Consultation on applications for authorisation of regulated products: Four novel foods December 2025

1. Consultation Summary Page

Date consultation launched:	Closing date for responses:
15 December 2025	8 February 2026

Who will this consultation be of most interest to?

This consultation will be of most interest to:

All Scottish food businesses, local and district councils, and other stakeholders with an interest in food safety.

A list of interested parties is included in Annex A.

What is the purpose of this consultation?

This consultation is conducted by Food Standards Scotland (FSS) on behalf of the Minister for Public Health and Women's Health and seeks stakeholders' views, comments, and feedback in relation to the regulated product applications considered in this document. FSS have recently assessed four novel foods.

The FSS opinions provided in the annexes to this document (including the proposed terms of authorisation) consider the FSS / FSA safety assessments. The views gathered through this consultation will be considered and included alongside those of officials across FSS

and other Government Departments to inform Ministers' decision-making on whether to authorise the individual regulated products for use in Scotland.

The Food Standards Agency (FSA) will publish a similar consultation for England and Wales.

FSS is responsible for providing the Minister for Public Health and Women's Health with recommendations on the applications for the authorisation of regulated products in respect of matters connected with food safety or other interests of consumers in relation to food (Section 3 of the Food (Scotland) Act 2015).

What is the subject of this consultation?

This consultation seeks stakeholders' views, comments and feedback in relation to the regulated product applications included and referenced in this document.

The consultation concerns the following applications:

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

We ask stakeholders to consider any relevant provisions of law and other legitimate factors (other evidence further supporting clear, rational, and justifiable risk analysis, such as consumer interests, technical feasibility, and environmental factors), including those that FSS have identified as relevant to these applications. This is an opportunity for stakeholders to express views on these applications which Scottish ministers will use to inform their decision making, which we consider crucial to the process of transparent policymaking.

Responses to this consultation

If you wish to comment on the applications in this consultation, all responses should be submitted through the Citizen Space entry, where the questions can be answered and other feedback given.

Contact details:

LabellingStandardsandRegulatedProducts@fss.scot

Postal address

Food Standards Scotland
Fourth Floor
Pilgrim House
Old Ford Road
Aberdeen
AB11 5RL

Is a Business & Regulatory Impact Assessment (BRIA) included with this consultation?

No☐☒

2. Introduction

To be placed on the market in Scotland, applications for the authorisation of regulated products must be submitted to the Great Britain (GB) regulated products process. The decision on authorisation is made by the respective Minister in Scotland, England, and Wales, with the Minister in Northern Ireland kept informed.

This is a function that was previously carried out at EU level. Regulated product applications for the GB market, including the four novel foods applications detailed within this consultation are now subject to the UK's own risk analysis process.

FSS has been working to ensure that the high standard of food safety and consumer protection in Scotland continues. This is in line with FSS responsibility to provide advice to ministers in respect of matters connected with food safety or other interests of consumers in relation to food Section 3, Food (Scotland) Act 2015.

Under current operating arrangements for Northern Ireland, businesses seeking a new authorisation for a regulated food and feed products to be placed on the Northern Ireland market will continue to follow EU rules.

FSS risk assessors deliver the science behind our advice. They are responsible for identifying and characterising hazards and risks to health and assessing levels of exposure. The applications within this consultation have each undergone a 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.

This consultation seeks to gather Scottish stakeholders' views on the proposed regulated product applications for authorisations.

The provisional Food and Feed Safety and Hygiene 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.

This consultation letter and the FSS Risk Management recommendations document present the opinions of FSS and any legitimate factors that FSS have identified as relevant to these applications, including the potential impact of any decision made by ministers. 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, Scottish ministers will decide on authorisation. They will consider the FSS recommendation, any relevant provisions of law and any other legitimate factors, including those raised during the consultation process.

3. Detail of Consultation

Novel foods

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 Scotland, the procedure for authorising the placing of new novel foods on the market, or to change the specifications or conditions of use of authorised novel foods, starts either on the initiative of the ministers or following the submission of an application by an applicant in accordance with Regulation (EU) 2015/2283. The applications for authorisation of novel foods which are included in this consultation have been made under Article 10 of this Regulation, which outlines the procedure for authorising the placing on the market of novel foods and the updating of the public list.

In accordance with Regulation (EU) 2015/2283 on novel foods and Regulation (EC) 1331/2008 which establishes a common authorisation procedure for food additives, food enzymes and food flavourings, the novel food applications included in this consultation have been submitted for new authorisations, modification and change of an existing authorisation.

4. Terms of reference

Assimilated Law and EU Regulations

Directly applicable EU legislation no longer applies in GB. EU legislation, retained when the UK exited the EU, is called assimilated law with effect from 1 January 2024. References to

any legislation with ‘EU’ or ‘EC’ in the title (e.g. Regulation (EU) 2015/2283 or Regulation (EC) 1333/2008) should now be regarded as assimilated law. Assimilated law is published on https://www.legislation.gov.uk.

5. Northern Ireland – Windsor Framework

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 the Northern Ireland Retail Movement Scheme (NIRMS).

- Under the Northern Ireland Retail Movement Scheme, 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 criterion.

- FSS 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.

6. Impacts

As part of the risk analysis process, FSS have assessed the potential impacts that may result should ministers decide to authorise these regulated product applications. Our collective assessment of the proposals did not identify any significant impacts. The impacts considered included those most frequently identified as potential impacts when introducing or amending food law (i.e. local authority delivery, health, environment, growth, innovation, trade, competition, consumer interests, or small and micro-businesses).

For the applications in this consultation, no significant impacts have been identified. Individual impacts, including trade, Northern Ireland and other legitimate factors for each

application are listed in the corresponding Risk Management (RM) document for each application. The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

7. Other legitimate factors

We have considered a range of other legitimate factors that ministers may wish to consider in making decisions about these regulated product applications including political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours. Our collective assessment of the other legitimate factors did not identify any impacts.

8. Engagement and Consultation Process

Regulated Products

Details of all valid applications for regulated products are published monthly on the Register of Regulated Product Applications, available here.

Stakeholders are invited to consider the questions below.

Following the consultation process responses will be published and made available to stakeholders and ministers.

9. Questions asked in this consultation (for all applications)

1. Do you have any concerns about the safety of the applications with respect to the intended consumers?

2. 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 FSS Risk Management recommendations)?

3. Are there any other factors that should be considered by ministers that have not already been highlighted?

4. 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)?

10. Responses

This consultation will run for eight weeks. Responses are required by close of 8 February 2026.

Please state in your response via the questionnaire:

- Whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents).
- Which application(s)/product(s) you are commenting on.
- If you give us permission to quote your name or organisation in the publication of the results (please also make sure you have read and understood the paragraphs below where we discuss GDPR, publication of personal data and confidentiality of responses) or that of the organisation on whose behalf you are participating in the consultation in the publication of the results. For information on how FSS handles your personal data, please refer to the Consultation Privacy notice.
- Please indicate which application(s)/product(s) you are responding to by using the following subject line for your response: “Response to and the subject of the consultation.
- FSS aim to publish all responses to this consultation on Citizen Space within three months of the consultation closing. All responses should be sent through the Citizen Space entry for this consultation. Reponses will be shared with the FSA and ministers.

11. Further information

If you require a more accessible format of this document, such as in Braille or in another language, please send details to the named contact for responses to this consultation and your request will be considered. Please let us know if you need paper copies of the consultation documents.

Please feel free to pass this document to any other interested parties or send us their full contact details and we will arrange for a copy to be sent to them direct.

This consultation has been prepared taking account of the Consultation Criteria. The Consultation Criteria from the HM Code of Practice on Consultation should be included in each consultation and they are listed below:

11. The Seven Consultation Criteria information

Criterion 1 — When to consult

Formal consultation should take place at a stage when there is scope to influence the policy outcome.

Criterion 2 — Duration of consultation exercises

Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible.

Criterion 3 — Clarity of scope and impact

Consultation documents should be clear about the consultation process, what is being proposed, the scope to influence and the expected costs and benefits of the proposals.

Criterion 4 — Accessibility of consultation exercises

Consultation exercises should be designed to be accessible to, and clearly targeted at, those people the exercise is intended to reach.

Criterion 5 — The burden of consultation

Keeping the burden of consultation to a minimum is essential if consultations are to be effective and if consultees' buy-in to the process is to be obtained.

Criterion 6 — Responsiveness of consultation exercises

Consultation responses should be analysed carefully, and clear feedback should be provided to participants following the consultation.

Criterion 7 — Capacity to consult.

Officials running consultations should seek guidance in how to run an effective consultation exercise and share what they have learned from the experience.

Criterion 2 states that *Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible*.

This consultation has been shortened to 8 weeks for the following reasons:

- The regulated product applications are considered routine and should not raise undue concern with users, industry or businesses.
- FSS Risk Management recommendations are informed by the FSS review of EFSA opinions.
- Consulting for 12 weeks will place undue pressure on adhering to legislative deadlines for authorisations.
- Making decisions on authorisations efficiently will demonstrate that processes previously completed by the EU can be delivered at pace post EU Exit, aligning processes' timelines to facilitate authorisation processes for GB businesses with stakes in EU markets.
- It is considered that, in this instance, an 8-week consultation period allows ample time for comments from stakeholders.
- It is important to aim for consistency across the four nations of the United Kingdom wherever possible. All four of the applications in this consultation have already been approved by the EU and by extension approved for use in Northern Ireland.
- However, the proposed terms of authorisation would result in divergence in particular food categories.
- With dual applications, regulation of products should keep pace with the EC.
- Any delay could create an uneven playing field for GB businesses and affect GB-NI trade.

The Code of Practice states that an impact assessment should normally be published alongside a formal consultation. An impact assessment was not required for this consultation.

12. Queries

If you have any queries relating to this consultation, please contact FSS using the contact details on page 4, and an FSS official will be able to respond to your questions.

13. GDPR, publication of personal data and confidentiality of responses

The European General Data Protection Regulation (GDPR) replaces the Data Protection Directive 95/46/EC and was developed to harmonize data privacy laws across Europe. The Data Protection Act (DPA) 2018 applies GDPR standards and transposes the EU Data Protection Directive 2016/680 (Law Enforcement Directive) into domestic UK law. In accordance with the GDPR, we are required to provide a privacy notice in relation to this public consultation. FSS will be known as the "Controller" of the personal data provided to us. We need to collect this information to allow us to effectively carry out our official duties of policy development and for the purposes of record keeping. In responding to this consultation, you have consented to provide this information to us but are able to withdraw your consent at any time by getting in touch with us.

Personal information will be stored on Scottish Government servers and cloud-based services have been procured and assessed against the national cyber security centre cloud security principles. Personal information will not be used for any purpose other than in relation to consultations. Personal information will be stored for as long as necessary to carry out the above functions and for five years from receipt in accordance with our retention policy. No third parties have access to your personal data unless the law allows them to do so.

You have a right to see the information we hold on you by making a request in writing to the email address below. If at any point you believe the information, we process on you is incorrect you can request to have it corrected. If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data not in accordance with the law, you can complain to the Information Commissioner's Office (ICO). Our Data Protection Officer in the FSS is the Head of Corporate Services who can be contacted at the following email address: dataprotection@fss.scot.

In accordance with the principle of openness, our office in Pilgrim House in Aberdeen will hold a copy of the completed consultation as per our retention policy. FSS will not publish

anything without your consent. If you have any queries, please email: dataprotection@fss.scot or return by post to the address given on page 4.
In accordance with the provisions of Freedom of Information Act (Scotland) 2002/Environmental Information (Scotland) Regulations 2004, all information contained in your response may be subject to publication or disclosure. If you consider that some of the information provided in your response should not be disclosed, you should indicate the information concerned, request that it is not disclosed and explain what harm you consider would result from disclosure. The final decision on whether the information should be withheld rests with FSS. However, we will consider your views when making this decision. Any automatic confidentiality disclaimer generated by your IT system will not be considered as such a request unless you specifically include a request, with an explanation, in the main text of your response.

A detailed Privacy Policy is available on our website, that explains how FSS will safeguard and process any personal identifiable information that we collect from you in relation to this consultation.

14. Comments on the consultation process

We are interested in what you thought of this consultation and would therefore welcome your general feedback on both the consultation package and overall consultation process. If you would like to help us improve the quality of future consultations, please feel free to share your thoughts with us by sending an email to openness@fss.scot or return by post to the address given on page 4.

Thank you on behalf of Food Standards Scotland for participating in this public consultation.

Regulated Products Team
Food Standards Scotland
LabellingStandardsandRegulatedProducts@fss.scot

15. List of Annexes

Details of the applications are given in the annexes below and in the FSS Risk Management recommendation documents which include the FSS opinions.

Annex A: List of interested parties

Annex B: Definitions – definitions which may be of use when responding to this consultation.

Annex C: RP1411 – extension of use of the authorised novel food, *Schizochytrium* sp.oil rich in DHA and EPA

Annex D: RP1476 – 2'-fucosyllactose (produced by a derivative strain of *Escherichia coli* W) (ATCC 9637).

Annex E: RP1477 – 3'-Sialyllactose (3'-SL) sodium salt (produced using a derivative strain of *Escherichia coli* W (ATCC 9637))

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

16. Annex A: List of interested parties

Key stakeholder trade associations who have an interest in food and feed across the wider sector will be contacted directly for feedback on this consultation:

Specialist Nutrition Association
British Nutrition Foundation
British Retail Consortium (BRC)
Chilled Food Association (CFA)
Food and Drink Federation FDF (Scotland)
British Dietetic Association
Food and Drink Federation FDF Sector Group: Food additives
Kantar Media
Kantar Worldpanel
UK Flavour Association (UKFA)
Food Additives & Ingredients Association (FAIA)
Federation of Bakers
Health Food Manufacturers' Association
Campden BRI
Council for Responsible Nutrition UK
Scottish Retail Consortium
International Organization of the Flavour Industry (IOFI)
Which
This is not an exhaustive list.

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Annex B: 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 GB 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 GB. EU legislation, retained when the UK exited the EU, was assimilated with effect from 1 January 2024 References to any legislation with 'EU' or 'EC' in the title should now be regarded as assimilated law where applicable to GB. Assimilated law is published on legislation gov.uk. 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 three-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 the Northern Ireland Retail Movement Scheme (NIRMS).

- Under the Northern Ireland Retail Movement Scheme, regulated products which have been authorised in Great Britain, will be able to be placed on the market in Northern Ireland if they meet these criteria.

- The FSS 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 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 FSS Risk Management recommendations document presents the factors 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.

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Annex C: RP1411 - extension of use of the authorised novel food, *Schizochytrium* sp.oil rich in DHA and EPA

17. 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 two additional food categories: analogues of; meat and meat products and fishery product analogues, in GB was received from DSM Nutritional Products (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, an application shall be submitted in accordance with assimilated EU Regulation 2015/2283.

18. Trade

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

19. 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.

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).

20. FSS RM recommendation

The FSS 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 full FSS risk management recommendation which includes a link to the safety assessment and details the proposed terms of use of the novel food, can be found on the consultation page.

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Annex D: RP1476 - 2’-fucosyllactose produced by a derivative strain of *Escherichia coli* W.

21. 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 following food categories: dairy products and analogues, bakery wares, table-top sweeteners, foods for special groups, beverages, and food supplements, including the authorisation for food supplements for infants, 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 GB, an application shall be submitted in accordance with assimilated EU Regulation 2015/2283.

22. Trade

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

23. European Union (EU)

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

Under Commission Implementing Regulation (EU) 2024/2036 authorising the pacing on the market of 2’-Fucosyllactose produced by a 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, 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.

24. Northern Ireland

Novel food (2'-FL) (produced by a derivative strain of *Escherichia coli* W (ATCC 9637)) is already authorised in Northern Ireland. The FSS's recommendation to authorise for use in food supplements for infants will lead to some divergence.

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 NIRMS.

25. FSS RM recommendation

The FSS Risk Management recommendation is t, 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 (general population including lactating and pregnant women and infants and young children), environmental safety and human health at the intended conditions of use.

The full FSS risk management recommendation which includes a link to the safety assessment and details the proposed terms of use of the novel food, can be found on the consultation page.

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

26. 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 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 GB, an application shall be submitted in accordance with assimilated EU Regulation 2015/2283.

27. Trade

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

28. European Union (EU)

3’-Sialyllactose (3’-SL) sodium salt (produced using a derivative strain of *Escherichia coli* W (ATCC 9637)) authorised in the EU under Commission Implementing Regulation (EU)2024/1047 of 9th April 2024 authorising the placing on the market of 3′-Sialyllactose sodium salt produced using a 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 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 GB have assessed the novel food to be safe at the proposed levels for infant and young children use.

Authorisation in GB in the terms proposed will mean there is divergence between the GB and EU authorisations. 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'.

29. Northern Ireland

Novel food 3'-Sialyllactose (3'-SL) sodium salt (produced using a derivative strain of *Escherichia coli* W (ATCC 9637)) is already authorised in Northern Ireland. The FSS'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. 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 NIRMS.

30. FSS Risk Management Recommendations

The 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.

The full FSS risk management recommendation which includes a link to the safety assessment and details the proposed terms of use of the novel food, can be found on the consultation page.

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

31. 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 (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 GB, an application shall be submitted in accordance with assimilated EU Regulation 2015/2283.

32. Trade

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

33. European Union (EU)

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

GB authorisation will mean there is divergence between GB and the EU regarding the authorised uses for this novel food.

34. Northern Ireland

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

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 NIRMS.

35. FSS Risk Management Recommendations

The 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 proposed levels of use.

The full FSS risk management recommendation which includes a link to the safety assessment and details the proposed terms of use of the novel food, can be found on the consultation page.

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