##### Consultation on applications for authorisation of miscellaneous regulated products: four novel foods, three food additives, the removal of twenty-two food flavouring authorisations, and a proposal to set a limit for ethylene oxide in all food additives.

**Consultation Summary Page**

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| **Date consultation launched:** | **Closing date for responses:** |
| 02/02/2024 | 29/03/2024 |

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| **Who will this consultation be of most interest to?*** Food businesses wishing to use the food additives in the proposed use categories and food businesses who may have used the twenty-two flavouring substances (authorisation of which is proposed to be removed) in their food products
* Producers and suppliers of novel foods, food additives and flavourings, importers, distributors and wholesalers and retailers
* Food Industry Trade Associations covering novel foods, food additives and flavourings
* Consumer groups
* Campaign Groups concerned with infant formula and follow-on formula
* Organisations representing consumer interests in the food-chain
* Enforcement authorities across the UK, including local authorities, Port Health Authorities and District Councils
* Consumers and wider stakeholders

See [Annex A](#AnnexA) for List of other interested parties   |
| **What is the subject of this consultation?**This consultation seeks stakeholders’ views, comments and feedback in relation to the regulated product applications included in this document, which have been submitted either as new authorisations or for extension of use/modification. We ask stakeholders to consider 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), including those that FSS and the FSA have identified as relevant to these applications. This is an opportunity for stakeholders to input on the advice given to Ministers to inform decision making, which we consider crucial to the process of transparent policymaking.The consultation concerns the following:* The proposal to set a limit for ethylene oxide in all food additives.

The proposed novel food and food additive applications: * New authorisations (four novel foods)
* Extension of use of an existing authorised food additive (one food additive)
* New production method of existing authorised food additives (two food additives)
* Removal of existing authorisations (one application for twenty-two flavourings).

In addition to the authorisations and removals, the statutory instrument will also make various minor and technical amendments to the list of authorised novel foods to correct any identified errors and omissions. |

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| **What is the purpose of this consultation?**FSS and the FSA have recently assessed four novel foods and three food additives applications, along with an application for the removal of twenty-two food-flavouring authorisations and are proposing a limit for ethylene oxide in all food additives.The FSS/FSA opinion provided in this document (including the proposed terms of authorisation) takes into account the FSS/FSA scientific opinions. The views gathered through this consultation will be considered and included alongside those of officials across FSS, the FSA and, for novel foods, other Government Departments to inform Ministers’ decision-making on whether to authorise the individual regulated products for use in GB.The FSA have also published their opinion and launched a [parallel consultation](https://www.food.gov.uk/news-alerts/consultations/consultation-on-applications-for-authorisation-of-miscellaneous-regulated-products-four-novel-foods-three-food-additives-removal) for English and Welsh stakeholders. 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, Food (Scotland) Act 2015](https://www.legislation.gov.uk/asp/2015/1/section/3/enacted)).  |

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| **Responses to this consultation should be sent to:** |
| If you wish to comment on this consultation, all responses should be submitted through the Citizen Space entry, where the questions can be answered and other feedback given. | Evangelos KatsoulisLabelling, Standards & Regulated ProductsFood Standards ScotlandTel**: 07471955978** E-mail address: Evangelos.Katsoulis@fss.scot | Postal address: Food Standards ScotlandFourth FloorPilgrim HouseOld Ford RoadAberdeenAB11 5RL |

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| **Is a Business & Regulatory Impact Assessment (BRIA) included with this consultation?** | Yes [ ]  | No[x]  See Annex for reason. |

**Consultation on applications for authorisations of four novel foods and three food additives, the removal of twenty-two food-flavouring authorisations and a proposal to set a limit for ethylene oxide in all food additives**

Introduction

In order to be placed on the market, applications for the authorisation of regulated products must be submitted for authorisation in GB, where the decision on authorisation is made by the respective Ministers in Scotland, England and Wales (with the Department of Health Permanent Secretary 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 novel foods, food additives and food flavourings (henceforth referred to as ‘flavourings’), are now subject to the UK’s own risk analysis process.

FSS/FSA have been working together to ensure that the high standard of food safety and consumer protection in the UK continues. This is in line with FSS/FSA’s 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](https://www.legislation.gov.uk/asp/2015/1/section/3/enacted) and [Section 6, Food Standards Act 1999](https://www.legislation.gov.uk/ukpga/1999/28/section/6)).

Our 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. A safety assessment is not required for applications to remove authorised substances.

The novel food and food additive applications have undergone a full FSS/FSA safety assessment, including a full review of the dossiers and supplementary information provided by the applicants. The views of the Advisory Committee on Novel Foods and Processes (ACNFP) have been taken into account in the FSS/FSA safety assessments for the novel food applications. The views of the Joint Expert Group on Additives, Enzymes and other Regulated products (AEJEG) have been taken into account in the FSS/FSA safety assessments for the food additive applications. Following risk assessment, this consultation seeks to gather stakeholders’ views on the proposed regulated product authorisations.

[The provisional Food and Feed Safety and Hygiene Common Framework](https://www.gov.uk/government/publications/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 Scotland, England, and Wales, and the Department of Health Permanent Secretary in Northern Ireland.

This consultation and the FSS/FSA risk management recommendations document present the recommendations of FSS/FSA and the factors that FSS/FSA 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, the next step of the authorisation process is for relevant Ministers in Scotland, England and Wales to make decisions on authorisation (with the Department of Health Permanent Secretary in Northern Ireland kept informed), taking into account the FSS/FSA risk management recommendations, any relevant provisions of assimilated law and any other legitimate factors, including those raised during the consultation process.

Detail of Consultation

In accordance with [EU Regulation 2015/2283](https://www.legislation.gov.uk/eur/2015/2283/contents) on novel foods and [Regulation (EC) No 1331/2008](https://www.legislation.gov.uk/eur/2008/1331/contents) which establishes a common authorisation procedure for food additives, food enzymes and food flavourings, the novel food and food additive applications included in this consultation have been submitted for new authorisations, modification and change of an existing authorisation, a new production method of an existing authorisation and removal of existing authorisations.

Ministers in all four nations have agreed to a [provisional common framework for Food and Feed Safety and Hygiene](https://www.gov.uk/government/publications/food-and-feed-safety-and-hygiene-provisional-common-framework). 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 in cooperation with the FSA. Final advice will be agreed on a four-nation basis before being presented to Ministers.

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 GB market, or to change the specifications or conditions of use of authorised novel foods, starts either on the initiative of the Scottish Ministers or following the submission of an application by an applicant in accordance with EU Regulation 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.

Food additives are substances which are added to food to perform a technological function, exerting an effect on a food. Regulation (EC) No 1333/2008 defines food additives as “any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods”.

[Regulation (EC) No 1334/2008](https://www.legislation.gov.uk/eur/2008/1334/contents) on flavourings and certain food ingredients with flavouring properties, defines flavourings as “products not intended to be consumed as such, which are added to food in order to impart or modify odour and/or taste; made or consisting of the following categories: flavouring substances, flavouring preparations, thermal process flavourings, smoke flavourings, flavour precursors or other flavourings or mixtures thereof”.

**Terms of reference**

**Infants and Young Children**

When referring to infants and young children, infants describe children under 12 months and young children describes children aged 1 year to 3 years.

**Assimilated Law and EU Regulations**

Directly applicable EU legislation no longer applies in GB. EU legislation, retained when the UK exited the EU, was assimilated on 31 December 2023. 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 where applicable to GB. Assimilated law is published on [www.legislation.gov.uk](http://www.legislation.gov.uk). References to ‘Retained EU Law’ or ‘REUL’ should now be regarded as references to assimilated law.

**Northern Ireland market – Windsor Framework**

Since 1 October 2023, the Windsor Framework allows GB standards for public health in relation to food, marketing and organics to apply for pre-packed retail goods moved via the [NI Retail Movement Scheme (NIRMS)](https://www.gov.uk/government/publications/retail-movement-scheme-how-the-scheme-will-work/retail-movement-scheme-how-the-scheme-will-work). Under the Windsor Framework, regulated products approved in GB will be able to be placed on the market in Northern Ireland, if eligible for, and moved through NIRMS.

Details of the individual regulated products are given in the annexes.

This consultation concerns four applications for novel foods and three applications for food additives and the proposed removal of twenty-two food flavouring authorisations. Each application is considered within a separate annex, including the regulated product ID number and title of the application:

[**Annex**](#Annexcrp19barley) **B**: RP19 - Barley rice protein (Ever grain, LLC, USA) (new authorisation, novel foods)

[**Annex C**:](#Annexdrp200cetylated) RP200 - Cetylated fatty acids (Pharmaneutra S.p.a., Italy) (new

authorisation, novel foods)

[**Annex**](#Annexerp549) **D**: RP549 - lacto-N-fucopentaose I (LNFP-l) and 2'-fucosyllactose (2'-FL) (Glycom A/S, Denmark) (new authorisation, novel foods)

[**Annex**](#AnnexFrp1202) **E**: RP1202 - 3-fucosyllactose (Glycom A/S, Denmark) (new authorisation, novel foods)

[**Annex F**:](#Annexgrp217) RP217 - Polyglycerol polyricinoleate (PGPR, E 476) (extension and change of use of an existing authorised food additive

[**Annex**](#Annexh) **G:** RP1084 - Rebaudioside M, AM and D produced via enzyme conversion of highly purified steviol glycosides from *Stevia* leaf extracts (new production method of an existing authorised food additive)

[**Annex H:**](#AnnexI) RP1140 - Steviol glycosides produced by *Yarrowia lipolytica* (new production method of an existing authorised food additive)

[**Annex I:**](#AnnexJ) RP1737 - Proposed removal of twenty-two flavouring substances from the domestic list

[**Annex J:**](#AnnexJproposaltoset)Ethylene oxide

**Impacts**

As part of the risk analysis process, the FSS/FSA have assessed the potential impacts that would result from the authorisation of these novel foods and food additives, and the removal of authorisation of the food flavouring substances, should Ministers decide to authorise the novel foods and food additives, and remove the authorisation of the food flavouring substances. 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.

Under the [provisional Common Framework for Food and Feed Safety and Hygiene](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/934750/food-and-feed-safety-and-hygiene-proposed-common-framework-command-paper-web-accessible.pdf), 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.

**Ethylene oxide**

FSS/FSA will continue to manage the risks associated with food additives containing unacceptably high levels of ethylene oxide (above the new limit). A product withdrawal would be required for any non-compliant food additive with levels above 0.1 mg/kg. FSS/FSA should be informed if a food additive is contaminated with ethylene oxide above 0.1 mg/kg and/or where any amount of ethylene oxide (including below 0.1 mg/kg) has been detected in infant formula.

**Other** **legitimate factors**

We have considered a range of other legitimate factors (including consumer interests, political, environmental, societal and technical feasibility) that Ministers may wish to consider in making decisions about these novel foods, food additives, flavouring removals, and proposed limit for ethylene oxide in all food additives. A summary of the impacts identified is outlined below.

**Trade Impacts**

**Regulated products**

Under the Windsor Framework, Cetylated fatty acids (RP200), Polyglycerol polyricinoleate (PGPR), E476 (RP217), 3-fucosyllactose (3-FL) (RP1202) & RP1084, Steviol glycosides produced by Yarrowia lipolytica (RP1140), lacto-N-fucopentaose I (LNFP-l) and 2'-fucosyllactose (2'-FL) (RP549) & Barley Rice Protein (RP19) approved in GB would all be able to be placed on the market in NI, if eligible for, and moved through NIRMS.

**Ethylene oxide**

This proposal would provide clarity and consistency to industry, something key stakeholders have been calling for.

**Requirements in assimilated law**

Requirements in assimilated law are given within the Annexes.

**Options for authorisation**

The next step of the authorisation process is for Ministers to make decisions on authorisation. In presenting advice and assisting Ministers FSS and the FSA are acting pursuant to their functions under the Food (Scotland) Act 2015 and the Food Standards Act 1999.

Having considered the risk assessment, legal requirements and other legitimate factors and impacts, Ministers will have the following options for each of the applications:

Option 1: Authorise for use in all requested food categories in line with the proposed terms of authorisation.

Option 2: To make a decision not to authorise in accordance with the FSS/FSA recommendation.

Stakeholders are invited to consider the questions posed in relation to any relevant provisions of assimilated law and other legitimate factors as detailed above. Stakeholders’ responses will be considered along with risk assessment and other factors in development of advice provided to Ministers. Unless the views gathered in the consultation provide additional evidence, FSS/FSA will recommend that these regulated products are authorised, or their use modified, extended or removed, as per applicable on the proposed terms.

**FSS Risk Management recommendation**

The FSS Risk Management recommendations can be found on Citizen Space:

FSS Risk Management recommendations

**Engagement and Consultation Process**

**Regulated Products:**

Details of all valid applications for regulated products are published monthly on the [Register of Regulated Product Applications](https://www.food.gov.uk/risk-analysis/register-of-regulated-product-applications), on the FSA website.

In relation to the applications for authorisation of the new novel foods, stakeholders are invited to consider the following:

* the general conditions, for the inclusion of novel foods in the list of such authorised foods, as set out in Article 7 of 2015/2283,
* any relevant provision of assimilated law, including the precautionary principle referred to in [Article 7 of Reg (EC) No 178/2002](https://www.legislation.gov.uk/eur/2002/178/article/7)
* the FSS/FSA Opinions on the applications for authorisation, and
* any other legitimate factors relevant to the applications under consideration, when responding to this consultation.

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

**Questions asked in this consultation**

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| **Novel Foods**: 1. Do you have any concerns about the safety of the novel foods with respect to the intended consumers?
2. Do you have any comments or concerns on the impacts of authorising or not authorising the novel foods? If in favour of authorisation, do you agree with the terms on which the novel foods are authorised (as outlined in the FSS/FSA Risk Management recommendations)?
3. Are there any other factors that should be considered by Ministers that have not already been highlighted?

 1. Do you have any other feedback? Including consideration of any relevant provisions of assimilated law (the new name of retained law) and other legitimate factors (other evidence further supporting clear, rational and justifiable risk analysis, such as consumer interests, technical feasibility and environmental factors).

**Food additives**:  1. Do you have any concerns on the safety of the food additives which have not

 been considered in the FSS/FSA opinions with respect to the intended  consumers?  1. Do you have any comments or concerns on the impacts in consideration of

 authorising or not authorising these food additives? If in favour of authorisation, do you agree with the terms these food additives are authorised (as outlined in the FSS/FSA risk management recommendations)? 1. Do you have any comments or concerns on other impacts if authorised (e.g.

 political, environmental, societal, technological, legal or economic)? 1. Are there any other factors that should be considered by Ministers that have not already been highlighted?

 1. Do you have any feedback concerning the proposed specification for E 960c(ii), Rebaudioside M, AM and D produced via enzymatic conversion of highly purified steviol glycosides from Stevia leaf extracts?

6. Do you have any feedback concerning the proposed specification for E 960b,  steviol glycosides from fermentation?  1. Do you have any concerns or comments on extending the use of the food additive PGPR (E 476) in the new food category 03. ‘Edible Ices’ (with the restriction 'except sorbets') and at higher levels in ‘Sauces’ food category 12.6 (with the restriction ‘only emulsified sauces with a fat content of 20% and more’) with respect to the intended consumers or other impacts e.g. political, environmental, societal, technological, legal or economic?

 1. 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).

 **Flavourings**:  1. Do you agree with the FSS and FSA’s view that there should be no significant impact on UK businesses from removing these flavouring substances from the domestic list, as UK industry has indicated that they do not use them, and therefore, the only impact would be on third country imports?
2. Do you believe that transitional arrangements are necessary or should be considered for foods containing these flavourings which are placed on the market before the coming into force date of any legislation to remove them from the domestic list? Should any such transitional measures also apply for foods dispatched for export to GB? Please explain your answer.
3. If you disagree with the FSS and FSA’s view or have particular concern about the removal of any of the twenty-two flavourings, please explain why and provide information to help us understand and evidence the impact. Please include details on which of the flavouring substances your feedback relates to and, if applicable, the type of product you are using it in.
4. For the flavourings to stay on the domestic list, industry will need to commit to providing the necessary safety studies to allow the risk assessment to be completed. If you believe any of the twenty-two flavourings should remain on the domestic list, please identify who would be willing to provide the necessary safety studies.
5. Impacts on international countries, outside of those within the EU, need to be considered. The International Organisation of the Flavourings Industry (IOFI) considers there will not be any impacts as they aren’t widely used globally. Do you agree with this assessment?  If not, please explain your answer. Any information gathered via this consultation will help inform the drafting of the WTO notification.

 1. Would you be willing to be contacted by FSS in relation to this application?

**Ethylene oxide**: 1. Do you have any concerns on the safety of setting a limit of 0.1 mg/kg for ethylene oxide and its breakdown product 2-chloro-ethanol in all food additives which have not been considered with respect to the intended consumers?
2. Do you have any comments or concerns on the impacts in consideration of setting a limit of 0.1 mg/kg for ethylene oxide and its breakdown product 2-chloro-ethanol in all food additives? Are you in favour of this proposal?
3. If a limit of 0.1 mg/kg is set for ethylene oxide and its breakdown product 2-chloroethanol across all food additives, this will replace the current limit of 0.2 mg/kg for following 8 food additives:

E 431 polyoxyethylene (40) stearate, E 432 polyoxyethylene sorbitan monolaurate (polysorbate 20), E 433 polyoxyethylene sorbitan monooleate (polysorbate 80), E 434 polyoxyethylene sorbitan monopalmitate (polysorbate 40), E 435 polyoxyethylene sorbitan monostearate (polysorbate 60), E 436 polyoxyethylene sorbitan tristearate (polysorbate 65), E 1209 polyvinyl alcohol-polyethylene glycol-graft-copolymer and E 1521 polyethylene glycol. Does the reduction in ethylene oxide limit for 8 food additives raise any comments or concerns?   1. Do you have any comments or concerns on other impacts of this proposal (e.g. political, environmental, societal, technological, legal or economic)?
2. Are there any other factors that should be considered by Ministers that have not already been highlighted?

 1. Do you have any other feedback?
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Responses

This consultation will run for 8 weeks. Responses are required by close of 25th March 2024.

How to respond

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.

For information on how FSS handles your personal data, please refer to the [Consultation Privacy Notice.](https://www.foodstandards.gov.scot/privacy/privacy-notices/consultations-privacy-notice)

All responses to this consultation will be published by Food Standards Scotland within 3 months of the consultation closing.

All responses should be sent through the Citizen Space entry for this consultation. Responses will be shared with the FSA and Ministers.

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 in accordance with HM Government [consultation principles](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/100807/file47158.pdf), which are listed below:

The Seven Consultation Criteria

**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:
* All draft recommendations are considered routine and should not raise undue concern with consumers, industry or businesses.
* FSS risk management recommendations are based on FSS/FSA review of EFSA opinions.
* Consulting for 12 weeks will place undue pressure on adhering to legislative deadlines for the determination of applications for authorisation.
* Delivering 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.
* An 8-week consultation period allows ample time for comments from industries.
* 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.

**Queries**

If you have any queries relating to this consultation, please contact the person named on [page 3](#Response), who will be able to respond to your questions.

### GDPR, Publication of personal data and confidentiality of responses

1. 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 (the DPA) 2018 applies GDPR standards and transposed 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. Food Standards Scotland 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.
2. Personal information is stored on servers within the European Union 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.
3. 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
4. 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 3.
5. 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 take into account your views when making this decision.
6. 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.
7. A detailed Privacy Policy is available on our [website](https://www.foodstandards.gov.scot/privacy), that explains how FSS will safeguard and process any personal identifiable information that we collect from you in relation to this consultation.

Further information

### Comments on the consultation process itself

1. 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 3.

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). If you are replying by post then please note our updated address details below.

We will summarise all comments received and the official response to each will be published on the FSS website within three months following the end of the consultation period.

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

Yours sincerely,

### Evangelos Katsoulis

Policy Advisor

Labelling, Standards & Regulated Products

Food Standards Scotland

**Annex A: List of interested parties**

Key stakeholder trade associations which are represented across all four nations of the UK who have a strong interest in feed additives and their use in animal nutrition and the wider agriculture sector will be contacted directly for feedback on this consultation:

* Breakfast Cereals UK
* British Dietetic Association
* British Nutrition Foundation
* British Fruit Juice Association
* British Retail Consortium (BRC)
* British Specialist Nutrition Association
* Baby Milk Action
* Business Wales
* Campden BRI
* Cereal Ingredient Manufacturers’ Association
* Chilled Food Association (CFA)
* Council for Responsible Nutrition UK
* Dairy UK
* European Flavour Association (EFFA)
* Federation of Bakers
* Federation of Small Businesses (Northern Ireland)
* Federation of Small Businesses (Wales)
* Food Additives & Ingredients Association (FAIA)
* Food and Drink Federation FDF (England)
* Food and Drink Federation FDF (Wales)
* Food and Drink Federation FDF (Scotland)
* Food and Drink Federation FDF Sector Group: Biscuit, Cake, Chocolate and Confectionery
* Food and Drink Federation FDF Sector Group: Food additives
* Health Food Manufacturers’ Association
* International Organization of the Flavor Industry (IOFI)
* Leatherhead Food International
* Northern Ireland Food and Drink Association
* Northern Ireland Retail Consortium
* Provision Trade Federation (PTF)
* Seasonings and Spice Association (SSA)
* Scientific Advisory Committee on Nutrition
* Scottish Retail Consortium
* Snack, Nut and Crisp Manufacturers’ Association
* The British Soft Drinks Association (BSDA)
* UK Flavour Association (UKFA)
* UK Flour Millers
* Welsh Retail Consortium
* Which?

**Annex B: RP19- Barley rice protein (Ever grain, LLC, USA) (new authorisation of a novel food)**

**Background**

In accordance with EU Regulation 2015/2283 on novel foods, the application RP19 for barley rice protein for a new authorisation (Article 10) as a novel food ingredient, was received from Evergrain, LLC, USA.

The subject matter of this application is Barley Rice Protein, a mixture of protein from barley (*Hordeum vulgare*) and rice (*Oryza sativa*). Barley Rice Protein is obtained by purification of the barley and rice mixture obtained from the mash step in the production of beer. The novel food ingredient is primarily comprised of protein (>85%, dry solids) with the remaining components being ash (typically <5%).

The applicant sought authorisation for food categories including: bakery products, breakfast cereals, spreadable fats and dressings, grain products and pastas, snack foods, jam, marmalade and other fruit spreads, candy/confectionery, dairy and dairy imitates, dessert sauces and syrups, meat imitates, soups and soup mixes, savoury sauces, legume-based spreads, nut-based spreads, energy drinks, foods and beverages intended for sportspersons and meal replacements for weight control.

**FSS/FSA Risk Management recommendations**

The FSS/FSA Risk Management recommendation is that Barley Rice Protein, as described in the 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 FSS/FSA Risk Management recommendations, which includes a link to the safety assessment and details of the proposed terms of use of the novel food, can be found on the consultation page.

**Annex C: RP200-  Cetylated fatty acids (Pharmaneutra S.p.a., Italy) (new authorisation, novel food)**

**Background**

In accordance with EU Regulation 2015/2283 on novel foods, the application RP200 for cetylated fatty acids for a new authorisation (Article 10) as a novel food ingredient, was received from Pharmaneutra S.p.a., Italy.

The novel food is a mixture of cetylated fatty acids, cetyl myristate and cetyl oleate, which are synthesised from cetyl alcohol with myristic acid and cetyl alcohol with oleic acid, respectively. These two cetylated fatty acids are then blended with olive oil to give a finished product containing 70 – 80% cetylated fatty acids.

Myristic acid and oleic acid, which are raw materials in the manufacture of the novel food, are reported to be naturally occurring fatty acids with a long history of use in the UK and the European Union. The fatty acids present in the novel food are also found in vegetable oils which are part of the regular UK diet.

Oleic acid is found in high concentrations in olive (80%), pecan (60%) and peanut (85%) oils (CIR, 1987). Esterified oleic acid is reportedly found in many vegetable oils and animal fats, usually at greater than 50% of the total fatty acid concentration. Myristic acid is sourced from coconut oil, nutmeg butter, palm seed oil and milk fats (CIR, 1987). The evidence provided supports that the use of these fatty acids is safe, and no specific risks were identified that required further evaluation.

The application is a new application, seeking to use cetylated fatty acids within the food category: food supplements for the general population.

**FSS/FSA Risk Management recommendations**

The FSS/FSA Risk Management recommendation is that cetylated fatty acids, 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 FSS/FSA Risk Management recommendations, which includes a link to the safety assessment and details of the proposed terms of use of the novel food, can be found on the consultation page.

**Annex D: RP549-  lacto-N-fucopentaose I (LNFP-l) and 2'-fucosyllactose (2'-FL) (Glycom A/S, Denmark) (new authorisation, of a novel food)**

**Background**

In accordance with EU Regulation 2015/2283 on novel foods, the application RP549 for lacto-*N*-fucopentaose I (LNFP-l) and 2'-fucosyllactose (2'-FL) (LNFP-l/2'-FL) for a new authorisation (Article 10) as a novel food ingredient, was received from Glycom A/S, Denmark.

The novel food is a mixture of LNFP-l and 2'-FL which is intended to be used as a source of human identical milk oligosaccharides. LNFP-l/2'-FL is manufactured by microbial fermentation using a genetically modified strain of *Escherichia coli* K-12, and then refined to yield the purified novel food.

The application is a new application, seeking to use LNFP-l/2'-FL in dairy products and analogues, bakery wares, beverages, foods for infants and young children, foods for special medical purposes, total diet replacement for weight control, and food supplements. Infants, children, and adults, including pregnant and lactating women, are identified as the target population of the novel food.

Food supplements are not intended to be used if other foods with added LNFP-l/2’-FL or breast milk are consumed the same day.

**FSS/FSA Risk Management recommendations**

The FSS/FSA Risk Management recommendation is that lacto-*N*-fucopentaose I (LNFP-l) and 2'-fucosyllactose (2'-FL), as described in the 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 FSS/FSA Risk Management recommendations, which includes a link to the safety assessment and details of the proposed terms of use of the novel food, can be found on the consultation page.

**Annex E: RP1202- 3-fucosyllactose (from strain of Escherichia coli K-12 DH1 (Glycom A/S, Denmark) (new authorisation of a novel food)**

**Background**

In accordance with Regulation 2015/2283 on novel foods, the application RP1202 for 3-fucosyllactose (3-FL) (from strain of Escherichia coli K-12 DH1) for a new authorisation (Article 10) as a novel food ingredient, was received from Glycom A/S, Denmark.

The novel food is 3-fucosyllactose which is intended to be used as a source of human identical milk oligosaccharides. 3-fucosyllactose (3-FL) (from strain of Escherichia coli K-12 DH1) is manufactured by microbial fermentation using a genetically modified (GM) strain of *Escherichia coli* K-12, and then refined to yield the purified novel food. However, this is not classed as GM because there is no GM DNA remaining in the final product.

This new application is seeking to use the novel food within the food following categories: dairy products and analogues, bakery wares, foods for special groups, beverages, and as a food supplement. Food supplements are not intended to be used if other foods with added 3-fucosyllactose or breast milk are consumed the same day.

**FSS/FSA Risk Management recommendations**

The FSA/FSS Risk Management recommendation is that, 3-fucosyllactose (3-FL) (from strain of Escherichia coli K-12 DH1) as described in the 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 FSS/FSA Risk Management recommendations, which includes a link to the safety assessment and details of the proposed terms of use of the novel food, can be found on the consultation page.

**Annex F: RP217 - polyglycerol polyricinoleate (PGPR, E 476) (extension and change of use of an existing authorised food additive)**

**Background**

In accordance with Regulation (EC) No 1331/2008 which establishes a common authorisation procedure for food additives, food enzymes and flavourings, the application RP217 for polyglycerol polyricinoleate (PGPR, E 476) for the extension of use of an existing authorised food additive, was received from Unilever.

This is an application for the extension of use of the already authorised additive polyglycerol polyricinoleate (PGPR, E 476) to allow use in ‘Edible Ices’, with the restriction ‘except sorbets’. A higher level of E 476 may be needed to emulsify sauces with a higher fat content and therefore, up to 8000mg/kg of E 476 should be authorised in sauces with a fat content of 20% or more. The existing level of 4000mg/kg will be retained for sauces with less than 20% fat.

The food additive polyglycerol polyricinoleate (PGPR, E 476) is already authorised for use in categories:

* 2.2.2 Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions
* 5.1 Cocoa and chocolate products as covered by Directive 2000/36/EC
* 5.2 Other confectionery including breath refreshening micro sweets
* 5.4 Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4
* 12.6 Sauces (current maximum limit 4000mg/kg)

The use of PGPR (E 476) in ice creams and frozen yoghurts (Edible Ices) allows for a more stable, improved quality product. It provides an emulsion structure which allows products to be formulated using healthier, low saturated fat oils and lower sugar levels. The manufacturing process is more sustainable, as an industrial ice cream freezer is not required.

Permitting higher concentrations of PGPR (E 476) in emulsified sauces would allow the production of reduced-oil products which offer health benefits without compromising on the sensory experience.

 **FSS/FSA Risk Management recommendation**

The FSS/FSA Risk Management recommendation is that the proposed extension of uses requested for polyglycerol polyricinoleate (PGPR, E 476) are safe and not liable to have an adverse effect on the target population, environmental safety and human health at the intended conditions of use.

The FSS/FSA Risk Management recommendations, which includes a link to the safety assessment and details of the proposed terms of use of the food additive, can be found on the consultation page.

**Annex G: RP1084 – Rebaudioside M, AM and D produced via enzyme conversion of highly purified steviol glycosides from Stevia leaf extracts (new production method of an existing authorised food additive)**

**Background**

In accordance with Regulation (EC) No 1331/2008 which establishes a common authorisation procedure for food additives, food enzymes and food flavourings, the application RP1084 for Rebaudioside M, AM and D produced via enzymatic conversion of highly purified steviol glycosides from stevia leaf extracts as a new production method of an existing authorized food additive, was received from Purecircle/Ingredion.

This is an application for changes to the existing production method of steviol glycosides to include an enzymatic conversion process to yield high purity steviol glycosides. Similar to already authorised steviol glycoside preparations, it would be used in food and beverages as a high-intensity sweetener for the replacement of sucrose in reduced-calorie or no-sugar-added products.

Steviol glycosides (from the *Stevia* plant) are non-nutritive sweeteners used in jams, chewing gum, drinks, yogurts and confectionery. It is also available in pure form for use in tea, coffee and baking.

This application is considered to provide technological advantages and benefits to consumers being suitable for individuals with diabetes and those who follow a low-glycaemic diet.

**FSS/FSA Risk Management recommendation**

The FSS/FSA Risk Management recommendation is that rebaudiosides M, AM and D produced via enzyme modification of steviol glycosides from *Stevia* leaf extracts, as described in this application, are safe and are not liable to have an adverse effect on the target population, environmental safety and human health at the intended concentrations of use.

The FSS/FSA Risk Management recommendations, which includes a link to the safety assessment and details of the proposed terms of use of the food additive, can be found on the consultation page.

**Annex H: RP1140 – Steviol glycosides produced by Yarrowia lipolytica (new production method of an existing authorised food additive)**

**Background**

In accordance with Regulation (EC) No 1331/2008 which establishes a common authorisation procedure for food additives, food enzymes and food flavourings, the application RP1140 for steviol glycosides produced by *Yarrowia lipolytica* as a new production method of an existing authorised food additive, was received from Cargill/Avansya.

This application is to allow a new method for production of steviol glycosides by the fermentation of sugars with genetically modified *Yarrowia lipolytica*. Steviol glycosides from *Yarrowia lipolytica* consist of a mixture predominantly composed of rebaudioside M, with some rebaudioside D, and smaller amounts of rebaudioside A and rebaudioside B. Steviol glycosides produced by *Y. lipolytica* are identical to steviol glycosides extracted from *Stevia* leaves.

Steviol glycosides (from the *Stevia* plant) are non-nutritive sweeteners used in jams, chewing gum, drinks, yogurts and confectionery. It is also available in pure form for use in tea, coffee and baking.

This application is considered to provide technological advantages and benefits to consumers being suitable for individuals with diabetes and those who follow a low-glycaemic diet.

**FSS/FSA Risk Management recommendation**

The FSS/FSA Risk Management recommendation is that steviol glycosides produced by *Y. lipolytica*, are safe and are not liable to have an adverse effect on the target population, environmental safety and human health at the intended concentrations of use.

The FSS/FSA Risk Management recommendations, which includes a link to the safety assessment and details of the proposed terms of use of the food additive, can be found on the consultation page.

**Annex I: RP1737 – Proposed removal of twenty-two flavouring substances from the domestic list**

**Background**

Flavourings are added to food to impart or modify their odour and/or taste.  Generally, a commercial flavouring consists of a variety of flavourings rather than a single substance.

The domestic list of approved flavouring substances is set out in Annex I, Part A, Section 2, Table 1 of Regulation (EC) No 1334/2008 which is applicable in England, Wales and Scotland.  This lists which flavouring substances are approved for use, purity criteria and any restrictions of use. The approvals are not linked to specific companies and are not time-bound.  Currently, there are over 2,000 approved flavouring substances.  There are some substances on the list which have a footnote. This is to indicate that their evaluation was ongoing when the list of approved substances was established in 2012 and has not yet been completed.

In 2020 the International Organisation of the Flavour Industry and European Flavour Associations (IOFI/EFFA) identified twenty-two flavouring substances which they no longer intended to support due to limited use by the flavourings industry. From 26 September 2022, these flavourings were no longer allowed on the EU as set out in [Commission Regulation (EU) 2022/1466](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32022R1466).

This application from the UK Flavour Association (UKFA) is to remove the same twenty-two flavouring substances from the domestic list. The flavourings industry has decided not to continue to support their evaluation and have decided not to provide any additional information required to complete their evaluation. This is because they are not widely used by the UK flavourings industry.

The twenty-two flavouring substances included in the application RP1737 that are proposed to be removed from the domestic list are:

* 1-(4-Methoxyphenyl)pent-1-en-3-one (FL No 07.030)
* Vanillylidene acetone (FL No 07.046)
* 1-(4-Methoxyphenyl)-4-methylpent-1-en-3-one (FL No 07.049)
* 4-(2,3,6-Trimethylphenyl)but-3-en-2-one (FL No 07.206)
* 6-Methyl-3-hepten-2-one (FL No 07.258)
* 5,6-Dihydro-3,6-dimethyl-benzofuran-2(4H)-one (FL No 10.034)
* 5,6,7,7a-Tetrahydro-3,6-dimethylbenzofuran-2(4H)-one (FL No 10.036)
* 3,4-Dimethyl-5-pentylidene-furan-2(5H)-one (FL No 10.042)
* 2,7-Dimethylocta-5(trans),7-dieno-1,4-lactone (FL No 10.043)
* Hex-2-eno-1,4-lactone (FL No 10.046)
* Non-2-eno-1,4-lactone (FL No 10.054)
* 2-Decen-1,4-lactone (FL No 10.060)
* 5-Pentyl-3H-furan-2-one (FL No 10.170)
* Allyl 2-furoate (FL No 13.004)
* 3-(2-furyl)acrylaldehyde (FL No 13.034)
* Furfurylidene-2-butanal (FL No 13.043)
* 4-(2-Furyl)but-3-en-2-one (FL No 13.044)
* 3-(2-Furyl)-2-methylprop-2-enal (FL No 13.046)
* 3-Acetyl-2,5-dimethylfuran (FL No 13.066)
* 2-Butylfuran (FL No 13.103),
* 3-(2-Furyl)-2-phenylprop-2-enal (FL No 13.137)
* 3-(5-Methyl-2-furyl)prop-2-enal (FL No 13.150)

A safety assessment is not required for an application to remove authorised substances.

**FSS/FSA Risk Management recommendation**

Evaluation is still ongoing for these flavourings and cannot be completed as the flavourings industry has decided not to provide any new information. Therefore, they should be removed from the domestic list. Food containing these flavourings which are placed on the market before the coming into force date of the legislation will be allowed to stay on sale until their use-by date or date of minimum durability.  The same applies to food containing these flavourings which are imported for the GB market as long as they were dispatched before the coming into force date of the legislation.

Proposed transitional measures:

1. Foods to which any of the proposed twenty-two flavouring substance removals has been added and which were lawfully placed on the market the entry into force of the proposed removals may continue to be marketed until their date of minimum durability or use-by date.

2. Foods imported into GB to which any of the proposed twenty-two flavouring substance removals has been added may be marketed until their date of minimum durability or use-by date, if the importer of such food can demonstrate that they were dispatched from the third country concerned and were in transit to GB before the entry into force of the proposed removals.

3. The transitional measures provided for in points 1 and 2 shall not apply to preparations, not intended to be consumed as such, to which any of the proposed twenty-two flavouring substances removals has been added.

4. For the purposes of these measures, preparations shall be understood as mixtures of one or more flavourings to which other food ingredients such as food additives, enzymes or carriers may be also incorporated to facilitate their storage, sale, standardisation, dilution or dissolution.

The FSS/FSA risk management recommendations can be found on the consultation page.

**Annex J: Proposal to set a limit for ethylene oxide in all food additives**

**Background**

Since 2021 there have been several Rapid Alert System for Food and Feed (RASFF) notifications concerning findings of ethylene oxide, or 2 chloro-ethanol in a variety of foods, and in a number of food additives in particular. This has been either from the presence of ethylene oxide (as a residue or contaminant from manufacturing methods) or the presence of 2-chloro-ethanol as a breakdown product from other sources. These have highlighted issues with locust bean gum (E 410), guar gum (E 412), xanthan gum (E 415) and calcium carbonate (E 170). These cases have instigated a number of recalls and withdrawals in the UK and across the EU.

Ethylene oxide can be harmful and is not approved for use in food. Therefore, when it is detected, FSS/FSA investigate individual incidents and assess the risk on a case-by-case basis. We are proposing to set a limit for this substance across all food additives as a proportionate approach to balance food safety with providing clarity and consistency to industry and enforcers when this substance is identified in food.

FSS/FSA have been engaging with a number of stakeholders in industry effected by these issues. FSS/FSA have advised food business operators (FBOs) to ensure they undertake root-cause analysis to identify the source of any contamination and make every effort to source stocks of products that are free from contamination. Investigations suggest a link to changes in production methods for the food additives. Given the EU’s approach, and the de-facto acceptance of a 0.1 mg/kg action level for ethylene oxide in food additives in many other markets, it has become very difficult to source certain food additives that are totally free of ethylene oxide, which is having a knock-on effect on food supply.

Local authorities (LAs) in Scotland were informed directly by FSS in October 2021, in relation to an increase in incidents involving contaminated xanthan gum (E 415), explaining the risks and a temporary action limit for reported incidents of 0.1 mg/kg. LAs and industry stakeholders in England, Wales and Northern Ireland were also informed by FSA.

FSS/FSA will continue to manage the risks associated with products containing unacceptably high levels of ethylene oxide (above the new action limit). A product withdrawal would be required for any non-compliant product with levels above 0.1 mg/kg. FSS/FSA should be informed if a food additive is contaminated with ethylene oxide above 0.1 mg/kg and/or where any amount of ethylene oxide (including below 0.1 mg/kg) has been detected in infant formulae.

We are proposing to set a limit of 0.1 mg/kg for this substance and its breakdown product 2-chloro-ethanol across all food additives as a proportionate approach to balance food safety with providing clarity and consistency to industry and enforcers when this substance is identified in food. It is the level set for some foods in pesticide legislation and would ensure consistency across all sectors of the food industry, providing enforcement authorities with much needed clarity. It reflects the approach already adopted by the EU.

**Main proposals:**

We propose to set a limit of 0.1 mg/kg for ethylene oxide and its breakdown product 2-chloro-ethanol in all food additives. This would require a change to legislation to set a maximum residue level at what is deemed to be a level that can be consistently quantified. The limit of 0.1 mg/kg has been proposed for incidents and is considered low risk by toxicologists. It is the level set for some foods in pesticide legislation as ethylene oxide is sometimes unavoidably present in food additives as a reside/contaminant due to manufacturing methods. 0.1 mg/kg is considered to pose a low risk to human health and therefore represents the highest tolerable level. It would ensure consistency of approach across all food additives and across all sectors of the food industry, providing enforcement authorities with much needed clarity.

The Annex to EU Regulation No 231/2012 states that ‘ethylene *oxide may not be used for sterilising purposes in food additives’.*

We propose to amend the Annex to [Regulation (EU) No 231/2012](https://www.legislation.gov.uk/eur/2012/231/contents) as regards the presence of ethylene oxide in food additives. This restates that ethylene oxide is not permitted to be used for sterilising food additives and sets a maximum residue level at what is deemed to be a level that can be consistently quantified. This applies to all food additives and replaces a slightly higher level for those particular food additives which utilise ethylene oxide as part of the manufacturing process.

It is proposed that Regulation (EC) No 1333/2008 will be amended to reflect that ethylene oxide (including sum of ethylene oxide and 2-chloro-ethanol expressed as ethylene oxide) cannot be present above 0.1 mg/kg in food additives listed in Annexes II and III to Regulation (EC) No 1333/2008, including mixtures of food additives.

**Detailed proposals**

There have been a number of ongoing incidents related to the presence of ethylene oxide and its breakdown product 2-chloro-ethanol in a wide range of food commodities across the UK and the EU. This resulted in the EU setting an action limit of 0.1 mg/kg for ethylene oxide in all food additives in September 2022.

UK investigations suggest the incidents are due to changes in the manufacturing processes for some food additives that have resulted in unavoidable contamination, not as a result of a deliberate misuse. Therefore, this consultation presents the proposal to set the same limit as the EU of 0.1 mg/kg.

Ethylene oxide is a chemical substance which has multiple uses, including as a sterilising agent and as a raw material in the manufacture of various products. Ethylene oxide, however, is a substance of concern classified as carcinogenic, mutagenic and toxic for reproduction and is subject to specific rules [Regulation (EC) No 1272/2008](https://www.legislation.gov.uk/eur/2008/1272/contents) on its labelling and packaging.

Ethylene oxide and its breakdown product 2-chloro-ethanol have known safety issues. However due to the very low level within food additives which are themselves used in low levels within food products, it is not liable to have any negative effect on human health under the proposed limit. This issue has therefore not been taken through the full GB risk assessment process. This is consistent with the approach adopted by the European Commission (EC), who decided not to request a safety assessment from the European Food Safety Authority (EFSA).

Nevertheless, both FSS/FSA and the EU have conducted rapid risk assessments in relation to various incidents involving additives (xanthan gum, guar gum, locust bean gum and calcium carbonate) where ethylene oxide or its breakdown product 2-chloro-ethanol was detected. The assessment considered the level of consumption of the various products using the additives and rates of inclusion of the additive and conducted exposure assessments. In each case action was taken where the ethylene oxide level was above 0.1 mg/kg in the affected additive. We are therefore proposing to proactively set this as the limit in law going forward.

If the proposal to set a limit of 0.1 mg/kg for ethylene oxide and its breakdown product 2-chloro-ethanol across all food additives were to be authorised, then eight food additives in Regulation (EU) No 231/2012 would also require an update to their specification purity criteria as a consequence. Currently, the following food additives have a limit of 0.2 mg/kg for ethylene oxide within their specifications: E 431 polyoxyethylene (40) stearate, E 432 polyoxyethylene sorbitan monolaurate (polysorbate 20), E 433 polyoxyethylene sorbitan monooleate (polysorbate 80), E 434 polyoxyethylene sorbitan monopalmitate (polysorbate 40), E 435 polyoxyethylene sorbitan monostearate (polysorbate 60), E 436 polyoxyethylene sorbitan tristearate (polysorbate 65), E 1209 polyvinyl alcohol-polyethylene glycol-*graft*-copolymer and E 1521 polyethylene glycol. The general limit of 0.1 mg/kg would apply for these food additives rather than their current level of 0.2 mg/kg.

**Impacts**

FSS/FSA will continue to manage the risks associated with products containing unacceptably high levels of ethylene oxide (above the new action limit). A product withdrawal would be required for any non-compliant product with levels above 0.1 mg/kg. FSS and the FSA should be informed if a food additive is contaminated with ethylene oxide above 0.1 mg/kg and/or where any amount of ethylene oxide (including below 0.1 mg/kg) has been detected in infant formula.

This proposal would provide clarity and consistency to industry, something key stakeholders have been calling for.