

# FSA/FSS opinions of applications for six novel foods

Date of original publication: 17 December 2021

Date of revision: 31 March 2022

## Document subject and purpose

In this document we publish the Food Standards Agency (FSA)/Food Standards Scotland (FSS) opinions, following the quality assurance of risk assessments conducted by the European Food Safety Authority (EFSA), of six novel foods (NFs) as outlined in the annexes.

The opinions will be considered by Ministers to inform decision making on whether to authorise the individual NFs for use in England, Scotland and Wales.

This opinion is being published in parallel with FSS.

## Comments and feedback

If you wish to comment on the FSA/FSS opinions, feedback should be sent to:

Email: [RPconsultations@food.gov.uk](mailto:RPconsultations@food.gov.uk)

Name: Regulated Products Approvals Team

Division/Branch: Chemical Safety Policy Unit

Please state, in your comment, whether you are commenting as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents) and in which country you are based.

Please indicate which application(s)/opinion(s) you are commenting on by using the following subject line for your response:

Comment on [insert RP number(s)] NF FSA/FSS opinion

Comments will be shared with FSS.

Comments will be published and made available to the public and Ministers.

## Document details

In accordance with [Retained EU Regulation 2015/2283](#) on NFs, the NFs included in this document have been submitted for authorisation.

Six NFs have been submitted for authorisation in each nation of Great Britain (GB), where the decision on authorisation is made by the respective Ministers in England, Scotland and Wales. This is a function that was previously carried out at a European Union (EU) level. Since the end of the transition period, protection of public health in relation to the consumption of food and consumer interests in relation to food in the UK is the responsibility of FSA/FSS and the authorisation of NFs is the responsibility of the relevant appropriate authority of each of the nations of GB.

In respect to Northern Ireland, EU Food Law on NFs continues to apply under the current terms of the Protocol on Ireland/Northern Ireland (NIP). This means NFs require authorisation under the EU's authorisation procedures, before being placed on the market in Northern Ireland.

Whilst it was a Member State of the EU, the UK accepted the assessments of EFSA in support of authorisations for regulated food and feed products. Since the end of the transition period, FSA/FSS has adopted equivalent technical guidance and quality assurance processes to make independent GB risk assessments. Where EFSA, prior to the end of the transition period, evaluated an application for a product for which an application is now made to GB, FSA/FSS has decided to make use of the EFSA risk assessment, where this is appropriate, in forming its own independent opinion.

Therefore, FSA/FSS risk assessors have reviewed the EFSA opinions for the products included in this document in the context of intended GB use and have concluded that the intended uses are safe. FSA/FSS has had access to all supporting documentation as provided to EFSA for forming the EFSA opinion.

The FSA/FSS opinion for each NF is published within a separate annex, including the regulated product ID number and title of the application (Ctrl+Click to follow link):

Annex A: RP8 – 3'-Sialyllactose (3'-SL) sodium salt (new)	4
Annex B: RP9 – 6'-Sialyllactose (6'-SL) sodium salt (new)	10
Annex C: RP14 – 2'-Fucosyllactose / difucosyllactose mixture ("2'-FL/DFL mixture") (extension of use for current authorisation)	15
Annex D: RP87 – DHA-rich algal oil from <i>Schizochytrium</i> sp strain WZU477 (extension of use for current authorisation)	20
Annex E: RP810 – DHA 550 - <i>Schizochytrium</i> sp. strain (FCC-3204) (application to increase the daily intake of DHA from this source to 1000 mg/day)-(extension of use for current authorisation)	24
Annex F: RP811 – DHA 550 - <i>Schizochytrium</i> sp. strain (FCC-3204) (application to extend the use of the authorisation to infant and follow-on formula) (extension of use for current authorisation)	28

## Further information

If you require a more accessible format of this document, please send details to email contact for comments and your request will be considered.

Yours,

Shaun Jacobs

Novel Foods Policy Advisor

Chemical Safety Policy Unit

# Annex A: RP8 – 3'-Sialyllactose (3'-SL) sodium salt (new)

FSA/FSS has reviewed the EFSA opinion and confirm that FSA/FSS agree with the safety conclusions outlined. FSA/FSS has had access to all supporting documentation as provided to EFSA for forming the EFSA opinion. Therefore, the information on which this opinion is based can be found in the EFSA opinion as detailed below. There has been no additional information received by FSA/FSS since the publication date of the EFSA opinion, therefore, the appropriateness of the EFSA opinion is maintained. Following the principles outlined in the introduction for making use of the EFSA opinion, the FSA/FSS opinion is that the NF, as described in this application, is safe and is not liable to have an effect on human health.

- The NF concerned is as safe as food from comparable food categories already placed on the market within GB.
- The composition of the NF and the proposed conditions of use do not pose a safety risk to human health in GB.
- Consumption of the NF within its proposed conditions of use would not be nutritionally disadvantageous for the consumer.

## EFSA Risk Assessment:

EFSA has published their risk assessment and opinion, which FSA/FSS has reviewed in the [EFSA Journal No.6098 \(2020\)](#) (safety of 3'-Sialyllactose (3'-SL) sodium salt as a novel food).

## Conclusions from EFSA Risk Assessment:

The EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) delivered an opinion on 3'-Sialyllactose (3'-SL) sodium salt as a NF pursuant to Regulation (EU) 2015/2283, and here we have detailed the conclusions from this opinion.

The NF is mainly composed of the human identical milk oligosaccharide (HiMO) 3'-SL but also containing D-lactose, sialic acid and a small fraction of other related oligosaccharides resulting in a fully characterised mixture of carbohydrates. The NF is produced by fermentation with a genetically modified strain of *Escherichia coli* K-12 DH1. The information provided on the manufacturing process, composition and specifications of the NF does not raise safety concerns.

The applicant intends to add the NF in a variety of foods, including infant and follow-on formula, foods for infants and toddlers, foods for special medical purposes and food supplements. The target population is the general population.

The anticipated daily intake of 3'-SL from the NF at the maximum proposed use levels is unlikely to exceed the intake level of naturally occurring 3'-SL in breastfed infants on a body weight basis. The intake of 3'-SL in breastfed infants on a body weight basis is expected to be safe also for other population groups. The intake of other carbohydrate-type compounds structurally related to 3'-SL is also considered of no safety concern. Food supplements are not intended to be used if other foods with added NF (as well as breast milk, milk, fermented milk-based products and selected cheeses retaining milk sugar (e.g. curd cheese) for infants and young children) are consumed on the same day. The Panel concluded that the NF is safe under the proposed conditions of use for the proposed target populations.

The Panel concluded that the NF, composed of 3'-SL sodium salt and other structurally related mono- and oligosaccharides, is safe under the proposed conditions of use, including the use as a food supplement. The target population is the general population.

Food supplements are not intended to be used if other foods with added NF (as well as breast milk, milk, fermented milk-based products and selected cheeses retaining milk sugar (e.g. curd cheese) for infants and young children) are consumed on the same day.

FSA/FSS accepts the EFSA conclusion on data protection since FSA/FSS could not have assessed the product without the proprietary data in order to grant data protection for the application made to GB nations as set out in Retained EU Regulation 2015/2283.

## Proposed terms for entry to the list of authorised novel foods:

**Table 1: Proposed uses**

Specified food category	Proposed Maximum Use Level (expressed as 3'-Sialyllactose)
Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	0.25 g/L
Flavoured fermented milk-based products including heat-treated products	0.25 g/L (beverages) 2.5 g/kg (products other than beverages)
Unflavoured fermented milk-based products	0.25 g/L (beverages) 0.5 g/kg (products other than beverages)
Beverages (flavoured drinks, excluding drinks with a pH less than 5)	0.25 g/L
Cereal bars	2.5 g/kg
Infant formula as defined under Retained EU Regulation 609/2013	0.2 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer
Follow-on formula as defined under Retained EU Regulation 609/2013	0.15 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer
Processed cereal-based food and baby food for infants and young children as defined under Retained EU Regulation 609/2013	0.15 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer 1.25 g/kg for products other than beverages
Milk-based drinks and similar products intended for young children	0.15 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer
Total diet replacement foods for weight control as defined under Retained EU Regulation 609/2013	0.5 g/L (beverages) 5 g/kg (products other than beverages)

<b>Specified food category</b>	<b>Proposed Maximum Use Level (expressed as 3'-Sialyllactose)</b>
Food for special medical purposes as defined under Retained EU Regulation 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended
Food Supplements as defined in each of the Food Supplements Regulations 2003 for England, Wales and Scotland, excluding food supplements for infants and young children	0.5 g/day

## Table 2: Specifications

### Specification

#### Description:

3'-Sialyllactose (3'-SL) sodium salt is a purified, white to off-white powder or agglomerate that is produced by a microbial process and contains limited levels of lactose, 3'-sialyl-lactulose, and sialic acid

**Source:** Genetically modified strain of *Escherichia coli* K-12 DH1

#### Definition:

- Chemical formula:  $C_{23}H_{38}NO_{19}Na$
- Chemical name: N-Acetyl- $\alpha$ -D-neuraminy-(2 $\rightarrow$ 3)- $\beta$ -D-galactopyranosyl-(1 $\rightarrow$ 4)-D-glucose, sodium salt
- Molecular mass: 655.53 Da
- CAS No 128596-80-5

#### Characteristics/Composition:

- Appearance: White to off-white powder or agglomerate
- Sum of 3'-Sialyllactose sodium salt, D-Lactose, and Sialic acid (% of dry matter):  $\geq 90.0$  % (w/w)
- 3'-Sialyllactose sodium salt (% of dry matter):  $\geq 88.0$  % (w/w)
- D-Lactose:  $\leq 5.0$  % (w/w)
- Sialic acid:  $\leq 1.5$  % (w/w)
- 3'-Sialyl-lactulose:  $\leq 5.0$  % (w/w)
- Sum of other carbohydrates:  $\leq 3.0$  % (w/w)
- Moisture:  $\leq 8.0$  % (w/w)
- Sodium: 2.5 – 4.5 % (w/w)
- Chloride:  $\leq 1.0$  % (w/w)
- pH (20 °C, 5 % solution): 4.5 -6.0

- Residual protein:  $\leq 0.01$  % (w/w)

**Microbiological criteria:**

- Aerobic mesophilic bacteria total plate count:  $\leq 1000$  CFU/g
- *Enterobacteriaceae*:  $\leq 10$  CFU/g
- *Salmonella* sp.: Absence in 25 g
- Yeast:  $\leq 100$  CFU/g
- Mould:  $\leq 100$  CFU/g
- Residual endotoxins:  $\leq 10$  EU/mg

[Return to top of document.](#)

# Annex B: RP9 – 6'-Sialyllactose (6'-SL) sodium salt (new)

FSA/FSS has reviewed the EFSA opinion and confirm that FSA/FSS agree with the safety conclusions outlined. FSA/FSS has had access to all supporting documentation as provided to EFSA for forming the EFSA opinion. Therefore, the information on which this opinion is based can be found in the EFSA opinion as detailed below. There has been no additional information received by FSA/FSS since the publication date of the EFSA opinion, therefore, the appropriateness of the EFSA opinion is maintained. Following the principles outlined in the introduction for making use of the EFSA opinion, the FSA/FSS opinion is that the NF, as described in this application, is safe and is not liable to have an effect on human health.

- The NF concerned is as safe as food from comparable food categories already placed on the market within GB.
- The composition of the NF and the proposed conditions of use do not pose a safety risk to human health in GB.
- Consumption of the NF within its proposed conditions of use would not be nutritionally disadvantageous for the consumer.

## EFSA Risk Assessment:

EFSA has published their risk assessment and opinion, which FSA/FSS has reviewed in the [EFSA Journal No.6097 \(2020\)](#) (safety of 6'-Sialyllactose (6'-SL) sodium salt as a novel food).

## Conclusions from EFSA Risk Assessment:

The EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) delivered an opinion on 6'-Sialyllactose (6'-SL) sodium salt as a NF pursuant to Regulation (EU) 2015/2283, and here we have detailed the conclusions from this opinion.

The NF is mainly composed of the human-identical milk oligosaccharide (HiMO) 6'-SL but also contains D-lactose, sialic acid and a small fraction of other related oligosaccharides. The NF is produced by fermentation with a genetically modified strain of *Escherichia coli* K-12 DH1. The information provided on the manufacturing process, composition and specifications of the NF does not raise safety concerns.

The applicant intends to add the NF in a variety of foods, including infant and follow-on formula, foods for infants and toddlers, foods for special medical purposes and food supplements. The target population is the general population.

The anticipated daily intake of 6'-SL from the NF at the maximum proposed use levels is unlikely to exceed the intake level of naturally occurring 6'-SL in breastfed infants on a body weight basis. The intake of 6'-SL in breastfed infants on a body weight basis is expected to be safe also for other population groups. The intake of other carbohydrate-type compounds structurally related to 6'-SL is also considered of no safety concern. Food supplements are not intended to be used if other foods with the added NF or breast milk are consumed on the same day. The Panel concluded that the NF is safe under the proposed conditions of use.

The Panel concluded that the NF, composed of 6'-SL sodium salt and other structurally related mono- and oligosaccharides, is safe under the proposed conditions of use, including the use as a food supplement. The target population is the general population.

Food supplements are not intended to be used if other foods with added NF or breast milk are consumed on the same day.

FSA/FSS accepts the EFSA conclusion on data protection since FSA/FSS could not have assessed the product without the proprietary data in order to grant data protection for the application made to GB nations as set out in Retained EU Regulation 2015/2283.

### **Proposed terms for entry to the list of authorised novel foods:**

The NF is not authorised for use in food categories other than those proposed for the NF under assessment. Therefore, the only relevant additional source for these oligosaccharides is human milk.

**Table 1: Proposed uses**

Specified food category	Proposed Maximum Use Level (expressed as 6'-Sialyllactose)
Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	0.5 g/L
Unflavoured fermented milk-based products	0.5 g/L (beverages) 2.5 g/kg (products other than beverages)
Flavoured fermented milk-based products including heat-treated products	0.5 g/L (beverages) 5.0 g/kg (products other than beverages)
Beverages (flavoured drinks, excluding drinks with a pH less than 5)	0.5 g/L
Cereal bars	5.0 g/kg
Infant formula as defined under Retained EU Regulation 609/2013	0.4 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer
Follow-on formula as defined under Retained EU Regulation 609/2013	0.3 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer
Processed cereal-based food and baby food for infants and young children as defined under Retained EU Regulation 609/2013	0.3 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer 2.5 g/kg for products other than beverages
Milk based drinks and similar products intended for young children	0.3 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer
Total diet replacement foods for weight control as defined under Retained EU Regulation 609/2013	1.0 g/L (beverages) 10.0 g/kg (products other than beverages)
Food for special medical purposes as defined under Retained EU Regulation 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended
Food Supplements as defined in each of the Food Supplements Regulations 2003	1.0 g/day

Specified food category	Proposed Maximum Use Level (expressed as 6'-Sialyllactose)
for England, Wales and Scotland, excluding food supplements for infants and young children	

**Table 2: Specifications**

**Description:**

6'-Sialyllactose (6'-SL) sodium salt is a purified, white to off-white powder or agglomerate that is produced by a microbial process and contains limited levels of lactose, 6'-sialyllactulose, and sialic acid.

**Source:** Genetically modified strain of *Escherichia coli* K-12 DH1

**Definition:**

Chemical formula: C<sub>23</sub>H<sub>38</sub>NO<sub>19</sub>Na

Chemical name: N-Acetyl- $\alpha$ -D-neuraminyl-(2 $\rightarrow$ 6)- $\beta$ -D-galactopyranosyl-(1 $\rightarrow$ 4)-D-glucose, sodium salt

Molecular mass: 655.53 Da

CAS No 157574-76-0

**Characteristics/Composition:**

Appearance: White to off-white powder or agglomerate

Sum of 6'-Sialyllactose sodium salt, D-Lactose and Sialic acid (% of dry matter):  $\geq 94.0$  % (w/w)

6'-Sialyllactose sodium salt (% of dry matter):  $\geq 90.0$  % (w/w)

D-Lactose:  $\leq 5.0$  % (w/w)

Sialic acid:  $\leq 2.0$  % (w/w)

6'-Sialyl-lactulose:  $\leq 3.0$  % (w/w)

Sum of other carbohydrates:  $\leq 3.0$  % (w/w)

Moisture:  $\leq 6.0$  % (w/w)

Sodium: 2.5-4.5 % (w/w)

Chloride:  $\leq 1.0$  % (w/w)

pH (20 °C, 5 % solution): 4.5-6.0

Residual protein:  $\leq 0.01$  % (w/w)

**Microbiological criteria:**

Aerobic mesophilic bacteria total plate count:  $\leq 1\,000$  CFU/g

*Enterobacteriaceae*:  $\leq 10$  CFU/g

*Salmonella* sp.: Absence in 25 g

Yeast:  $\leq 100$  CFU/g

Mould:  $\leq 100$  CFU/g

Residual endotoxins:  $\leq 10$  EU/mg

[Return to top of document.](#)

# Annex C: RP14 – 2'- Fucosyllactose / difucosyllactose mixture (“2’- FL/DFL mixture”) (extension of use for current authorisation)

FSA/FSS has reviewed the EFSA opinion and confirm that FSA/FSS agree with the safety conclusions outlined. FSA/FSS has had access to all supporting documentation as provided to EFSA for forming the EFSA opinion. Therefore, the information on which this opinion is based can be found in the EFSA opinion as detailed below. There has been no additional information received by FSA/FSS since the publication date of the EFSA opinion, therefore, the appropriateness of the EFSA opinion is maintained. Following the principles outlined in the introduction for making use of the EFSA opinion, the FSA/FSS opinion is that the NF, as described in this application, is safe and is not liable to have an effect on human health.

- The NF concerned is as safe as food from comparable food categories already placed on the market within GB.
- The composition of the NF and the proposed conditions of use do not pose a safety risk to human health in GB.
- Consumption of the NF within its proposed conditions of use would not be nutritionally disadvantageous for the consumer.

## **EFSA Risk Assessment:**

EFSA has published their risk assessment and opinion, which FSA/FSS has reviewed in the [EFSA Journal No.5717 \(2019\)](#) (safety of 2'-fucosyllactose/difucosyllactose mixture as a novel food). Since this concerns an application for an extension of use for a current authorisation within GB, where an additional risk assessment was not requested of EFSA when the application was made in the EU, we refer to the original EFSA risk assessment that FSA/FSS has reviewed where necessary.

## Conclusions from EFSA Risk Assessment:

An additional EFSA risk assessment was not undertaken for this amendment when the application was made in the EU, since the requested extension of use was covered by the original EFSA opinion and the requested changes to the specification and identity do not impact on the safety of the product.

For the original application in the EU, the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) delivered an opinion on 2'-FL/DFL mixture as a NF pursuant to Regulation (EU) 2015/2283, and here we have detailed the conclusions from this opinion.

The NF is a powdered mixture mainly composed of two oligosaccharides, 2'-FL and DFL, which are produced together by fermentation with a genetically modified strain of *Escherichia coli* K12 (no GM material present in end product). The information provided on the manufacturing process, composition and specifications of the NF does not raise safety concerns.

The applicant intends to add the NF in a variety of foods, including infant and follow-on formula, foods for infants and young children, foods for special medical purposes and food supplements. The target population is the general population except for food supplements, for which the target population is individuals above 1 year of age.

Since the intake of 2'-FL and DFL from the NF at the proposed use levels is unlikely to exceed the intake level of naturally occurring 2'-FL and DFL in breastfed infants per kilogram body weight, the Panel concluded that the NF, a mixture of 2'-FL and DFL, is safe under the proposed conditions of use for the proposed target population.

The Panel concluded that the NF, a mixture of 2'-FL and DFL, is safe under the proposed conditions of use. The target population is the general population, except for food supplements for which the target population is individuals above 1 year of age. Food supplements are not intended to be used if other foods with added NF or 2'-FL (as well as breast milk for young children) are consumed the same day.

The Panel could not have reached the conclusions on the safety of the NF under the proposed conditions of use without the following data claimed as proprietary by the applicant:

- annexes to the dossier which relate to the identity, the production process, production microorganism, composition and specifications of the NF (see annexes indicated in Section [2.1](#))
- bacterial reverse mutation test (unpublished study report, [2017a](#)), in vitro micronucleus test (unpublished study report, [2017b](#)), and 90-day oral toxicity study with the NF (unpublished study report, [2018](#)) including the summary table of the statistically significant observations in the 90-day study (Appendix B.3 to the dossier). The results of these studies have been published by Phipps et al. ([2018](#)).

FSA/FSS accepts the EFSA conclusion on data protection since FSA/FSS could not have assessed the product without the proprietary data in order to grant data protection for the application made to GB nations as set out in Retained EU Regulation 2015/2283.

### Proposed terms for entry to the list of authorised novel foods:

FSA/FSS recommends that it is appropriate to amend the description of the production process for the NF and to remove ‘spray drying’ from the description of the final drying step (as specified in Table 2).

FSA/FSS recommends to remove the term ‘amorphous’ from the description of the NF, and to include 3-fucosyllactose in the sum of the main oligosaccharides comprising the NF (as specified in Table 2).

**Table 1: Proposed uses; conditions under which the NF may be used**

Specified food category	Proposed maximum levels
Milk-based drinks and similar products intended for young children	1.2 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer’

**Table 2: Specifications**

Authorised Novel Food	Specification
‘2’-Fucosyllactose/Difucosyllactose mixture (‘2’-FL/DFL’) (microbial source)	<b>Description/Definition:</b> 2’-Fucosyllactose/Difucosyllactose mixture is a purified, white to off-white <del>amorphous powder</del> that is produced by a microbial process. After

Authorised Novel Food	Specification
	<p>purification, the 2'-</p> <p>Fucosyllactose/Difucosyllactose mixture is isolated by spray drying powder or agglomerates thereof that is produced by a microbial process.</p> <p><b>Source:</b> Genetically modified strain of <i>Escherichia coli</i> strain K-12 DH1</p> <p><b>Characteristics/Composition:</b></p> <p>Appearance: White to off white powder or agglomerates</p> <p>Sum of 2'-</p> <p>Fucosyllactose, Difucosyllactose, <del>Lactose and Fucose</del> (% of dry matter): <math>\geq 92.0\%</math> (w/w) D-Lactose, L-Fucose, and 3-Fucosyllactose (% of dry matter): <math>\geq 92.0\%</math> (w/w)</p> <p>Sum of 2'-fucosyllactose and difucosyllactose (% of dry matter): <math>\geq 85.0\%</math> (w/w)</p> <p>2'-Fucosyllactose (% of dry matter): <math>\geq 75.0\%</math> (w/w)</p> <p>Difucosyllactose (% of dry matter): <math>\geq 5.0\%</math> (w/w)</p> <p>D-Lactose: <math>\leq 10.0\%</math> (w/w)</p> <p>L-Fucose: <math>\leq 1.0\%</math> (w/w)</p> <p>2'-Fucosyl-D-lactulose: <math>\leq 2.0\%</math> (w/w)</p> <p>Sum of other carbohydrates*: <math>\leq 6.0\%</math> (w/w)</p> <p>Moisture: <math>\leq 6.0\%</math> (w/w)</p> <p>Ash, sulfated: <math>\leq 0.8\%</math> (w/w)</p> <p>pH (20 °C, 5 % solution): 4.0-6.0</p> <p>Residual protein: <math>\leq 0.01\%</math> (w/w)</p> <p><b>Microbiological criteria:</b></p> <p>Aerobic mesophilic total plate count: <math>\leq 1000</math> CFU/g</p> <p><i>Enterobacteriaceae</i>: <math>\leq 10</math> CFU/g</p>

Authorised Novel Food	Specification
	<i>Salmonella</i> sp.: Negative/25 g Yeast: ≤ 100 CFU/g Mould: ≤ 100 CFU/g Residual endotoxins: ≤ 10 EU/mg CFU: Colony Forming Units; EU: Endotoxin Units

\*3'-Fucosyllactose, 2'-Fucosyl-galactose, Glucose, Galactose, Mannitol, Sorbitol, Galactitol, Trihexose, Allo-lactose and other structurally related carbohydrates.

[Return to top of document.](#)

# Annex D: RP87 – DHA-rich algal oil from *Schizochytrium* sp strain WZU477 (extension of use for current authorisation)

FSA/FSS has reviewed the EFSA opinion and confirm that FSA/FSS agree with the safety conclusions outlined. FSA/FSS has had access to all supporting documentation as provided to EFSA for forming the EFSA opinion. Therefore, the information on which this opinion is based can be found in the EFSA opinion as detailed below. There has been no additional information received by FSA/FSS since the publication date of the EFSA opinion, therefore, the appropriateness of the EFSA opinion is maintained. Following the principles outlined in the introduction for making use of the EFSA opinion, the FSA/FSS opinion is that the NF, as described in this application, is safe and is not liable to have an effect on human health.

- The NF concerned is as safe as food from comparable food categories already placed on the market within GB.
- The composition of the NF and the proposed conditions of use do not pose a safety risk to human health in GB.
- Consumption of the NF within its proposed conditions of use would not be nutritionally disadvantageous for the consumer.

## EFSA Risk Assessment:

EFSA has published their risk assessment and opinion, which FSA/FSS has reviewed in the [EFSA Journal No.6242 \(2020\)](#) (safety of *Schizochytrium* sp. oil as a novel food). Since this concerns an extension of use for a current authorisation, the EFSA opinion refers to existing EFSA opinions that FSA/FSS has also reviewed where necessary.

## Conclusions from EFSA Risk Assessment:

The EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) delivered an opinion on the safety of *Schizochytrium* sp. oil as a NF pursuant to Regulation (EU) 2015/2283, and here we have detailed the conclusions from this opinion.

*Schizochytrium* sp. is a single-cell microalga. The strain WZU477, used by the applicant (Progress Biotech bv), was found to belong to the species *Schizochytrium limacinum* and was obtained in a marine environment from rotted mangrove forest leaves. The NF, an oil rich in docosahexaenoic acid (DHA), is isolated from the microalgae by mechanical extraction.

The applicant proposed to use the NF in infant and follow-on formula. The use level defined by the applicant was derived from Regulation (EU) 2016/127, which states the mandatory addition of DHA to infant and follow-on formula at the level of 20–50 mg/100 kcal. The intake of DHA resulting from the use of the NF in infant and follow-on formula is not expected to pose safety concerns.

The composition of the NF indicates the absence of marine biotoxins in the NF. Furthermore, *Schizochytrium limacinum* was attributed the qualified presumption of safety (QPS) status with the qualification ‘for production purposes only’. Based on the information provided, the microalga is not expected to survive the manufacturing process. Toxicological tests conducted with the NF were not performed. However, based on the available toxicological data on various forms of oils derived from *Schizochytrium* sp., the QPS status of the source of the NF, the production process and the composition of the NF, the Panel considered there were no concerns with regard to toxicity of the NF. The Panel concluded that the NF is safe under the proposed conditions of use.

The Panel concluded that the NF, i.e. *Schizochytrium* sp. oil (produced from the strain WZU477 belonging to species *Schizochytrium limacinum*), is safe under the proposed conditions of use. The target population is infants and young children.

FSA/FSS accepts the EFSA conclusion on data protection since FSA/FSS could not have assessed the product without the proprietary data in order to grant data protection for the application made to GB nations as set out in Retained EU Regulation 2015/2283.

## Proposed terms for entry to the list of authorised novel foods:

The application was submitted for an extension of use of docosahexaenoic acid (DHA)-rich algal oil sourced from the marine microalgae *Schizochytrium* sp. to include strain WZU477 as a NF ingredient for use in infant and follow-on formula (as defined in Retained EU Regulation 609/2013) in the list of authorised novel foods as an alternative source of fatty acids presently permitted in these products. No other changes to the existing specifications are proposed.

Taking into account that authorised *Schizochytrium* sp. oil for which an extension of use has been requested is neither species-specific nor strain-specific, it is necessary to authorise the placing on the market of oil from strain WZU477 of *Schizochytrium* sp. under the assessed conditions of use, and not as an extension of use of oil from all strains of the *Schizochytrium* genus as requested by the applicant.

The FSA and FSS conclude that the proposed extension of authorisation would not be appropriate, and instead propose that a new authorisation is added to the list of authorised novel foods.

**Table 1: Proposed uses; conditions under which the NF may be used**

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

**Table 2: Specifications**

Authorised Novel Food	Specification
' <i>Schizochytrium</i> sp. (WZU477) oil	<b>Description/Definition:</b> The novel food is an oil produced from the strain WZU477 of the microalgae <i>Schizochytrium</i> sp. <b>Composition:</b> Acid value: ≤ 0.5 mg KOH (potassium hydroxide)/g Peroxide value (PV): ≤ 5.0 meq (milliequivalent)/kg oil Moisture and volatiles: ≤ 0.05 %

	Unsaponifiables: $\leq 4.5$ % Trans-fatty acids: $\leq 1.0$ % Docosahexaenoic acid (DHA): $\geq 32.0$ % p-anisidine value: $\leq 10'$
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[Return to top of document.](#)

# Annex E: RP810 – DHA 550 - Schizochytrium sp. strain (FCC-3204) (application to increase the daily intake of DHA from this source to 1000 mg/day)–(extension of use for current authorisation)

FSA/FSS has reviewed the EFSA opinion and confirm that FSA/FSS agree with the safety conclusions outlined. FSA/FSS has had access to all supporting documentation as provided to EFSA for forming the EFSA opinion. Therefore, the information on which this opinion is based can be found in the EFSA opinion as detailed below. There has been no additional information received by FSA/FSS since the publication date of the EFSA opinion, therefore, the appropriateness of the EFSA opinion is maintained. Following the principles outlined in the introduction for making use of the EFSA opinion, the FSA/FSS opinion is that the NF, as described in this application, is safe and is not liable to have an effect on human health.

- The NF concerned is as safe as food from comparable food categories already placed on the market within GB.
- The composition of the NF and the proposed conditions of use do not pose a safety risk to human health in GB.
- Consumption of the NF within its proposed conditions of use would not be nutritionally disadvantageous for the consumer.

## EFSA Risk Assessment:

EFSA has published their risk assessment and opinion, which FSA/FSS has reviewed in the [EFSA Journal No.6345 \(2021\)](#) (safety of oil from *Schizochytrium limacinum* (strain FCC-3204) for use in food supplements as a novel food). Since this concerns an

extension of use for a current authorisation, the EFSA opinion refers to existing EFSA opinions that FSA/FSS has also reviewed where necessary.

### Conclusions from EFSA Risk Assessment:

The EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) delivered an opinion on the safety of *Schizochytrium* sp. oil as a NF pursuant to Regulation (EU) 2015/2283, and here we have detailed the conclusions from this opinion.

*Schizochytrium* sp. is a single-cell microalga. The strain FCC-3204, used by the applicant (Fermentalg), belongs to the species *Schizochytrium limacinum*. The NF, an oil rich in docosahexaenoic acid (DHA), is obtained from microalgae after enzymatic lysis.

The applicant proposed to increase the use level of the NF as a food supplement, from 250 mg DHA/day (currently authorised for the general population, excluding pregnant and lactating women) to 3000 mg DHA/day for adults, excluding pregnant and lactating women. *S. limacinum* was attributed the qualified presumption of safety (QPS) status with the qualification 'for production purposes only'. Data provided by the applicant demonstrated the absence of viable cells in the NF. No toxicological studies were performed with the NF. However, based on the available toxicological data on oils derived from *Schizochytrium* sp., the QPS status of the source of the NF, the production process, the composition of the NF and the absence of viable cells in the NF, the Panel considered there were no concerns with regard to toxicity of the NF.

The Panel considered that the data provided by the applicant were not sufficient to conclude on the safety of the NF at the proposed uses (3000 mg DHA/day as a food supplement) in adults. However, in 2012, the Panel concluded that supplemental intakes of DHA alone up to about 1000 mg/day do not raise safety concerns for the general population. The Panel concluded that the NF is safe for the use in food supplements at the maximum intake level of 1000 mg DHA/day for the target population (adults, excluding pregnant and lactating women).

The Panel concluded that the NF, i.e. *Schizochytrium* sp. oil (produced from the strain FCC-3204 belonging to species *S. limacinum*), is safe for the use in food supplements at the maximum intake level of 1000 mg DHA/day for the target population proposed by the applicant (adults, excluding pregnant and lactating women).

## Proposed terms for entry to the list of authorised novel foods:

The application was submitted for an increased level of use for the authorised docosahexaenoic acid (DHA)-rich oil from *Schizochytrium* sp. (produced from the strain FCC-3204 belonging to species *S. limacinum*) to obtain the authorisation to use such oils in food supplements up to 1000 mg/day. This application is related to a *Schizochytrium* sp. oil compliant with the specifications laid down in Retained EU Regulation 2017/2470.

The applicant intends to increase the use level of the NF as a food supplement, from 250 mg DHA/day (currently authorised for the general population, excluding pregnant and lactating women) to 1000 mg DHA/day for adults, excluding pregnant and lactating women.

Taking into account that authorised *Schizochytrium* sp. oil for which an extension of use has been requested is neither species-specific nor strain-specific, it is necessary to authorise the placing on the market of oil from strain FCC-3204 of *Schizochytrium* sp. under the assessed conditions of use, and not as an extension of use of oil from all strains of the *Schizochytrium* genus as requested by the applicant.

The FSA and FSS conclude that the proposed extension of authorisation would not be appropriate, and instead propose that a new authorisation is added to the list of authorised novel foods.

### Proposed uses and use levels

**Table 1: Proposed uses; conditions under which the NF may be used**

Specified food category	Proposed Maximum Levels of DHA
Food supplements as defined in The Food Supplements Regulations 2003 for England, Wales and Scotland, for the general population above 3 years of age.	1000 mg DHA/day for the proposed target population (adults, excluding pregnant and lactating women).

**Table 2: Specifications**

Parameter	Specification for <i>Schizochytrium</i> sp. oil
Acid value (mg KOH/g)	≤ 0.5

Parameter	Specification for <i>Schizochytrium</i> sp. oil
Peroxide value (PV) (meq/kg)	≤ 5.0
Moisture and volatile (%)	≤ 0.05
Unsaponifiables (%)	≤ 4.5
Trans-Fatty acids (%)	≤ 1.0
DHA content (%)	≥ 32.0
P-anisidine	≤ 10'

[Return to top of document.](#)

# **Annex F: RP811 – DHA 550 - Schizochytrium sp. strain (FCC-3204) (application to extend the use of the authorisation to infant and follow-on formula) (extension of use for current authorisation)**

FSA/FSS has reviewed the EFSA opinion and confirm that FSA/FSS agree with the safety conclusions outlined. FSA/FSS has had access to all supporting documentation as provided to EFSA for forming the EFSA opinion. Therefore, the information on which this opinion is based can be found in the EFSA opinion as detailed below. There has been no additional information received by FSA/FSS since the publication date of the EFSA opinion, therefore, the appropriateness of the EFSA opinion is maintained. Following the principles outlined in the introduction for making use of the EFSA opinion, the FSA/FSS opinion is that the NF, as described in this application, is safe and is not liable to have an effect on human health.

- The NF concerned is as safe as food from comparable food categories already placed on the market within GB.
- The composition of the NF and the proposed conditions of use do not pose a safety risk to human health in GB.
- Consumption of the NF within its proposed conditions of use would not be nutritionally disadvantageous for the consumer.

## EFSA Risk Assessment:

EFSA has published their risk assessment and opinion, which FSA/FSS has reviewed in the [EFSA Journal No.6344 \(2021\)](#) (safety of oil from *Schizochytrium limacinum* (strain FCC-3204) for use in infant and follow-on formula as a novel food). Since this concerns an extension of use for a current authorisation, the EFSA opinion refers to existing EFSA opinions that FSA/FSS has also reviewed where necessary.

## Conclusions from EFSA Risk Assessment:

The EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) delivered an opinion on the safety of *Schizochytrium* sp. oil as a NF pursuant to Regulation (EU) 2015/2283, and here we have detailed the conclusions from this opinion.

*Schizochytrium* sp. is a single-cell microalga. The strain FCC- 3204, used by the applicant belongs to the species *S. limacinum*. The NF, an oil rich in DHA, is obtained from microalgae after enzymatic lysis.

The applicant proposed to use the NF in infant and follow-on formula. The use level defined by the applicant was derived from Regulation (EU) 2016/127, which states the mandatory addition of DHA to infant and follow-on formula at the level of 20–50 mg/100 kcal. The intake of DHA resulting from the use of the NF in infant and follow-on formula is not expected to pose safety concerns. *S. limacinum* was attributed the qualified presumption of safety (QPS) status with the qualification ‘for production purposes only’. Data provided by the applicant demonstrated the absence of viable cells in the NF. No toxicological studies were performed with the NF. However, based on the available toxicological data on oils derived from *Schizochytrium* sp., the QPS status of the source of the NF, the production process, the composition of the NF and the absence of viable cells in the NF, the Panel considered there were no concerns with regard to toxicity of the NF. The Panel concluded that the NF is safe under the proposed conditions of use.

The Panel concluded that the NF, i.e. *Schizochytrium* sp. oil (produced from the strain FCC-3204 belonging to species *S. limacinum* is safe under the proposed conditions of use. The target population is infants and young children.

## Proposed terms for entry to the list of authorised novel foods:

The application was submitted for an extension of use, and it refers to a *Schizochytrium* sp. oil rich in docosahexaenoic acid (DHA) which is already authorised

as a NF. This extension of use is for use in infant and follow-on formula. This application is related to a Schizochytrium sp. oil compliant with the specifications laid down in Retained EU Regulation 2017/2470.

Taking into account that authorised Schizochytrium sp. oil for which an extension of use was requested is neither species-specific nor strain-specific, it is necessary to authorise the placing on the market of oil from strain FCC-3204 of Schizochytrium sp. under the assessed conditions of use, and not as an extension of use of oil from all strains of the Schizochytrium genus as requested by the applicant.

The FSA and FSS conclude that the proposed extension of authorisation would not be appropriate, and instead propose that a new authorisation is added to the list of authorised novel foods.

### **Proposed uses and use levels**

The applicant intends for the NF to be added to infant and follow-on formula. The proposed use levels are 1000 mg DHA/day in accordance with Regulation (EU) No 609/2013 and its supplementing Regulation (EU) 2016/127, which states the mandatory addition of DHA to infant and follow-on formula at levels ranging between 4.8 and 12 mg/100 kJ (eq. 20–50 mg/100 kcal). Considering a standard energy content of maximum 70 kcal/100 mL of infant and follow-on formula defined in Regulation (EU) 2016/127, the DHA level in the reconstituted formula is expected to range between 14 and 35 mg = DHA/100 mL. Considering a minimum DHA concentration of 550 mg DHA/g in the NF, the use level for the NF corresponds to 25–63 mg NF/100 mL, to reach the target of 14–35 mg DHA/100 mL.

It should be noted that manufacturers of infant and follow-on formula who may powder the NF and incorporate it into their formulae shall guarantee that the concentration of DHA meets the requirement of the Regulation. This is also the case if other sources of DHA are used in combination with the NF.

**Table 1: Proposed uses; conditions under which the NF may be used**

Specified food category	Proposed Maximum Levels of DHA
Infant formula and follow-on formula as defined in retained Regulation (EU) No 609/2013	The NF is intended to be added to infant and follow-on formula. The proposed use levels are in accordance with Regulation (EU) No 609/2013

**Table 2: Specifications**

Parameter	Specification for <i>Schizochytrium</i> sp. oil
Acid value (mg KOH/g)	≤ 0.5
Peroxide value (PV) (meq/kg)	≤ 5.0
Moisture and volatile (%)	≤ 0.05
Unsaponifiables (%)	≤ 4.5
Trans-Fatty acids (%)	≤ 1.0
DHA content (%)	≥ 32.0
P-anisidine	≤ 10'

[Return to top of document.](#)