Consultation Pack on Market Authorisation of 4 Regulated Food Products December 2025

This consultation seeks stakeholders' views, comments and feedback in relation to regulated product applications considered in this document.
Launch date: 15 December 2025 Respond by: 08 February 2026

This consultation will be of most interest to

All England, Wales, and Northern Ireland food and feed businesses, local and port health authorities, district councils, and other stakeholders with an interest in food and feed safety. A parallel consultation is being published by Food Standards Scotland (FSS) .

Purpose of the consultation

This consultation seeks stakeholders' views, comments and feedback in relation to the regulated product applications considered in this document, which have been submitted for:

- An extension of use of one authorised novel food
- 3 new authorisations for 3 novel foods

How to respond

Responses to this consultation should be submitted via the online survey. If this is not possible, you can email a response to:

Email: RPconsultations@food.gov.uk

Full details on how to respond are given below.

Definitions

The following information and definitions may be of use when responding to this consultation.

Regulated Products - Certain food and feed products, called regulated products, must go through a risk analysis process, and require authorisation before they can be sold in the UK. You can find out more about the application process, including the risk analysis and risk management processes, and ministerial involvement here: Background on placing a regulated product on the market.

Novel foods are foods that were not used for human consumption to a significant degree within the UK or EU before 15 May 1997. In order to place new novel foods on the Great Britain market

or to change the specifications or conditions of use of authorised novel foods, applicants must submit an application in accordance with Assimilated Regulation 2015/2283. Novel foods authorisation guidance

Assimilated Regulations - Directly applicable EU legislation no longer applies in Great Britain. EU legislation, retained when the UK exited the EU, was assimilated on 01 January 2024. References to any legislation with 'EU' or 'EC' in the title should now be regarded as assimilated law where applicable to Great Britain. Assimilated law is published on legislation gov.uk. References to 'Retained EU Law' or 'REUL' should now be regarded as references to assimilated law.

The Food and Feed Safety and Hygiene Provisional Common Framework is a non-statutory arrangement between the UK Government and Devolved Administrations to establish common approaches to policy areas where powers have returned from the EU within areas of devolved competence. This consultation has been developed under the commitments to collaborative four-nation working set out in this framework. As such, this consultation has been developed through a four-nation approach. Final recommendations will be agreed on a four-nation basis before being presented to ministers in England, Scotland and Wales, with the Northern Ireland Health Minister kept informed. Northern Ireland continues to fully participate in the risk analysis processes concerning food and feed safety. This reflects Northern Ireland's integral role within the

UK and ensures that any decision made, fully considers the potential impacts on the whole of the UK.

Windsor Framework - For pre-packaged retail agrifood goods eligible for Northern Ireland Retail Movement Scheme (NIRMS):

- In October 2023, the Windsor Framework was implemented providing a unique set of arrangements to support the flow of pre-packaged agrifood retail food products for final consumption from Great Britain to Northern Ireland.
- These goods can meet the same standards applied in the rest of the UK in public health, marketing (including labelling) and organic foods when moving through NIRMS.
- Under NIRMS, regulated products which have been authorised in Great Britain, will be able to be placed on the market in Northern Ireland if they meet this criteria.
- The FSA remain committed to ensuring that consumers across the UK can be confident that food is safe and is what it says it is, even where rules applicable to the same type of food may be slightly different.

Safety Assessment - The FSA and FSS risk assessors deliver the science behind our advice. They are responsible for identifying and characterising hazards and risks to health and assessing exposure levels. Links to the safety assessment for each application can be found in the relevant corresponding annex below.

Risk Management - Our policy advisors are responsible for the risk management outputs. The FSA risk management recommendations document present the factors that they have identified as relevant to these applications, including the potential impact of any decision made by ministers, and contain proposed terms of authorisation and other relevant provisions. Links to the risk management recommendations document for each application can be found in the relevant corresponding annex below.

Details of consultation

Introduction

This consultation seeks views on the regulated products applications for 4 novel foods.

An overview of the details for each of the applications can be found in the below annexes. For full and further information, please refer to the technical documents of the FSA and FSS safety assessments and risk management recommendations documents as hyperlinked in the corresponding annex.

Annexes to applications

- **Annex A: RP1411** - Schizochytrium sp.oil rich in DHA and EPA (extension of use of the authorised novel food)
- **Annex B: RP1476 -** 2’-fucosyllactose (produced by a derivative strain of Escherichia coli W (ATCC 9637))
- **Annex C: RP1477** - 3’-Sialyllactose (3’-SL) sodium salt (produced using a derivative strain of Escherichia coli W (ATCC 9637))
- **Annex D: RP1478** - 6’-Sialyllactose (6’-SL) sodium salt (produced using a derivative strain of Escherichia coli W (ATCC 9637))

In consulting, the FSA is seeking views from stakeholders on the proposed terms of authorisation, any labelling requirements, and on any other legitimate factors (i.e. social, environmental, economic) as identified. Stakeholders are invited to use this opportunity to comment on these factors or highlight any additional factors that should be brought to the attention of ministers before a final decision is made.

Following the consultation, the next step is for the FSA to write to ministers in England and Wales with their recommendations. FSS will write to the minister in Scotland with their recommendations. Ministers in Northern Ireland will be kept informed. This is in line with FSA and FSS responsibility to provide advice, information or assistance to ministers in respect of matters connected with food safety or other interests of consumers in relation to food (section 6, Food Standards Act 1999 and section 3, Food (Scotland) Act 2015). Relevant ministers will then make decisions on authorisation, taking into account the risk management recommendations, any relevant provisions of assimilated law and any other legitimate factors, including those raised during the consultation process.

Impacts

As part of the risk analysis and risk management process, the FSA has assessed the potential impacts that would result from the proposals. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, political, environmental, societal, technical feasibility, and consumer interests).

For the applications in this consultation, no significant impacts have been identified. Individual impacts, including trade, Northern Ireland, other legitimate factors, and others, for each application are listed in the corresponding risk management document for each application. The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

Engagement and Consultation Process

Details of all valid applications for regulated products are published monthly on the Register of Regulated Product Applications - available on the FSA website.

Stakeholders are invited to consider the questions posed below in relation to any relevant provisions of assimilated law and other legitimate factors.

Following the consultation process, responses will be made available on the FSA website and shared with ministers.

Questions

Questions asked in this consultation (for all applications):

- Do you have any concerns about the safety of the applications with respect to the intended consumers?
- Do you have any comments or concerns on the impacts of authorising or not authorising the applications and, if in favour of authorisation, the terms on which the applications are authorised (as outlined in the FSA and FSS risk management recommendations)?
- Are there any other factors that should be considered by ministers that have not already been highlighted?
- Do you have any other feedback? Including consideration of any relevant provisions of assimilated law and other legitimate factors (other evidence further supporting clear, rational and justifiable risk analysis, such as consumer interests, technical feasibility and environmental factors).

Responses

Responses are required by 23:59 08 February 2026. Please state, in your response, whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents). Please respond to the consultation via the online survey. If this is not possible, you can email a response to: RPconsultations@food.gov.uk

Please indicate which application(s)/product(s) you are responding about by using the following subject line for your response: Response to RP1411, RP1476, RP1477 or RP 1478 (select which is/are appropriate) consultation on novel foods.

If responding by email, please state in your response whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents) and in which nation you are based.

We aim to publish a summary of responses to this consultation within around 3 months of the consultation closing. For information on how the FSA handles your personal data, please refer to the Consultation privacy notice.

Responses will be shared with ministers in England, Wales and Northern Ireland.

Further information

If you require a more accessible format of this document, please send details to the named contact for responses to this consultation and your request will be considered. This consultation has been prepared in accordance with HM Government Consultation Principles.

Thank you on behalf of the FSA for participating in this public consultation.

Annex A: RP1411 - Schizochytrium sp.oil rich in DHA and EPA (extension of use of the authorised novel food)

Background

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 2 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.

Trade

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

European Union (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 (NI) 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.

FSA Risk Management Recommendations

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.

The FSA risk management recommendations and safety assessment can be found below:

PDF
View FSA Consultation Risk Management Recommendation as PDF(Open in a new window) (402.71 KB)

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

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

Background

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.

Trade

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

European Union (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 authorised 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.

FSA Risk Management Recommendations

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.

The FSA risk management recommendations and safety assessment can be found below:

PDF
View FSA Consultation Risk Management Recommendation as PDF(Open in a new window)
(402.71 KB)

FSA and FSS safety assessment: Safety Assessment of 2’-Fucosyllactose (2’-FL) as a Novel Food for Use in Food and Food Supplements (RP1476) | Published in FSA Research and Evidence

Annex C: RP1477 - 3’-Sialyllactose (3’-SL) sodium salt (produced using a derivative strain of Escherichia coli W (ATCC 9637))

Background

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.

Trade

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

European Union (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 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 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.

FSA Risk Management Recommendations

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 intended concentrations of use.

The FSA risk management recommendations and safety assessment can be found below:

PDF
View FSA Consultation Risk Management Recommendation as PDF(Open in a new window)
(402.71 KB)

FSA and FSS 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

Annex D: RP1478 - 6'-Sialyllactose (6'-SL) sodium salt (produced using a derivative strain of Escherichia coli W (ATCC 9637))

Background

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 shall be submitted in accordance with assimilated EU Regulation 2015/2283.

Trade

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

European Union (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 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.

FSA Risk Management Recommendations

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.

The FSA risk management recommendations and safety assessment can be found below:

PDF
View FSA Consultation Risk Management Recommendation as PDF(Open in a new window)
(402.71 KB)

FSA and FSS safety assessment: Safety Assessment RP1478 6'-Sialyllactose (6'-SL) Sodium Salt as a Novel Food for Use in Food and Food Supplements