Risk Management Recommendations on Market Authorisation of 4 Regulated Food Products December 2025

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Document subject and purpose

In this document we publish the Food Standards Agency (FSA) risk management recommendations on 4 novel food applications.

Our risk assessors deliver the science behind our advice and publish their safety assessments, links to which are available within each recommendation annex. Risk assessors are responsible for identifying and characterising hazards and risks to health and assessing levels of exposure.

The risk management recommendations consider the safety assessments (which represent the opinion of the FSA for each application) as well as potential impacts that may result from the authorisation of these applications. They also consider other legitimate factors that ministers may want to consider before making a decision on authorisation of these applications.

The final FSA recommendations that are made to ministers in England, Wales, Scotland and Northern Ireland will consider stakeholders' views received from this consultation.

List of Annexes

Annex A
FSA Risk Management Recommendations
RP1411 - *Schizochytrium* sp. oil rich in DHA and EPA (Extension of use) (Novel Foods)

An application for the extension of use in Great Britain of this authorised novel food on the terms below has been submitted. It is for ministers in England, Wales and Scotland to decide whether to authorise the extension of use of this novel food.

Introduction

An application for the authorisation of the proposed extension of use of *Schizochytrium* sp. oil rich in DHA and EPA, as a novel food in two additional food categories: analogues of; meat and meat products and fishery product analogues in Great Britain, was received by the FSA from DSM Nutritional Products Switzerland.

For new novel foods and extensions of use to authorised novel foods to be placed on the market in Great Britain, an application shall be submitted in accordance with assimilated EU Regulation 2015/2283.

Safety Assessment Summary

Following the submission of application RP1411, the FSA and FSS have assessed the safety of *Schizochytrium* sp. oil rich in DHA and EPA as a novel food for two additional categories: analogues of; meat and meat products and fishery product analogues. The assessment concluded that the novel food is safe under the proposed extended conditions of use, poses no risk to human health, and its consumption in place of another food is unlikely to be nutritionally disadvantageous to consumers.

In accordance with Article 11 of assimilated Regulation (EU) 2015/2283, the safety assessment represents the opinion of the FSA and FSS. The views of the ACNFP were considered in preparing the safety assessment.

Safety assessment: Safety Assessment RP1411 Schizochytrium sp. oil rich in DHA and EPA | Food Standards Agency

Any Relevant Provisions of assimilated law

- Article 7 of assimilated Regulation (EU) 2015/2283 of the European Parliament and of the Council; on the general conditions for authorisation of novel foods
- Article 10 of assimilated Regulation (EU) 2015/2283 of the European Parliament and of the Council; on the procedure for determining authorisation status of novel foods
- Assimilated Regulation (EU) 2017/2469 of the European Parliament and of the Council; laying down administrative and scientific requirements for novel food applications
- Assimilated Regulation (EU) 1169/2011 of the European Parliament and of the Council; on the provision of food information to consumers

TOA

The proposed terms of authorisation are set out below:

The authorised novel food, *Schizochytrium* sp. oil rich in DHA and EPA, is set out in the Authorised Register of Novel Food Authorisations under 'Novel-129'.

The terms of authorisation in the Register of Regulated Food and Feed Products for Great Britain, will need to be amended to include the use of this novel food in 'analogues of; meat and meat

products' and 'fishery product analogues'. The maximum permitted level ('Maximum levels of DHA and EPA combined') is proposed to be 300 mg/100 g.

Conditions under which the novel food may be used

Specified Food Category	Maximum levels of DHA and EPA combined
Food supplements as defined in The Food Supplements (England) Regulations 2003) and The Food Supplements (Wales) Regulations 2003 for persons aged 18 years or above excluding pregnant and lactating women	3000 mg/day
Food supplements as defined in The Food Supplements (England) Regulations 2003 and The Food Supplements (Wales) Regulations 2003 for pregnant and lactating women aged 18 years or above	450 mg/day
Food for special medical purposes as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control.	In accordance with the particular nutritional requirements of the persons for whom the products are intended
Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control	250 mg/meal
Milk-based drinks and similar products intended for young children (aged between one and 3 years)	200 mg/100 g
Processed cereal based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013	
Foods intended to meet the expenditure of intense muscular effort, especially for sportspeople	
Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Regulation (EU) No 828/2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food	
Bakery products (breads, rolls and sweet biscuits)	200 mg/100 g
Breakfast cereals	500 mg/100 g
Cooking fats	360 mg/100 g
Dairy analogues except drinks	600 mg/100 g for cheese analogues; 200 mg/100 g analogues of milk products (excluding drinks)
Dairy products except milk-based drinks	600 mg/100 g for cheese; 200 mg/100 g for milk products (including milk, fromage frais and yoghurt products; excluding drinks)
Non-alcoholic beverages (including dairy analogue and milk-based drinks)	80 mg/100 g
Cereal/nutrition bars	500 mg/100 g
Dressings and spreadable fats	600 mg/100 g
Fishery product analogues	300 mg/100 g
Analogues of; meat and meat products	300 mg/100 g

Additional specific labelling requirements:
The designation of the novel food on the labelling of the food containing it is 'DHA and EPA-rich oil from the microalgae *Schizochytrium* sp.'

The food information must be presented in accordance with the provisions of Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers (EUR 2011/1169) which apply to mandatory food information.

Other Requirements: N/A

Specification
No change to the current specification is required for this extension of use.

Proposed uses
This novel food is an algal oil that is rich in DHA and EPA and is currently authorised. It is proposed to extend the use of the novel food within the food categories: Fishery product analogues, and analogues of; meat and meat products.

Supplementary information
N/A

Labelling
The designation of the novel food on the labelling of the food containing it shall be 'DHA and EPA-rich oil from the microalgae *Schizochytrium* sp.'

Transitional requirements/ provisions
N/A

Further explanation/ Rationale
N/A

Post Market Monitoring
N/A

Definitions
- 'Infant' means a child under the age of 12 months, as defined by Article 2(2)(a) of assimilated Regulation (EU) No. 609/2013.

- 'Young child' means a child aged between one and three years, as defined by Article 2(2)(b) of assimilated Regulation (EU) No. 609/2013.

Other Legitimate Factors
In developing the risk management recommendations, the FSA has had regard to the other legitimate factors (including consumer interests, political, environmental, societal and technical feasibility) that ministers will consider as part of their decision on authorisation. The FSA has not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this novel food. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant other legitimate factors as part of the consultation process.

The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

Impacts

As part of the risk analysis process, FSA has assessed the potential impacts that would result from the authorisation of this novel food, should ministers decide to authorise. No significant impacts were identified. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

Trade

Food exported from the UK to other countries / blocs will need to continue to meet the rules of those countries/blocs.

EU

The European Commission has already approved the extension of use in Regulation (EU) 2022/1365 of 4 August 2022 amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food Schizochytrium sp. oil rich in DHA and EPA at the same use levels as requested in this application and using the same food category names. To note the Commission did not ask EFSA for an opinion in this extension of use.

Northern Ireland

Schizochytrium sp.oil rich in DHA and EPA is already authorised in Northern Ireland as a novel food and with the proposed extension of use. The FSA's recommendation to authorise aligns with the product authorisation in Northern Ireland.

Risk Management Recommendation

The FSA risk management recommendation is the extension of use of *Schizochytrium sp*. oil rich in DHA and EPA, an approved novel food, as described in this application, is safe and is not liable to have an adverse effect on the target population (general population including lactating and pregnant women and infants and young children), environmental safety and human health at the intended conditions of use.

Annex B

FSA Risk Management Recommendations
RP1476 - 2'-fucosyllactose (2'-FL) (produced by a derivative strain of *Escherichia coli* W (ATCC 9637)) (New authorisation) (Novel Foods)

An application for authorisation in Great Britain of this novel food on the terms below has been submitted. It is for ministers in England, Wales and Scotland to decide whether to authorise the novel food.

Introduction

An application for 2'-fucosyllactose (2'-FL) (produced by a derivative strain of *Escherichia coli* W (ATCC 9637)) as a novel food within the food categories detailed in the proposed terms of authorisation, in Great Britain, was received by the FSA from Kyowa Hakko Bio Company Ltd. 2'-fucosyllactose (2'-FL) produced synthetically and from other microbial sources has already been authorised for conditions of use in other food categories in Great Britain.

For new novel foods and extensions of use to authorised novel foods to be placed on the market in Great Britain, an application shall be submitted in accordance with assimilated Regulation (EU) 2015/2283.

Safety Assessment Summary

Following the submission of application RP1476, the FSA and FSS have undertaken a safety assessment on the new authorisation of 2'-fucosyllactose (2'-FL) (produced by a derivative strain of *Escherichia coli* W (ATCC 9637)) as a novel food. The assessment concluded its composition is safe under the proposed conditions of use, poses no risk to human health, and that the anticipated intake levels and proposed uses in food and food supplements are not considered nutritionally disadvantageous.

Safety assessment: Safety Assessment of 2'-Fucosyllactose (2'-FL) as a Novel Food for Use in Food and Food Supplements (RP1476)

Relevant legislation

- Article 7 of assimilated Regulation (EU) 2015/2283 of the European Parliament and of the Council; on the general conditions for authorisation of novel foods
- Article 10 of assimilated Regulation (EU) 2015/2283 of the European Parliament and of the Council; on the procedure for determining authorisation status of novel foods
- Assimilated Regulation (EU) 2017/2469 of the European Parliament and of the Council; laying down administrative and scientific requirements for novel food applications
- Assimilated Regulation (EU) 1169/2011 of the European Parliament and of the Council; on the provision of food information to consumers

TOA

The proposed terms of authorisation are set out below:

Specified food category	Maximum levels
Unflavoured pasteurised and sterilised (including UHT) milk-based products	1.2 g/l
Unflavoured fermented milk-based products	1.2 g/l (beverages) 19.2g/kg (products other than beverages)
Flavoured fermented milk-based products including heat-treated products	1.2 g/l (beverages) 19.2 g/kg (for products other than beverages)
Dairy analogues, including beverage whiteners	1.2 g/l (beverages) 12.0 g/kg (products other than beverages) 400 g/kg (whitener)
Cereal bars	12.0 g/kg

Specified food category	Maximum levels
Table-top sweeteners	200 g/kg
Infant formula as defined in Regulation (EU) No. 609/2013 of the European Parliament and of the Council on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control	1.2 g/l in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer
Follow-on formula as defined in Regulation (EU) No. 609/2013	1.2 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 in Regulation (EU) No. 609/2013	12.0 g/kg (for products other than beverages) 1.2 g/l (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer
Milk-based drinks and similar products intended for young children (aged between one and three years)	1.2 g/l (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer
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
Total diet replacement for weight control as defined in Regulation (EU) No. 609/2013	4.8 g/l (beverages) 40 g/kg (products other than beverages)
Bread and pasta products bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Regulation (EU) No. 828/2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food	60 g/kg
Flavoured drinks	1.2 g/l
Coffee, tea (excluding black tea), herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant, fruit and cereal preparations for infusions, as well as mixes and instant mixes of these products	9.6 g/l – the maximum level refers to the products ready to use
Food supplements as defined in the Food Supplements (England) Regulations 2003 and Food Supplements (Wales) Regulations 2003 for infants (under the age of 12 months)	1.2 g/day

Specified food category	Maximum levels
and young children (aged between one and three years)	
Food supplements as defined in the Food Supplements (England) Regulations 2003 and Food Supplements (Wales) Regulations 2003 excluding food supplements for infants and young children	3.0 g/day
Infant formula as defined in Regulation (EU) No. 609/2013 of the European Parliament and of the Council on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control	1.2 g/l in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer
Follow-on formula as defined in Regulation (EU) No. 609/2013	1.2 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 in Regulation (EU) No. 609/2013	12.0 g/kg (for products other than beverages) 1.2 g/l (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer

Additional specific labelling requirements

The designation of the novel food on the labelling of the food containing it is '2'-fucosyllactose'.

The labelling of food supplements containing 2′-fucosyllactose must bear a statement that the supplements should not be consumed if food with added 2′-fucosyllactose is consumed on the same day.

The labelling of food supplements containing 2′-fucosyllactose intended for infants and young children must bear a statement that they should not be consumed if breast milk or food with added 2′-fucosyllactose are consumed on the same day.

The food information must be presented in accordance with the provisions of Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers (EUR 2011/1169) which apply to mandatory food information.

Data Protection

Authorised on XX Month 20XX (date will be added if the product is authorised).

This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.

Applicant: Kyowa Hakko Bio Company, Ltd., 4-10-2, Nakano, Nakano-ku, Tokyo, 164-0001 Japan. During the period of data protection 2'-fucosyllactose (produced by a derivative strain of *Escherichia coli* W (ATCC 9637)) is authorised for placing on the market within England and Wales only by Kyowa Hakko Bio Company, LTD., unless a subsequent applicant obtains

authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Kyowa Hakko Bio Company. LTD.

The data protection ends at the end of [5 years from Authorisation]

Specification

Description / Definition / Source:

Category	Information
Description	The novel food is a white to off-white powder which is mainly composed of *2'-FL* which is manufactured by microbial fermentation using a derivative strain of *Escherichia coli* W(ATCC 9637).
Chemical name	*(2S,3S,4R,5S,6S)-2-[(2S,3R,4S,5R,6R)-4,5-dihydroxy-6-(hydroxymethyl)-2-[(2R,3S,4R,5R)-4,5,6-trihydroxy-2-(hydroxymethyl)oxan-3-yl]oxyoxan-3-yl]oxy-6-methyloxane-3,4,5-triol*
CAS No	*41263-94-9*
Molecular weight	*488.44 g/mol*
Chemical formula	$C_{18}H_{32}O_{15}$
Source	Genetically modified strain of Escherichia coli W (ATCC 9637)

Characteristics / Composition*:*

Category	Information
Appearance	powder
Colour	white to off-white
2'-FL	≥ 82.0 % w/w DM
D-lactose	≤ 5.0 % w/w DM
L-fucose	≤ 1.0 % w/w DM
D-glucose and D-galactose	≤ 1.0 % w/w DM
Fucosylgalactose	≤ 3.0 % w/w DM
Difucosyllactose	≤ 3.0 % w/w DM
Sum of other carbohydrates	≤ 8.0 % w/w DM
Water	≤ 9.0 % w/w
Protein	≤ 0.01 % w/w
Ash	≤ 0.5 % w/w
pH	(5% solution, 25°C): 4.5 – 8.5

Heavy metals and contaminants:

Category	Information
Arsenic	≤ 0.2 mg/kg
Cadmium	≤ 0.1 mg/kg

Category	Information
Lead	≤ 0.02 mg/kg
Mercury	≤ 0.1 mg/kg
Aflatoxin M1	≤ 0.025 µg/kg

Microbiological criteria:

- CFU = Colony Forming Units
- EU = Endotoxin Units

Category	Information
Aerobic plate count	≤ 1000 CFU/g
Yeast and mould	≤ 100 CFU/g
Enterobacteriaceae	Absent in 10g
Salmonella spp.	Absent in 25g
Cronobacter spp.	Absent in 10g
Listeria monocytogenes	Absent in 25g
Presumptive *Bacillus cereus*	≤ 50 CFU/g
Endotoxins: ≤ 10 EU/mg	Endotoxins: ≤ 10 EU/mg

Proposed uses

The application is to authorise 2'-fucosyllactose (produced by a derivative strain of *Escherichia coli* W (ATCC 9637)) as a novel food to be placed on the market, or used in or on food, in Great Britain.

Infants, children and adults, including pregnant and lactating women, are identified as the target population of the novel food for the following food categories: unflavoured pasteurised and sterilised (including UHT) milk-based products, unflavoured fermented milk-based products, flavoured fermented milk-based products including heat-treated products, dairy analogues including beverage whiteners, cereal bars, table-top sweeteners, infant formula as defined in Regulation (EU) No 609/2013, follow-on formula as defined in Regulation (EU) No 609/2013, processed cereal -based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013, milk-based drinks and similar products intended for young children (aged between one and three years) foods for special medical purposes as defined in Regulation (EU) No 609/2013, total diet replacement for weight control as defined in Regulation (EU) No 609/2013, bread and pasta products bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Regulation (EU) No 828/2013, flavoured drinks, coffee, tea (excluding black tea), herbal and fruit infusions and chicory extracts; tea, plant, fruit and cereal preparations for infusions, as well as mixes and instant mixes of these products and food supplements as defined in the Food Supplements (England) Regulations 2003 and Food Supplements (Wales) Regulations 2003.

The intended uses and use levels for 2'-FL (produced by a derivative strain of *Escherichia coli* W (ATCC 9637)) and the food categories are in the Register of Authorised Novel Foods in Great Britain. However, the use of 2'-FL as a food supplement for infants is not currently authorised.

Supplementary information

N/A

Labelling

Article 9(3)(b) of assimilated Regulation (EU) 2015/2283 provides that an authorisation of a novel food should include additional specific labelling requirements.

It is proposed that 2'-fucosyllactose (produced by a derivative strain of *Escherichia coli* W (ATCC 9637)) should be authorised with the same additional specific labelling requirements as the existing authorisations for 2'-fucosyllactose as set out in the register and these are:

- The designation of the novel food on the labelling of the food containing it must be '2′-fucosyllactose'.
- The labelling of food supplements containing 2′-fucosyllactose must bear a statement that the supplements should not be used if other foods with added 2′-fucosyllactose are consumed on the same day.
- The labelling of food supplements containing 2′-fucosyllactose intended for infants and young children must bear a statement that the supplements should not be used if breast milk or other foods with added 2′-fucosyllactose are consumed on the same day.

Transitional requirements/ provisions

N/A

Further explanation/ Rationale

N/A

Post Market Monitoring

N/A

Definitions

- 'Infant' means a child under the age of 12 months, as defined by Article 2(2)(a) of assimilated Regulation (EU) No. 609/2013.
- 'Young child' means a child aged between one and three years, as defined by Article 2(2)(b) of assimilated Regulation (EU) No. 609/2013.

Other Legitimate Factors

In developing the risk management recommendations, the FSA has had regard to the other legitimate factors (including consumer interests, political, environmental, societal and technical feasibility) that ministers will consider as part of their decision on authorisation. The FSA has not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this novel food. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant other legitimate factors as part of the consultation process.

The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

Impacts

As part of the risk analysis process, FSA has assessed the potential impacts that would result from the authorisation of this novel food, should ministers decide to authorise. No significant impacts were identified. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

Trade

Food exported from the UK to other countries/blocs will need to continue to meet the rules of those countries/blocs.

EU

2'-fucosyllactose (produced by a derivative strain of *Escherichia coli* W (ATCC 9637)) is already approved for use in the EU.

Apart from use in food supplements for infants, the food categories and intended use levels within this application align with those listed in the EU List of Novel Foods under Regulation (EU) 2017/2470. While the EU has not authorised the novel food for use in food supplements for infants, this decision is not based on safety concerns, as both the EU and UK have assessed the novel food to be safe at the proposed levels for infant use.

If authorised, this will mean there is divergence between Great Britain and the EU in the uses athorised for this novel food.

Northern Ireland

This novel food is already authorised in Northern Ireland. The FSA's recommendation to authorise for use in food supplements for infants will lead to some divergence. However, under the Windsor Framework, goods authorised in Great Britain can be placed on the market in Northern Ireland, if eligible for, and moved through Northern Ireland Retail Movement Scheme.

Risk Management Recommendation

The FSA risk management recommendation is that 2'-fucosyllactose (produced by a derivative strain of *Escherichia coli* W (ATCC 9637)) as described in this application, is safe and is not liable to have an adverse effect on the target population, environmental safety and human health at the proposed levels of use.

Annex C

FSA Risk Management Recommendations

RP1477 3'-Sialyllactose (3'-SL) sodium salt (produced using a derivative strain of *Escherichia coli* W (ATCC 9637)) (New authorisation) (Novel Foods)

An application for authorisation in Great Britain of this novel food on the terms below has been submitted. It is for ministers in England, Wales and Scotland to decide whether to authorise the novel food.

Introduction

An application for 3'-Sialyllactose (3'-SL) sodium salt (produced using a derivative strain of *Escherichia coli* W (ATCC 9637)) as a novel food within the food categories detailed in the proposed terms of authorisation, in Great Britain, was received by the FSA from Kyowa Hakko Bio Company Ltd.

For new novel foods and extensions of use to authorised novel foods to be placed on the market in Great Britain, an application shall be submitted in accordance with assimilated EU Regulation 2015/2283.

Safety Assessment Summary

Following the submission of application RP1477, the FSA and FSS have undertaken a safety assessment on the new authorisation of 3'-Sialyllactose (3'-SL) sodium salt (produced using a derivative strain of *Escherichia coli* W (ATCC 9637)) as a novel food.

The safety assessment concluded that the composition of the novel food is safe under the proposed conditions of use and does not pose a safety risk to human health. The anticipated intake levels and the proposed uses in food and food supplements was not considered to be nutritionally disadvantageous.

Safety assessment: Safety Assessment of 3'-Sialyllactose (3'-SL) Sodium Salt as a Novel Food for Use in Food and Food Supplements (RP1477) | Published in FSA Research and Evidence

Relevant legislation

- Article 7 of assimilated Regulation (EU) 2015/2283 of the European Parliament and of the Council; on the general conditions for authorisation of novel foods
- Article 10 of assimilated Regulation (EU) 2015/2283 of the European Parliament and of the Council; on the procedure for determining authorisation status of novel foods
- Assimilated Regulation (EU) 2017/2469 of the European Parliament and of the Council; laying down administrative and scientific requirements for novel food applications
- Assimilated Regulation (EU) 1169/2011 of the European Parliament and of the Council; on the provision of food information to consumers

TOA

The proposed terms of authorisation are set out below:

Conditions under which the novel food may be used

Specific food category	Maximum levels
Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	0.25 g/l
Unflavoured fermented milk-based products	0.25 g/l beverages 0.5 g/kg for products other than beverages

Specific food category	Maximum levels
Flavoured fermented milk-based products including heat-treated products	0.25 g/l beverages 2.5 g/kg for products other than beverages
Cereal bars	2.5 g/kg
Infant formula as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control	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 in Regulation (EU) No 609/2013	0.15 g/l in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer

Specific food category	Maximum levels
Processed cereal-based food and baby food or infants and young children as defined in Regulation (EU) No 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 (aged between one and three years)	0.15 g/l (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer
Foods for special medical purposes as defined in Regulation (EU) 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended
Total diet replacement for weight control as in Regulation (EU) No 609/2013	0.5 g/l beverages (equivalent to 0.125 g/meal based on a standard 250 g meal replacement beverage) 5 g/kg for products other than beverages (equivalent to 0.15 g/meal based on a standard 30 g meal replacement bar)
Flavoured drinks (excluding cola flavour and cola flavoured drinks)	0.25 g/l
Food supplements as defined in the Food Supplements (England) Regulations 2003 and Food Supplements (Wales) Regulations 2003 excluding food supplements for infants and young children	1.0 g/day
Food supplements as defined in the Food Supplements (England) Regulations 2003 and Food Supplements (Wales) Regulations 2003 for young children (aged between one and three years)	0.15 g/day
Food supplements as defined in the Food Supplements (England) Regulations 2003 and Food Supplements (Wales) Regulations 2003 for infants (under the age of 12 months)	0.2 g/day

Additional specific labelling requirements

The designation of the novel food on the labelling of the food containing it is '3 -Sialyllactose sodium salt'.

The labelling of food supplements containing 3′-Sialyllactose sodium salt must bear a statement that the supplements should not be consumed if food with added 3′-Sialyllactose sodium salt is consumed on the same day.

The labelling of food supplements for infants and young children must bear a statement that they should not be consumed if breast milk or other foods containing 3'-Sialyllactose sodium salt are consumed on the same day.

The food information must be presented in accordance with the provisions of Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers (EUR 2011/1169) which apply to mandatory food information.

Other Requirements: N/A

Data Protection

Authorised on XX Month 20XX (date will be added if the product is authorised).

This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.
Applicant: -Kyowa Hakko Bio Company., Ltd., 4-10-2, Nakano, Nakano-ku, Tokyo, 164-0001 Japan

During the period of data protection, the novel food 3'-Sialyllactose (3'-SL) sodium salt (produced using a derivative strain of *Escherichia coli* W (ATCC 9637)) is authorised for placing on the market within England and Wales only by Kyowa Hakko Bio Company., Ltd in Tokyo, Japan., unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Kyowa Hakko Bio Company., Ltd in Tokyo, Japan.

The data protection ends at the end of [5 years from Authorisation]

Specification

Description / Definition / Source:

Category	Information
Description	3'-Sialyllactose (3'-SL) sodium salt is a water-soluble white to off-white powder composed of ≥ 82.0% w/w dry matter (DM) of 3'-SL sodium salt
Chemical formula	C23H38NO19Na
Chemical name	sodium;(2S,4S,5R,6R)-5-acetamido-2-[(2R,3S,4S,5R,6S)-3,5-dihydroxy-2-(hydroxymethyl)-6-[(2R,3S,4R,5R)-4,5,6-trihydroxy-2-(hydroxymethyl)oxan-3-yl]oxyoxan-4-yl]oxy-4-hydroxy-6-[(1R,2R)-1,2,3-trihydroxypropyl]oxane-2-carboxylate
CAS number	128596-80-5
Molecular mass	655.53 Da

Category	Information
Source	Genetically modified strain of *Escherichia coli* W (ATCC 9637)

Composition:

Category	Information
3'-Sialyllactose sodium salt	≥ 82.0 % w/w dry matter
Sialic acid	≤ 6.0 % w/w dry matter
D-glucose	≤ 3.0 % w/w dry matter
D-lactose	≤ 3.0 % w/w dry matter
Sum of 3'-sialyllactulose and 6′-Sialyllactose sodium salt	≤ 5.0 % w/w dry matter
Sum of other carbohydrates	≤ 12.0 % w/w dry matter
Water	≤ 10.5 % w/w
Residual Protein	≤ 0.01 % w/w
Sodium	≤ 5.0 % w/w dry matter
pH	(5% solution, 25°C) 4.5 – 7.5

Heavy Metals and Contaminants:

Category	Information
Arsenic	≤ 0.2 mg/kg
Cadmium	≤ 0.2 mg/kg
Lead	≤ 0.2 mg/kg
Mercury	≤ 0.1 mg/kg
Aflatoxin M1	≤ 0.025 µg/kg

Microbiological Criteria:

- CFU = Colony Forming Units;
- EU = Endotoxin Units

Category	Information
Total plate count	≤ 1,000 CFU/g
Yeast and mould	≤ 100 CFU/g
Enterobacteriaceae	Absent in 10g
Salmonella spp.	Absent in 25g
Cronobacter spp.	Absent in 10g
Listeria monocytogenes	Absent in 25g
Presumptive *Bacillus cereus*	≤ 50 CFU/g
Residual Endotoxins	≤ 10 EU/mg

Proposed uses

The application is to authorise 3'-Sialyllactose (3'-SL) sodium salt (produced using a derivative strain of *Escherichia coli* W (ATCC 9637)) as a novel food to be placed on the market, or used in or on food, in Great Britain.

Infants, children and adults, including pregnant and lactating women, are identified as the target population of the novel food for the following food categories: unflavoured pasteurised and

unflavoured sterilised (including UHT) milk products, unflavoured fermented milk-based products, flavoured fermented milk-based products including heat-treated products, cereal bars, infant formula as defined in Regulation (EU) No 609/2013, follow-on formula as defined in Regulation (EU) No 609/2013, processed cereal-based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013, milk-based drinks and similar products intended for young children (aged between one and three years), foods for special medical purposes as defined in Regulation (EU) No 609/2013, total diet replacement for weight control as defined in Regulation (EU) No 609/2013, flavoured drinks (excluding cola flavour and cola-flavoured drinks), food supplements as defined in the Food Supplements (England) Regulations 2003 and Food Supplements (Wales) Regulations 2003, adults, young children (aged between one and three years) and for infants (under the age of 12 months).

Supplementary information
N/A

Labelling
Article 9(3)(b) of assimilated Regulation (EU) 2015/2283 provides that an authorisation of a Novel Food should include additional specific labelling requirements.

It is proposed that 3'-Sialyllactose (3'-SL) sodium salt (produced using a derivative strain of *Escherichia coli* W (ATCC 9637)) should be authorised with the following specific labelling requirements:

- The designation of the novel food on the labelling of the food containing it must be '3'-Sialyllactose sodium salt'.
- The labelling of food supplements containing 3'- Sialyllactose sodium salt must bear a statement that the supplements should not be used if other foods with added 3'-Sialyllactose sodium salt are consumed on the same day.
- The labelling of food supplements containing 3'- Sialyllactose sodium salt intended for infants and young children must bear a statement that the supplements should not be used if breast milk or other foods with added 3'- Sialyllactose sodium salt are consumed on the same day.

Transitional requirements/ provisions
N/A

Further explanation/ Rationale
N/A

Post Market Monitoring
N/A

Definitions
- 'Infant' means a child under the age of 12 months, as defined by Article 2.2(a) of assimilated Regulation (EU) No. 609/2013.
- 'Young child' means a child aged between one and three years, as defined by Article 2.2(b) of assimilated Regulation (EU) No. 609/2013.

Other Legitimate Factors
In developing the risk management recommendations, the FSA has had regard to the other legitimate factors (including consumer interests, political, environmental, societal and technical feasibility) that ministers will consider as part of their decision on authorisation. The FSA has not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this novel food. As noted above, stakeholders and the broader

public are equally invited to consider and provide their views on any relevant other legitimate factors as part of the consultation process.

The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

Impacts

As part of the risk analysis process, FSA has assessed the potential impacts that would result from the authorisation of this novel food, should ministers decide to authorise. No significant impacts were identified. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

Trade

Food exported from the UK to other countries/blocs will need to continue to meet the rules of those countries / blocs.

EU

3'-Sialyllactose (3'-SL) sodium salt (produced using a derivative strain of *Escherichia coli* W (ATCC 9637)) is already approved for use in the EU.

Apart from use in food supplements for infants and young children and for use in "flavoured drinks (excluding cola flavour and cola flavoured drinks)", the food categories and intended use levels within this application are the same as those in the EU List of Novel Foods listed in Regulation (EU) 2017/2470.

While the EU has not authorised the novel food for use in food supplements for infants, and young children, this decision is not based on safety concerns, as both the EU and UK have assessed the novel food to be safe at the proposed levels for use by infants and young children.

If authorised, this will mean there is divergence between Great Britain and the EU in the uses authorised for this novel food.

There will also be divergence in the food category of 'flavoured drinks (excluding cola flavour and cola flavoured drinks)' which, in the EU, comes under 'flavoured drinks, excluding drinks with a pH less than 5'.

Northern Ireland

This novel food is already authorised for use in Northern Ireland. The FSA's recommendation to authorise for use in food supplements for infants and young children will lead to divergence. Additionally, there will be minor differences in the categories of flavoured drinks that this novel food is permitted to be used in. However, under the Windsor Framework, goods authorised in Great Britain can be placed on the market in Northern Ireland, if eligible for, and moved through Northern Ireland Retail Movement Scheme.

Risk Management Recommendation

The FSA risk management recommendation is that 3'-Sialyllactose (3'-SL) sodium salt (produced using a derivative strain of *Escherichia coli* W (ATCC 9637)) as described in this application, is safe and is not liable to have an adverse effect on the target population, environmental safety and human health at the proposed levels of use.

Annex D
FSA Risk Management Recommendations
RP1478, 6'-Sialyllactose (6'-SL) sodium salt (produced using a derivative strain of *Escherichia coli* W (ATCC 9637)) (New authorisation) (Novel Foods)

An application for authorisation in Great Britain of this novel food has been submitted. It is for ministers in England, Wales and Scotland to decide whether to authorise the novel food on the terms below.

Introduction

An application for 6'-Sialyllactose (6'-SL) sodium salt (produced using a derivative strain of *Escherichia coli* W (ATCC 9637)) as a novel food within the food categories detailed in the proposed terms of authorisation, in Great Britain, was received by the FSA from Kyowa Hakko Bio Company Ltd.

For new novel foods and extensions of use to authorised novel foods to be placed on the market in Great Britain, an application must be submitted in accordance with assimilated EU Regulation 2015/2283.

Safety Assessment Summary

Following the submission of application RP1478, the FSA and FSS assessed the safety of 6'-Sialyllactose (6'-SL) sodium salt, produced using a derivative strain of *Escherichia* coli W (ATCC 9637), as a novel food. The assessment concluded that its composition is safe under the proposed conditions of use, poses no risk to human health, and that the anticipated intake levels and proposed uses in food and food supplements are not considered nutritionally disadvantageous.

Safety assessment: Safety Assessment of 6'-Sialyllactose (6'-SL) Sodium Salt as a Novel Food for Use in Food and Food Supplements (RP1478) | Published in FSA Research and Evidence

Relevant legislation

- Article 7 of assimilated Regulation (EU) 2015/2283 of the European Parliament and of the Council; on the general conditions for authorisation of novel foods
- Article 10 of assimilated Regulation (EU) 2015/2283 of the European Parliament and of the Council; on the procedure for determining authorisation status of novel foods
- Assimilated Regulation (EU) 2017/2469 of the European Parliament and of the Council; laying down administrative and scientific requirements for novel food applications
- Assimilated Regulation (EU) 1169/2011 of the European Parliament and of the Council; on the provision of food information to consumers
-

TOA

The proposed terms of authorisation are set out below:

Conditions under which the novel food may be used

Category	Information
Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	0.5 g/l

Category	Information
Unflavoured fermented milk-based products	0.5 g/l for beverages 2.5 g/kg for products other than beverages
Flavoured fermented milk-based products including heat-treated products	0.5 g/l for beverages 5 g/kg for products other than beverages
Cereal bars	5.0 g/kg
Infant formula as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control	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 in Regulation (EU) No 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 in Regulation (EU) No 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 (aged between one and three years).	0.3 g/l (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer.
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
Total diet replacement for weight control as defined in Regulation (EU) No 609/2013	1.0 g/l (beverages) (equivalent to 0.25 g/meal based on a standard 250 g/meal replacement beverage) 10 g/kg for products other than beverages (equivalent to 0.30 g/meal based on a standard 30 g meal replacement bar)
Flavoured drinks (excluding cola flavour and cola flavoured drinks	0.5 g/l
Food supplements as defined in the Food Supplements (England) Regulations 2003 and Food Supplements (Wales) Regulations 2003 excluding food supplements for infants and young children	1.0 g/day
Food supplements as defined in the Food Supplements (England) Regulations 2003 and Food Supplements (Wales) Regulations 2003 for young children (aged between one and three years)	0.3 g/day

Category	Information
Food supplements as defined in the Food Supplements (England) Regulations 2003 and Food Supplements (Wales) Regulations 2003 for infants (under the age of 12 months)	0.4 g/day

Additional specific labelling requirements

The designation of the novel food on the labelling of the food containing it is 6'- Sialyllactose sodium salt'.

The labelling of food supplements containing 6′-Sialyllactose sodium salt must bear a statement that the supplements should not be consumed if food with added 6′-Sialyllactose sodium salt is consumed on the same day.

The labelling of food supplements for infants and young children must bear a statement that they should not be consumed if breast milk or other foods containing 6'-sialyllactose are consumed on the same day.

The food information must be presented in accordance with the provisions of Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers (EUR 2011/1169) which apply to mandatory food information.

Other Requirements: N/A

Data Protection

Authorised on XX Month 20XX (date will be added if the product is authorised).

This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.

Applicant: Kyowa Hakko Bio Company., Ltd., 4-10-2, Nakano, Nakano-ku, Tokyo, 164-0001 Japan

During the period of data protection, 6'-Sialyllactose (6'-SL) sodium salt (produced using a derivative strain of *Escherichia coli* W (ATCC 9637)) is authorised for placing on the market within England and Wales only by Kyowa Hakko Bio Company Ltd unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Kyowa Hakko Bio Company Ltd.

The data protection ends at the end of [5 years from Authorisation]

Specification

Description / Definition / Source:

Category	Information
Description	Water-soluble white to off-white powder composed of ≥ 82.0% w/w dry matter (DM) of 6'-SL sodium salt produced by microbial fermentation.
Chemical formula	$C_{23}H_{38}NO_{19}Na$

Category	Information
Chemical name	Sodium; (2R,4S,5R,6R)-5-acetamido-4-hydroxy-6-[(1R,2R)-1,2,3-trihydroxypropyl]-2-[[(2R,3R,4S,5R,6S)-3,4,5-trihydroxy-6-[(2R,3R,4R,5R)-1,2,4,5-tetrahydroxy-6-oxohexan-3-yl] oxyoxan-2-yl] methoxy]oxane-2-carboxylate
Molecular mass	655.53 Da
CAS No	157574-76-0
Source	Genetically modified strain of *Escherichia coli* W (ATCC 9637)

Characteristics/Composition:

Category	Information
6'- Sialyllactose sodium salt (% w/w dry matter)	6'- Sialyllactose sodium salt (% w/w dry matter): ≥ 82.0
Sialic acid (% w/w dry matter)	≤ 6.0
D-glucose (% w/w dry matter)	≤ 3.0
D-lactose (% w/w dry matter)	≤ 3.0
Sum of 6'-sialyllactulose and 3′-sialyllactose sodium salt (% w/w dry matter, sum of both)	≤ 5.0
Sum of other carbohydrates (% w/w dry matter)	≤ 13.0
Water (% w/w)	≤ 10.5
Residual Protein (% w/w)	≤ 0.01
Sodium (% w/w dry matter)	≤ 5.0
pH	(5% solution, 25◦C), 4.5 – 7.5

Heavy Metals and Contaminants:

Category	Information
Arsenic (mg/kg)	≤ 0.2
Aflatoxin M1 (µg/kg)	≤ 0.025

Microbiological Criteria:

- CFU = Colony Forming Units
- EU = Endotoxin Units

Category	Information
Total plate count	≤ 1,000 CFU/g
≤ 100 CFU/g	≤ 100 CFU/g
Enterobacteriaceae	Absent in 10g

Salmonella spp.	Absent in 25g
Cronobacter spp.	Absent in 10g
Listeria monocytogenes	Absent in 25g
Presumptive *Bacillus cereus*	≤ 50 CFU/g
Residual Endotoxins	≤ 10 EU/mg

Proposed uses

The application is to authorise 6'-Sialyllactose (6'-SL) sodium salt (produced using a derivative strain of *Escherichia coli* W (ATCC 9637)) as a novel food to be placed on the market, or used in or on food, in Great Britain.

Infants, children and adults, including pregnant and lactating women, are identified as the target population of the novel food for the following food categories: unflavoured pasteurised and unflavoured sterilised (including UHT) milk products, unflavoured fermented milk-based products, flavoured fermented milk-based products including heat-treated products, cereal bars, infant formula as defined in Regulation (EU) No 609/2013, follow-on formula as defined in Regulation (EU) No 609/2013, processed cereal-based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013, milk-based drinks and similar products intended for young children (aged between one and three years) foods for special medical purposes as defined in Regulation (EU) No 609/2013, total diet replacement for weight control as defined in Regulation (EU) No 609/2013, flavoured drinks (excluding cola flavour and cola flavoured drinks) and food supplements as defined in the Food Supplements (England) Regulations 2003 and Food Supplements (Wales) Regulations 2003 adults, young children (aged between one and three years) and for infants (under the age of 12 months).

Supplementary information

N/A

Labelling

Article 9(3)(b) of assimilated Regulation (EU) 2015/2283 provides that an authorisation of a novel food should include additional specific labelling requirements.

It is proposed that 6'-Sialyllactose sodium salt (produced using a derivative strain of *Escherichia coli* W (ATCC 9637)) should be authorised with the following specific labelling requirements:

- The designation of 6'-Sialyllactose sodium salt on the labelling of the food containing it shall be '6-Sialyllactose sodium salt'.
- The labelling of food supplements containing 6'-Sialyllactose sodium salt must bear a statement that they should not be consumed if other foods containing added 6'-Sialyllactose sodium salt are consumed the same day.
- The labelling of food supplements containing 6'-Sialyllactose sodium salt intended for infants and young children must bear a statement that the supplements should not be used if breast milk or other foods with added 6'-Sialyllactose sodium salt are consumed on the same day

Transitional requirements/ provisions

N/A

Further explanation/ Rationale

N/A

Post Market Monitoring
N/A

Definitions
- 'Infant' means a child under the age of 12 months, as defined by Article 2.2(a) of assimilated Regulation (EU) No. 609/2013.
- 'Young child' means a child aged between one and three years, as defined by Article 2.2(b) of assimilated Regulation (EU) No. 609/2013.

Other Legitimate Factors
In developing the risk management recommendations, the FSA has had regard to the other legitimate factors (including consumer interests, political, environmental, societal and technical feasibility) that ministers will consider as part of their decision on authorisation. The FSA has not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this novel food. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant other legitimate factors as part of the consultation process.

The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

Impacts
As part of the risk analysis process, FSA has assessed the potential impacts that would result from the authorisation of this novel food, should ministers decide to authorise. No significant impacts were identified. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

Trade
Food exported from the UK to other countries / blocs will need to continue to meet the rules of those countries/blocs.

EU
6'-Sialyllactose (6'-SL) sodium salt (produced using a derivative strain of *Escherichia coli* W (ATCC 9637)) is already approved for use in the EU.

Apart from use in food supplements for infants and young children, the food categories and intended use levels within this application align with those listed in the EU List of Novel Foods under Regulation (EU) 2017/2470. While the EU has not authorised the novel food for use in food supplements for infants and young children, this decision is not based on safety concerns, as both the EU and UK have assessed the novel food to be safe at the proposed levels for infant use.

There will also be divergence over the food category of "flavoured drinks (excluding cola flavour and cola flavoured drinks)" which in the EU comes under "Flavoured drinks, excluding drinks with a pH less than 5".

If authorised, this will mean there is divergence between Great Britain and the EU in the authorised uses for this novel food.

Northern Ireland
This novel food is already authorised for use in Northern Ireland. The FSA's recommendation to authorise for use in food supplements for infants and young children will lead to some divergence. However, under the Windsor Framework, goods authorised in Great Britain can be placed on the

market in Northern Ireland, if eligible for, and moved through Northern Ireland Retail Movement Scheme.

Risk Management Recommendation

The FSA risk management recommendation is that 6'-Sialyllactose (6'-SL) sodium salt (produced using a derivative strain of *Escherichia coli* W (ATCC 9637)), as described in this application, is safe and is not liable to have an adverse effect on the target population, environmental safety and human health at the proposed levels of use.