FSS Risk Management recommendations on applications for authorisation of regulated products: four novel foods

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1. Document Subject and Purpose

In this document, we publish Food Standards Scotland's (FSS) risk management recommendations on applications for four novel foods.

Since the end of the EU exit transition period, FSS and the Food Safety Authority (FSA) have adopted technical guidance and quality assurance processes used by the European Food Safety Authority (EFSA) to enable us to undertake Great Britain (GB) safety assessments for regulated product applications. Further information is available on our website: Regulated products application guidance

These risk management recommendations take into account the opinion of FSS, which itself considers:

- The safety assessments of FSS for each application;
- Potential impacts that would result from the authorisation of these regulated products; and
- Other legitimate factors that Scottish ministers may want to consider before making a decision regarding authorisation.

The final FSS proposed risk management recommendations made to the Scottish ministers will also consider stakeholders' views received from this consultation.
A parallel consultation is being published by the FSA to inform ministers' determination in England and Wales (with Northern Ireland kept informed).

2. Our safety assessment and opinion

Our risk assessors deliver the science behind our advice, links to which are available within each recommendation annex. They are responsible for identifying and characterising hazards and risks to health and assessing levels of exposure.
The applications within this consultation have undergone a full FSS safety assessment (arrived at in collaboration with FSA and meeting our obligation to carry out a risk assessment), including a full review of the dossiers and supplementary information provided by the applicants.

The risk management recommendations will be considered by the Scottish ministers to inform determinations on the authorisations of the regulated product applications in Scotland.

3. Risk management recommendations

FSS have made risk management recommendations on the applications for the authorisations for four novel foods.

The FSS risk management recommendation for each application is published within a separate annex (linked below), including the regulated product ID number and title of the application. A link to the individual opinion/safety assessments is provided in each Annex.

ANNEX A RP1411 - *Schizochytrium* sp. oil rich in DHA and EPA

ANNEX B RP1476 - 2'-fucosyllactose (2'-FL) (produced by a derivative strain of *Escherichia coli* W (ATCC 9637))

4. Further information

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

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Return to top of Document

Annex A

RP1411 - *Schizochytrium* sp. oil rich in DHA and EPA (Extension of use) (Novel Foods)

An application for the extension of use in Great Britain (GB) of this authorised novel food on the terms below has been submitted. It is for ministers in Scotland, England and Wales 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 Docosahexaenoic acid (DHA) and Eicosapentaenoic acid (EPA), as a novel food in two additional food categories: analogues of; meat and meat products and fishery product analogues, in GB was received from DSM Nutritional Products Switzerland (DSM Nutritional Products Ltd, Wurmisweg 576, 4303 Kaiseraugst, Switzerland).

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

The applicant originally sent the application in for an extension of use in meat and fish analogues. However, it was considered that “meat and meat products analogues” and “fishery product analogues” would be more suitable categories for these products to fall under due to the fact that:

- “Analogues of meat” was considered limiting as it would only permit the product to be used in products which would imitate whole cuts of meat and therefore could not be used in products which imitate processed meat products like sausages, which would require to be categorised as analogues of meat products.

- “Analogues of fish” was considered limiting as it would only apply to analogues of aquatic species with swimming fins and would only be permitted in products which would imitate whole cuts of fish and therefore could not be used in products which

imitate processed fish products like fish fingers, which would require to be categorised as analogues of fish products.

- The term “fishery products” covers a wider array of species, including but not limited to cephalopods, crustaceans and fish including edible products and parts from such animals e.g. roe. As analogous products are highly processed and composite products, the term “fishery product analogues” was considered more suitable.

Therefore, the two extensions of use will now be referred to as “analogues of: meat and meat products” and “fishery product analogues”.

Safety Assessment Summary

Following the submission of application RP1411, 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.

The views of the Advisory Committee on Novel Foods and Processes (ACNFP) have been considered in the safety assessment. The safety assessment represents the opinion of FSS, as required by Article 11 in Regulation (EU) 2015/2283.

Safety assessment: Safety Assessment RP1411 Schizochytrium sp. oil rich in DHA and EPA

Relevant Legislation

Legislation

Regulation (EU) 1169/2011 on the provisions of food information to consumers https://www.legislation.gov.uk/eur/2011/1169/contents

Regulation (EU) 2015/2283 sets out requirements and process for the approval of novel foods

https://www.legislation.gov.uk/eur/2015/2283/contents

Regulation (EU) 2017/2469 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283

https://www.legislation.gov.uk/eur/2017/2469/contents

Relevant provisions of Regulation

Article 7 of Regulation (EU) 2015/2283 on the general conditions for inclusions of novel foods in the list

Article 10 of Regulation (EU) 2015/2283 on the procedure for authorising the placing on the market of a novel food and updating the list.

Terms Of Authorisation

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 register of authorised novel foods under 'Novel-129'. If this extension of use is authorised by ministers, the determination will consolidate and replace the authorisation of the placing on the market of *Schizochytrium* sp. oil rich in DHA and EPA and all existing authorised uses of this novel food.

The terms of authorisation in the register 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 300 mg/100 g. The terms of authorisation in the register should also be amended to change 'Soy and imitation milk products (excluding drinks)' to 'Analogues of milk products (except drinks)' as well as amending from 'spreadable fats and dressings' to 'dressings and spreadable fats', as drafted in the table below. These changes are being made to better clarify the definition of the food categories and update references to relevant regulations.

Authorised Novel Food	**Conditions under which the novel food may be used**		**Other requirements**	**Additional specific labelling requirements**
Schizochytrium sp. oil rich in DHA and EPA	***Specified food category***	***Maximum levels of DHA and***		The designation of the novel food on the labelling of the food containing it is 'DHA and

		EPA combined:		EPA-rich oil from the microalgae *Schizochytrium* sp.' The food information must be presented in accordance with the provisions of Regulation (EU) 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.
	Food supplements as defined in The Food Supplements (Scotland) 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 (Scotland) 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) 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended		
	Total diet replacement for	250 mg/meal		

	weight control as defined in Regulation (EU) 609/2013			
	Milk-based drinks and similar products intended for young children (persons aged 1 year (12 months) up to the age of 3 years (36 months))	200 mg/100 g		
	Processed cereal based food and baby food for infants and young children as defined in Regulation (EU) 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) 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		

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.

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.'

The food information must be presented in accordance with the provisions of Regulation (EU) 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers which apply to mandatory food information.

Definitions

- Docosahexaenoic Acid (DHA)
- Eicosapentaenoic acid (EPA)
- Food supplements – as defined in the Food Supplements (Scotland) Regulations 2003
- 'Infant' means a child under the age of 12 months, as defined by Article 2.2(a) of Regulation (EU) 609/2013.
- 'Young child' means a child aged between one and three years, as defined by Article 2.2(b) of Regulation (EU) 609/2013.

Other Legitimate Factors

In developing the Risk Management recommendations, FSS 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 FSS have 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, FSS have 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

Schizochytrium sp. oil rich in DHA and EPA is already approved for use in the EU under 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. To note they did not ask EFSA for an opinion in this simple extension of use.

Northern Ireland

Schizochytrium sp.oil rich in DHA and EPA is already authorised in Northern Ireland (NI) as a Novel Food and with the proposed extension of use, although the extensions of use fall under different categories from those chosen to be used in GB. 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. Where the EU/NI authorisation states "fish analogue" this consultation and proposed TOA's will use the term "fishery product analogues.

However, under the Windsor Framework, if this product is approved in GB, it can be placed on the market in Northern Ireland, if it is eligible for, and moved through Northern Ireland Retail Movement Scheme (NIRMS).

Risk Management Recommendation

The FSS Risk Management recommendation is the extension of use of *Schizochytrium sp.*oil rich in DHA and EPA in fishery product analogues and analogues of; meat and meat products both at a combined maximum level of 300 mg per 100 g, as 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.

Return to top of Document

Annex B

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 (GB) of this novel food on the terms below has been submitted. It is for ministers in Scotland, England and Wales 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 GB was received from Kyowa Hakko Bio Co., Ltd.,1-9-2, Otemachi, Chiyoda-ku, Tokyo, 100-0004 Japan.

2’-fucosyllactose (2’-FL) produced synthetically and from other microbial sources has already been authorised for conditions of use in other food categories in GB.

For new novel foods and extensions of use to authorised novel foods to be placed on the market in GB, applications are submitted in accordance with Regulation (EU) 2015/2283.

Safety Assessment Summary

Following the submission of application RP 1476, 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.

The views of the ACNFP have been considered in the safety assessment. The safety assessment represents the opinion of FSS, as required by Article 11 in Regulation (EU) 2015/2283.

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 Regulation (EU) 2015/2283 of the European Parliament and of the Council on the general conditions for authorisation of novel foods

- Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council; on the procedure for determining authorisation status of novel foods

- Regulation (EU) 2017/2469 of the European Parliament and of the Council; laying down administrative and scientific requirements for novel food applications

- Regulation (EU) 1169/2011 of the European Parliament and of the Council; on the provision of food information to consumers

Terms Of Authorisation

The proposed terms of authorisation are set out below

Authorised Novel Food	**Conditions under which the novel food may be used**		**Additional specific labelling requirements**	**Other Requirements**	**Data Protection**
2'-fucosyllactose (2'-FL) (produced by a derivative strain of *Escherichia coli* W (ATCC 9637))	Specific food category	Maximum levels	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		Authorised on XX XX 2025 This application is authorised based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Kyowa Hakko Bio Co.,
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk 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)	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		Ltd., 4-10-2, Nakano, Nakano-ku, Tokyo, 164-0001 Japan During the period of data protection2'-fucosyllactose (produced by a derivative strain of *Escherichia coli* W (ATCC 9637)) is authorised for placing on the market within Scotland only by Kyoka Hakko Bio Co. 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
	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			
	Table-top sweeteners	200 g/kg			
	Infant formula as defined in Regulation (EU) 609/2013	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) 609/2013	1.2 g/l n 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) 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	provisions of Regulation (EU) 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.		the agreement of Kyoka Hakko Bio Co.LTD. The data protection ends at the end of [Date 5 years from Authorisation]
	Milk-based drinks and similar products intended for young children (persons aged 1 year (12 months) up to the age of 3 years (36 months))	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) 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	4.8 g/l (beverages)			

	defined in Regulation (EU) 609/2013	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) 828/2014	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	1.2 g/day			

	Supplements (Scotland) Regulations for infants (persons under the age of 1 year (12 months) and young children (persons aged 1 year (12 months) up to the age of 3 years (36 months))				
	Food supplements as defined in the Food Supplements (Scotland) Regulations 2003 excluding food supplements for infants and young children	3.0g/day			

Specification

Authorised Novel Food	*Specifications*
2'-fucosyllactose (2'-FL) (produced by a derivative strain of *Escherichia coli* W (ATCC 9637))	*Description/Definition:* *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).* *Source:* Genetically modified strain of Escherichia coli W (ATCC 9637 Composition*:* *Appearance: white to off-white powder*

	• 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 • Arsenic: ≤ 0.2 mg/kg • Cadmium: ≤ 0.1 mg/kg • Lead: ≤ 0.02 mg/kg • Mercury: ≤ 0.1 mg/kg Microbiological Criteria • Aflatoxin M1: ≤ 0.025 µg/kg • Aerobic plate count): ≤ 1,000 CFU/g • Yeast and mould: ≤ 100 CFU/g • Enterobacteriaceae: Absent in 10g • *Salmonella* spp.: Absent in 25g • *Cronobacter* spp.: Absent in10g • *Listeria monocytogenes:* Absent in 25g • Presumptive *Bacillus cereus:* ≤ 50 CFU/g • Endotoxins: ≤ 10 EU/mg

Proposed uses

The application is to authorise 2'-fucosyllactose (produced by a derivative strain of *Escherichia coli* W (ATCC 9647)) as a novel food to be placed on the market, or used in or on food, in GB.

The target is the general population, including infants and young children and 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, dairy analogues including beverage whiteners, cereal bars, table-top sweeteners, infant formula as defined in Regulation (EU) 609/2013, follow-on formula as defined in Regulation (EU) 609/2013, processed cereal - based food and baby food for infants and young children as defined in Regulation (EU) 609/2013, milk-based drinks and similar products intended for young children (persons aged 1 year (12 months) up to the age of 3 years (36 months), foods for special medical purposes as defined in Regulation (EU) 609/2013, total diet replacement for weight control as defined in Regulation (EU) 609/2013, bread and pasta products bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Regulation (EU) 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.

The intended uses and use levels for 2'-FL (produced by a derivative strain of *Escherichia coli* W (ATCC 9647)) and the food categories are listed to be the same as those for existing 2'-FL authorisations in the List of Novel Foods 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.

Labelling

As set out in additional specific labelling requirements for 2-'FL in the authorisations recorded in the register of authorised novel foods in GB, the following should apply in accordance with Article 9 (3) (b) of Regulation (EU) 2015/2283:

- 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.

- The food information must be presented in accordance with the provisions of Regulation (EU) 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.

Definitions

- Food supplements – as defined in the Food Supplements (Scotland) Regulations 2003

- 'Infant' means a child under the age of 12 months, as defined by Article 2.2(a) of Regulation (EU) 609/2013.

- 'Young child' means a child aged between one and three years, as defined by Article 2.2(b) of Regulation (EU) 609/2013.

Other Legitimate Factors

In developing the Risk Management recommendations, FSS 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. FSS have 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 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, FSS have 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 GB have assessed the novel food to be safe at the proposed levels for infant use.

Authorisation in GB in the terms proposed will mean there is divergence between the GB and EU authorisations for this novel food.

Northern Ireland

This novel food is already authorised in Northern Ireland. The recommendation for use in food supplements for infants will lead to some divergence.

However, under the Windsor Framework, if this product is approved in goods authorised in GB, it can be placed on the market in Northern Ireland, if they are eligible for, and moved through The Northern Ireland Retail Movement Scheme (NIRMS).

Risk Management Recommendation

The FSS 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.

Return to top of Document

Annex C

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 (GB) of this novel food on the terms below has been submitted. It is for ministers in Scotland, England and Wales 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 GB was received from Kyowa Hakko Bio Company Ltd. (1-9-2, Otemachi, Chiyoda-ku, Tokyo, 100-0004, Japan).

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

Safety Assessment Summary

Following the submission of application RP1477, 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 and 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.

The views of the ACNFP have been considered in the safety assessment. The safety assessment represents the opinion of FSS, as required by Article 11 in Regulation (EU) 2015/2283.

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

Relevant legislation

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

Terms Of Authorisation

The proposed terms of authorisation are set out below:

<table>
<tr><th>Authorised Novel Food</th><th colspan="2">Conditions under which the novel food may be used</th><th>Additional specific labelling requirements</th><th>Other requirements</th><th>Data protection</th></tr>
<tr><td rowspan="2">3'-Sialyllactose (3'-SL) sodium salt (produced using a derivative strain of Escherichia coli W (ATCC 9637))</td><td>Specific food category</td><td>Maximum levels</td><td rowspan="2">The designation of the novel food on the labelling of the food containing it is '3′-Sialyllactose sodium salt'.</td><td rowspan="2"></td><td rowspan="2">Authorised on XX Month 20XX. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with</td></tr>
<tr><td>Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products</td><td>0.25 g/l</td></tr>
</table>

	Unflavoured fermented milk-based products	0.25 g/l beverages 0.5 g/kg for products other than beverages	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'-		Article 26 of Regulation (EU) 2015/2283. Applicant: Kyowa Hakko Bio Co., 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 E. coli W (ATCC 9637)) is authorised for placing on the market within Scotland only by Kyowa Hakko Bio Co., Ltd in Tokyo, Japan., unless a subsequent
	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) 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 in Regulation (EU) 609/2013	0.15 g/l in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer	Sialyllactose sodium salt are consumed on the same day. The food information must be presented in accordance with the provisions of Regulation (EU) 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.		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 Co., Ltd in Tokyo, Japan. The data protection will expire at the end of [TBC]
	Processed cereal-based food and baby food or infants and young children as defined in Regulation (EU) 609/2013	0.15 g/l 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 (persons aged 1 year (12 months) up to the age of 3 years (36 months))	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 defined in Regulation (EU) 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 (Scotland) Regulations 2003 excluding food supplements for infants and young children	1.0 g/day			

	(persons above 3 years of age)				
	Food supplements as defined in the Food Supplements (Scotland) Regulations 2003 for young children (persons aged 1 year (12 months) up to the age of 3 years (36 months))	0.15 g/day			
	Food supplements as defined in the Food Supplements (Scotland) Regulations 2003 for infants (persons aged under 1 year (12 months)	0.2 g/day			

Specification

Authorised Novel food	Specification
3'- Sialyllactose (3'-SL) sodium salt (produced using a derivative strain	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

of *Escherichia coli* W (ATCC 9637))	Source: • Genetically modified strain of *Escherichia coli* W (ATCC 9637) Definition: • Chemical formula: $C_{23}H_{38}NO_{19}Na$ • 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 weight 655.53 Da Composition: • 3'-SL 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'-SL sodium salts ≤ 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: • 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: • 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 GB.

The target population is adults, including pregnant and lactating women, children, and infants and 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) 609/2013, follow-on formula as defined in Regulation (EU) 609/2013, processed cereal--based food and baby food for infants and young children as defined in Regulation (EU) 609/2013, milk-based drinks and similar products intended for young children (persons aged 1 year (12 months) up to the age of 3 years (36 months), foods for special medical purposes as defined in Regulation (EU) 609/2013, total diet replacement for weight control as defined in Regulation (EU) 609/2013, flavoured drinks (excluding cola and cola-flavoured drinks) and food supplements as defined in the Food Supplements (Scotland) Regulations 2003, excluding food supplements for infants and young children, for young children (persons aged 1 year (12 months) up to the age of 3 years (36 months)) and for infants (persons aged under 1 year (12 months).

Labelling

As set out in additional specific labelling requirements for 3-'SL sodium salt in the authorisations recorded in the register of authorised novel foods in GB, the following should apply in accordance with Article 9 (3) (b) of Regulation (EU) 2015/2283:

- The designation of the novel food on the labelling of the foodstuffs 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.

- The food information must be presented in accordance with the provisions of Regulation (EU) 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers which apply to mandatory food information.

Definitions

- Food supplements – as defined in the Food Supplements (Scotland) Regulations 2003

- 'Infant' means a child under the age of 12 months, as defined by Article 2.2(a) of Regulation (EU) 609/2013.

- 'Young child' means a child aged between one and three years, as defined by Article 2.2(b) of Regulation (EU) 609/2013.

Other Legitimate Factors

In developing the Risk Management recommendations, FSS 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.

FSS have 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, FSS have 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 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 t use by infants and young children.

Authorisation in GB in the terms proposed will mean there is divergence between GB and the EU authorisation 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 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, authorised in GB, can be placed on the market in Northern Ireland, if it is eligible for, and moved through The Northern Ireland Retail Movement Scheme (NIRMS).

Risk Management Recommendation

FSS 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 intended concentrations of use.

Return to top of Document

Annex D

RP 1478, 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 (GB) of this novel food has been submitted. It is for ministers in Scotland, England and Wales 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 GB, was received from Kyowa Hakko Bio Company Ltd. (1-9-2, Otemachi, Chiyoda-ku, Tokyo, 100-0004, Japan).
For new novel foods and extensions of use to authorised novel foods to be placed on the market in Great Britain, applications are submitted in accordance with EU Regulation 2015/2283.

Safety Assessment Summary

Following the submission of application RP1478, 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.

The views of the ACNFP have been considered in the safety assessment. The safety assessment represents the opinion of FSS, as required by Article 11 in Regulation (EU) 2015/2283.

Safety assessment: https://science.food.gov.uk/article/120921-safety-assessment-of-6-sialyllactose-6-sl-sodium-salt-as-a-novel-food-for-use-in-food-and-food-supplements-rp1478

Relevant legislation

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

Terms Of Authorisation

The proposed terms of authorisation are set out below:

Authorised novel food	**Conditions under which the novel food may be used**		**Additional specific labelling requirements**	**Other requirements**	**Data Protection**
6'-Sialyllactose (6'-SL) sodium salt (produced using a derivative strain of *Escherichia coli* W (ATCC 9637))	**Specified food category**	**Maximum Levels**	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		Authorised on (tbc) XX XX XXXX This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.

			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) 1169/2011 of the European Parliament and of the Council on the provision of		Applicant: Kyowa Hakko Bio Co., 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 Scotland, 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

			food information to consumers (EUR 2011/1169) which apply to mandatory food information.		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 will expire at the end of (tbc)
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	0.5 g/l			
	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) 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 in Regulation (EU) 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) 609/2013	0.3 g/l 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 (persons aged 1 year (12 months) up to the age of 3 years (36 months))	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	In accordance with the particular nutritional			

	purposes as defined in Regulation (EU) 609/2013	requirements of the persons for whom the products are intended			
	Total diet replacement for weight control as defined in Regulation (EU) 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	1.0 g/day			

	Supplements (Scotland) Regulations 2003 (excluding food supplements for infants and young children)				
	Food supplements as defined in the Food Supplements (Scotland) Regulations 2003 for young children (persons aged 1 year (12 months) up to the age of 3 years (36 months))	0.3 g/day			
	Food supplements as defined in the Food Supplements (Scotland) Regulations 2003 for infants	0.4 g/day			

	(persons under the age of 1 year (12 months)				

Specification

Authorised Novel Food	Specifications
6'-Sialyllactose (6'-SL) sodium salt (produced using a derivative strain of *Escherichia coli* W (ATCC 9637))	**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. **Source**: • Genetically modified strain of *Escherichia coli* W(ATCC 9637) **Definition** • Chemical formula: $C_{23}H_{38}NO_{19}Na$ • 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 **Characteristics/Composition:** • 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'-SL 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:** • Arsenic (mg/kg): ≤ 0.2 • Aflatoxin M1 (µg/kg): ≤ 0.025 **Microbiological criteria:** • 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 • CFU: Colony Forming Units; • EU: Endotoxin Units

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 GB.

The target population is adults including pregnant and lactating women, children, and infants and 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) 609/2013, follow-on formula as defined in Regulation (EU) 609/2013, processed cereal--based food and baby food for infants and young children as defined in Regulation (EU) 609/2013, milk-based drinks and similar products intended for young children (persons aged 1 year (12 months) up to the age of 3

years (36 months), foods for special medical purposes as defined in Regulation (EU) 609/2013, total diet replacement for weight control as defined in Regulation (EU) 609/2013, flavoured drinks (excluding cola flavour and cola flavoured drinks) and food supplements as defined in the Food Supplements (Scotland) Regulations 2003 , for adults, young children and for infants.

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 6′-SL 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.

- The food information must be presented in accordance with the provisions of Regulation (EU) 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers which apply to mandatory food information.

Definitions

- 'Infant' means a child under the age of 12 months, as defined by Article 2.2(a) of Regulation (EU) 609/2013.

- ‘Young child’ means a child aged between one and three years, as defined by Article 2.2(b) of Regulation (EU) 609/2013.

Other Legitimate Factors

In developing the Risk Management recommendations, FSS 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. FSS have 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, FSS have 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 applicant’s novel food was authorised in the EU with effect from 13 October 2023 by Commission Implementing Regulation (EU) 2023/2215 of 23 October 2023 authorising the placing on the market of 6′-Sialyllactose sodium salt produced by derivative strain of

Escherichia coli W (ATCC 9637) as a novel food and amending Implementing Regulation (EU) 2017/2470.

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 GB 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 and cola flavoured drinks)” which in the EU comes under “Flavoured drinks, excluding drinks with a pH less than 5”.

GB Authorisation in the terms proposed will mean there is divergence between GB and the EU in the authorised uses for this novel food. This divergence will also be reflected in the labelling of supplements.

Northern Ireland

This novel food is already authorised for use in Northern Ireland. The 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 GB can be placed on the market in Northern Ireland, if eligible for, and moved through NIRMS.

Risk Management Recommendation

FSS 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 intended proposed levels of use.

Return to top of Document