Europe Ltd, Switzerland ("the applicant") submitted an application to the FSA and FSS for a change in conditions of use for *Schizochytrium* sp. (ATCC PTA-9695). The application sought to increase the daily intake of the novel food in the form of food supplements to 1 g DHA/day for those 3 years of age and above including pregnant and lactating women, whilst maintaining 250 mg DHA/day in food supplements for those below 3 years of age (see Table 2).

The FSA and FSS have undertaken the safety assessment of the change in conditions of use to extend the use of *Schizochytrium* sp. oil (ATCC PTA-9695) under the novel foods legislation, assimilated Regulation (EU) 2015/2283.

Under Article 3(4) of assimilated Implementing Regulation (EU) 2017/2469, 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 extension of use of the novel food.

The evaluation by the FSA and FSS assessed the food safety risks of the novel food and its production, in line with Article 11 of assimilated Regulation (EU) 2015/2283 and Article 7 of assimilated Implementing Regulation (EU) 2017/2469. The basis and structure of the assessment was conducted in accordance with the relevant technical guidance put in place by the European Food Safety Authority (EFSA) for full novel food

applications (EFSA NDA Panel, 2016) which the FSA and FSS considers is relevant and should be applied to this novel food application owing to similarities in the regulatory regimes.

This assessment outlines the conclusions of the FSA and FSS on the extension of use of *Schizochytrium* sp. oil (ATCC PTA-9695) to an upper intake in food supplements of 1 g DHA/day for those 3 years of age and above (including pregnant and lactating women), whilst maintaining 250 mg DHA/day in food supplements for those below 3 years of age.

2. Assessment

2.1.1. Identity of the novel food

The novel food is *Schizochytrium* sp. oil high in DHA produced by fermentation using the microalgae *Schizochytrium* sp. (ATCC PTA-9695).

The identity of the novel food is not changed by the current application made to the FSA and FSS, and as such has not been subject to further assessment.

2.1.2. Production process

Schizochytrium sp. (ATCC PTA-9695) oil is produced via a self-contained fermentation process using the algae *Schizochytrium*. The algae are grown in a pure heterotrophic fed-batch fermentation process; the crude oil is recovered from the fermentation broth and subject to a series of refinement steps typical to the refined oil industry. Suitable antioxidants may be added to aid stability.

The production process is unchanged from the previous authorisation, and as such has not been subject to further assessment.

2.1.3. Compositional information

There is no change to the composition of the novel food from the previous authorisation. The novel food continues to meet the specification as laid out in the GB list of authorised novel foods and as such it has not been subject to further assessment.

2.1.4. Stability

The stability of the novel food was assessed in the original authorisation and no concerns were raised. No additional data on stability was provided by the applicant. The FSA and FSS conclude that the proposed extension of use sought does not change the original conclusion on stability.

2.1.5. Specification

The specification of the novel food is given in Table 1. There is no change to the specification of the novel food from its original authorisation; as such, it has not been subject to further assessment.

Table 1. Specification for *Schizochytrium* sp. (ATCC PTA-9695) oil, as currently authorised.

Description	The novel food is obtained from the strain ATCC PTA-9695 of the microalgae *Schizochytrium* sp.
Peroxide value (PV)	≤ 5.0 meq/kg oil
Unsaponifiables	≤ 3.5 %
Trans-fatty acids	≤ 2.0 %
Free fatty acids	≤ 0.4 %
Docosapentaenoic acid (DPA) n-6	≤ 7.5 %
Docosahexaenoic acid (DHA) content	≥ 35 %

2.1.6. History of use

Docosahexaenoic acid (DHA) is an omega-3 long chain polyunsaturated fatty acid (n-3 LCPUFA) which plays an important role in the structure and function of cell membranes. It is naturally occurring in various food groups, especially fish. Dietary recommendations for n-3 LCPUFAs (mostly as eicosapentaenoic acid (EPA) and DHA) in EU member states range from 40 to 250 mg/day for infants and children, and from 200 to >600 mg/day for adults (EFSA NDA Panel, 2012).

In the UK, the recommended daily intake for n-3 LCPUFAs is 200 mg/day for children over 5 years of age and 450 mg/day for adults (DoH, 1991, 1994; SACN, 2004). In the EU, specific recommendations for additional DHA intake have also been made for infants and young children (70 to 100 mg/day), and for pregnant and lactating women (100-200 mg/day), on the basis of DHA's role in central nervous system development in the foetus and infant (EFSA NDA Panel, 2012). However, various adverse effects have been associated with high LCPUFA intake (≥3 g/day), including bleeding episodes, impaired immune function, increased lipid peroxidation, and impaired lipid and glucose metabolism. In a 2012 evaluation of EPA, DHA and docosapentaenoic acid (DPA) intakes, EFSA concluded that the available data were not sufficient to establish a tolerable upper intake level for n-3 LCPUFA (DHA, EPA, and DPA, individually or combined) for any population group, however, intakes of combined EPA and DHA up to 5 g/day, or supplemental intakes of DHA alone up to about 1 g/day, did not raise safety concerns for the general population (EFSA NDA Panel, 2012).

High-DHA *Schizochytrium* sp. oil, produced using any production strain, was authorised in the European Union in 2003 in various food categories, and in food supplements up to 200 mg DHA/day (assimilated Implementing Decision (EU) 2003/427). In 2009 and 2014, extensions of use were authorised for additional food categories, and an increase in the maximum use level of DHA in food supplements to 250 mg/day for the general population and 450 mg/day for pregnant and lactating women (assimilated Implementing Decision (EU) 2009/778, assimilated Implementing Decision (EU) 2014/463).

The applicant (DSM Nutritional Products Europe Ltd., the same applicant as for this application) initially applied under the previous novel food regulations to use *Schizochytrium* sp. (ATCC PTA-9695) oil in a range of food categories. The maximum use level in food supplements of 3 g DHA+EPA/ day was sought. Following reasoned objections from Member States under Article 6 of Regulation (EU) 258/97, the maximum use level in food supplements was revised to 250 mg DHA/day for the general population and 450 mg DHA/day for pregnant and lactating women, in line with the authorised use levels of non-strain specific high-DHA *Schizochytrium* sp. oil. This was reflected in the EU authorisation for *Schizochytrium* sp. (ATCC PTA-9695) oil in 2015, while the UK was a member state, which authorised use of the novel food in various food categories (EC, 2015).

2.1.7. Intended use and maximum use levels

Schizochytrium sp. (ATCC PTA-9695) oil is currently authorised in supplements at a maximum intake of 250 mg DHA/day for the general population and 450 mg DHA/day in pregnant and lactating women. The current application requests a change to the conditions of use to increase the maximum intake in supplements to 1 g DHA/day for those 3 years of age and above, including pregnant and lactating women (Table 2). No change is proposed to the level of 250 mg DHA/day in food supplements for the general population below 3 years of age. Nor is any change being sought to the other food categories that have been authorised for oil produced by this strain of *Schizochytrium*.

The purpose of the change in conditions of use is to align with the authorised conditions of use of another high-DHA *Schizochytrium* oil produced using strain FCC-3204 (Regulation (UK) 2022/560).

Table 2. Current and proposed conditions of use for *Schizochytrium* sp. (ATCC PTA-9695) oil.

Specified Food Category	Current Conditions of Use (Maximum Levels of DHA)	Proposed Conditions of Use (Maximum Levels of DHA)
Bakery products (breads, rolls, and sweet biscuits)	200 mg/100 g	No change
Breakfast cereals	500 mg/100 g	No change
Cereal bars	500 mg/100 g	No change
Cooking fats	360 mg/100 g	No change
Dairy analogues except drinks	200 mg/100 g or for analogues to cheese products 600 mg/100 g	No change
Dairy products except milk-based drinks	200 mg/100 g or for cheese products 600 mg/100 g	No change
Food Supplements as defined in Directive 2002/46/EC	250 mg/day for general population 450 mg/day for pregnant and lactating women	250 mg/day for the general population below 3 years of age 1 g/day for the general population above 3 years of age* *Including pregnant and lactating women
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	No change
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	No change
Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen	200 mg/100 g	No change
Fruit/vegetable puree	100 mg/100 g	No change
Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013	No change
Milk-based drinks and similar products intended for young children	200 mg/100 g	No change
Non-alcoholic beverages (including dairy analogue and milk-based drinks)	80 mg/100 mL	No change
Processed cereal-based foods and baby foods for infants and young children as defined in Regulation (EU) No 609/2013	200 mg/100 g	No change
Spreadable fats and dressings	600 mg/100 g	No change
Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control	250 mg/meal	No change

Consideration of the additional exposure of DHA rich oil from *Schizochytrium* species has been considered in a number of EU opinions for these oils. In 2019, an application was made for an extension of the conditions of use to the authorisation of high-DHA *Schizochytrium* sp. oil (produced by any production strain), to increase the maximum intake in supplements to 3 g DHA/day for those above 3 years of age, excluding pregnant and lactating women. In their opinion (EFSA, 2021), EFSA concluded that there was insufficient evidence to support a maximum intake of 3 g DHA/day, but that an upper intake of 1 g DHA/day would not raise safety concerns for the general population (EFSA NDA Panel, 2021). This view is considered applicable in GB.

In a subsequent positive safety assessment on an oil from a related *Schizochytrium* sp. (FCC-3204), EFSA concluded that "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." (EFSA, 2024). The change to the conditions of use for *Schizochytrium* sp. (ATCC PTA-9695) oil matches the permitted uses for FCC-3204 and as such it is not expected to have a significant impact on total exposure to DHA

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

The FSA and FSS conclude that the proposed extension of use does not change the original conclusion on the ADME properties of the novel food.

2.1.9. Nutritional Information

Information concerning the nutritional profile of the novel food was assessed in the original assessment (ACNFP, 2014; EFSA, 2014). It was concluded that the novel food was not nutritionally disadvantageous for consumers.

The applicant proposes a maximum daily intake from supplements of the novel food of 250 mg DHA/day for those under 3 years of age and 1 g DHA/ day for those 3 years of age and above, including pregnant and lactating women.

In the UK, the recommended daily intake for n-3 LCPUFAs (mainly EPA and DHA) is 450 mg/day for adults and 200 mg/day for children over 5 years of age (DoH, 1991, 1994; SACN, 2004). A daily intake of 1 g DHA is considered safe for the general population (EFSA NDA Panel, 2012). This view is applicable to consumers in GB. The FSA and FSS therefore conclude that the changes to the proposed conditions of use do not raise any nutritional concerns.

2.1.10. Toxicological information

The toxicological profile of *Schizochytrium* sp. (ATCC PTA-9695) oil was reviewed in the initial safety assessment (ACNFP, 2014; EFSA, 2014) and raised no concerns, with a NOAEL (no observed adverse effect level) of 4,122 and 4,399 mg/kg bw/day for male and female rats respectively, the highest doses tested. This is equivalent to around 300 g/day for a 70 kg adult human, or around 20 g/day for a 5 kg infant. No further toxicological information was provided for assessment, because there are no changes to the production process or the specification of the novel food.

Information from other assessments by EFSA of oil from *Schizochytrium* species provide additional data on the toxicology of DHA oil produced by this species which is of relevance to the assessment of the change of use sought in this application.

In 2012, the EFSA NDA Panel concluded that supplemental intake of DHA alone up to 1g/day did not raise any safety concerns in the context of a review of DHA from all sources, however, the available data was not sufficient to establish a tolerable upper intake level for n-3 LCPUFA (DHA, EPA, and DPA, individually or combined) for any population group (EFSA NDA Panel, 2012).

In 2021, EFSA concluded that the data submitted to support the assessment of an oil from a related *Schizochytrium strain* (*Schizochytrium* sp. FCC-3204) demonstrated that supplemental intakes of DHA alone up to 1 g/day do not raise safety concerns for the general population. Whilst no toxicological studies were provided for the specific strain, EFSA noted that toxicity of DHA-rich algal oils from *Schizochytrium* species have been extensively evaluated. The panel considered a variety of guideline compliant studies, including bacterial reverse mutation tests, *in vitro* chromosomal aberration tests, *in vivo* mammalian cell micronucleus tests, subchronic toxicity studies with rats, and developmental and reproductive toxicity studies with rats. A study performed on DHA-oil produced from strain ATCC PTA-9695 (Fedorova-Dahms et al., 2011), the subject of the current application, was also included in the assessment. EFSA noted that in previous assessments, no concerns regarding genotoxicity or subchronic toxicity had been noted (EFSA, 2021).

EFSA concluded that, based on the available data on DHA-rich oils, the QPS status of the production organism and the demonstration of absence of viable cells in the final product there were no safety concerns for the novel food produced by *Schizochytrium* sp. (FCC-3204) with an upper intake of 1 g DHA/day (Assimilated Regulation (EU) 2021/1326). The same decision was adopted in GB in 2022 (FSA & FSS, 2022, Assimilated Regulation (UK) 2022/560). This data was not data protected under the novel foods regulation.

The EFSA assessment noted that the conclusions did not extend the safety conclusion to non-strain specific high-DHA *Schizochytrium* sp. oils. However, the toxicological assessment was based on studies carried out on several *Schizochytrium* sp. including *Schizochytrium* sp. (ATCC PTA-9695) oil, the novel food that is the subject of this assessment. As such the evidence is considered relevant to the assessment of the extension of oil from strain ATCC PTA-9695 and supports safe use of the novel food at an intake of 1g a day.

2.1.11. Allergenicity

The original assessment did not consider the novel food to carry any allergenic risks (ACNFP, 2014; EFSA, 2014).

No further allergenicity information was provided for assessment because there are no changes to the production process and the specification of the novel food.

3. Discussion

The novel food is a DHA-rich oil produced by the microalgae *Schizochytrium* sp. (ATCC PTA-9695), which is currently authorised in various food categories and in food supplements. The application is for an extension of use in food supplements to 1 g DHA/day for those 3 years of age and above (including pregnant and lactating women), whilst maintaining 250 mg DHA/ day in food supplements for the general population below 3 years of age. This is to align with the authorised conditions of use of a similar novel food, *Schizochytrium* sp. (FCC-3204) oil.

There is no change to the production process, composition, stability, specification, ADME properties, nutrition or toxicological information of the novel food since its original assessment (ACNFP, 2014; EFSA, 2014).

An intake of up to 1 g DHA/day is considered to be safe for the general population (EFSA NDA Panel, 2012) and has been authorised in GB for another *Schizochytrium* sp. (FCC-3204) oil (Regulation (UK) 2022/560). The safety assessment of *Schizochytrium* sp. (FCC-3204) oil undertaken in the EU and GB was based on the established safe intake level for DHA and on toxicological data from DHA-rich oils derived from *Schizochytrium* sp., including *Schizochytrium* sp. (ATCC PTA-9695), with no concerns identified regarding genotoxicity or subchronic toxicity (EFSA, 2021). In addition, exposure to DHA resulting from the revised daily intake in food supplements is considered to be low when compared to exposure from already authorised food categories (EFSA, 2024). Therefore, the proposed change to the conditions of use for *Schizochytrium* sp. (ATCC PTA-9695) oil does not raise further safety concerns.

Conclusions

The FSA and FSS have undertaken the assessment of the change to the conditions of use of *Schizochytrium* sp. (ATCC PTA-9695) oil and concluded that the novel food does not pose a safety risk to human health. The increase in proposed intake in supplements to 1 g DHA/day for those 3 years of age and above, including pregnant and lactating women, does not pose a safety concern.

These conclusions were based on the information provided in the novel food dossier submitted by the applicant.

Abbreviations

Abbreviation	Definition
ADME	Absorption, distribution, metabolism and excretion
DHA	Docosahexaenoic acid
DPA	Docosapentaenoic acid
EFSA	European Food Safety Authority
EU	European Union
FSA	Food Standards Agency
FSS	Food Standards Scotland
GB	Great Britain
LCPUFA	Long-chain polyunsaturated fatty acid
NOAEL	No observed adverse effect level
n-3	Omega-3

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