Consultation pack on applications for authorisations of four novel foods and three food additives, application for twenty-two food flavouring substances removals and proposal to set a limit for ethylene oxide in all food additives

This consultation seeks stakeholders' views, comments and feedback in relation to regulated product applications and the proposal to set a limit for ethylene oxide in all food additives considered in this document.
PDF
View Consultation pack on eight Regulated Products applications and proposed limits of ethylene oxide as PDF(Open in a new window) (354.01 KB)

This consultation will be of most interest to:

- food businesses wishing to use the food additive in the proposed use categories and food businesses who may have used the twenty-two flavouring substances in their food
- 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

A list of key stakeholders is provided in Annex A.

1.0 Consultation subject and purpose

Regulated products

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

- new authorisations (four novel foods)
- extension of use for an existing authorised food additive (one food additive)
- new production method of existing authorised food additives (two food additives)
- removal of authorisation of existing authorisations (one application for twenty-two flavourings)

The FSA/FSS risk management recommendation, the safety assessments and the views gathered through this consultation will be shared to inform Ministers in England, Scotland, Wales and the Department of Health Permanent Secretary in Northern Ireland.

A decision to authorise the novel foods and food additives and remove the food flavourings will need to be given legal effect by a statutory instrument which will update the relevant statutory lists of authorised products accordingly. 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 identified errors and omissions.

Ethylene oxide

This consultation also provides the opportunity for stakeholders' views to be taken into account, to inform Ministers in England and in Wales (with the Department of Health Permanent Secretary in Northern Ireland kept informed) before they make a decision on the proposal included in this consultation to set a limit for ethylene oxide in all food additives. A parallel consultation is being published by FSS to inform the Minister in Scotland before they make a decision.

2.0 Details of the consultation

Introduction

This consultation is to gather stakeholders' views on:

- four regulated product applications for novel foods
- three regulated product applications for food additives (Extension of use for the approved food additive polyglycerol polyricinoleate E 476 and two applications for new production methods for steviol glycosides)
- the removal of twenty-two flavouring substances from the authorised list
- a proposal to set a limit for ethylene oxide of 0.1mg/kg in all food additives

3.0 Regulated product applications

In order to be placed on the market, applications for the authorisation of regulated products must be submitted in Great Britain (GB), where the decision on authorisation and removal of authorisation, is made by the respective Ministers in England, Scotland and Wales (with the Department of Health Permanent Secretary in Northern Ireland kept informed). This is a function that was previously carried out at European Union (EU) level. Regulated product applications for the GB market, including novel foods and food additives, are now subject to the UK's own risk analysis process.

The FSA and FSS have been working together to ensure that the high standards of food and feed safety and consumer protection in the UK continues. This is in line with FSA/FSS responsibility to provide recommendations to Ministers in respect of matters connected with food safety or other interests of consumers in relation to food (section 6, Food Standards Act 1999 and section 3, Food (Scotland) Act 2015).

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). 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.

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 FSA/FSS safety assessment, including a full review of the dossier and supplementary information provided by the applicant. The views of the Advisory Committee on Novel Foods and Processes (ACNFP) have been taken into account in the FSA/FSS safety assessment 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 FSA/FSS safety assessment for the food additive applications. Following the safety assessments, this consultation seeks to gather stakeholders' views on the proposed novel food and food additive authorisations.

The Food and Feed Safety and Hygiene Provisional Common Framework is a non-statutory arrangement between the UK Government and Devolved Administrations to establish common approaches to policy areas where powers have returned from the EU within areas of devolved competence. This consultation has been developed under the commitments to collaborative four-nation working set out in this Framework. As such, this consultation has been developed through a four-nation approach. Final recommendations will be agreed on a four-nation basis before being presented to Ministers in England, Scotland and Wales, and the Department of Health Permanent Secretary in Northern Ireland.

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

4.0 Ethylene oxide

Ethylene oxide is a residue/contaminant which can be harmful and is not approved for use in food. Therefore, when it is detected, the FSA and FSS investigate individual incidents and assess the risk on a case-by-case basis.

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 a 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.

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. Therefore, this consultation presents the proposal to set the same limit as the EU of 0.1 mg/kg.

5.0 Subject of this consultation

Definition of Terms

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.

Barley Rice Protein (RP19) is also referred to as. ‘Partially hydrolysed protein from spent barley and rice’ in these documents.

6.0 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 legislation gov.uk. References to ‘Retained EU Law’ or ‘REUL’ should now be regarded as references to assimilated law.

7.0 Regulated products

In accordance with assimilated law which establishes a common authorisation procedure for food additives, food enzymes and 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 authorisation of existing authorisations.

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 Regulation2015/2283. The applications for authorisation 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. Assimilated Regulation1333/2008 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”.

Assimilated Regulation 1334/2008 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.”

This consultation concerns four applications for novel foods and three applications for food additives. Details of each application and proposal are given in the annexes and in the FSA/FSS

risk management recommendations document.

Each novel food and food additive authorisation, and the application for the proposed removal of twenty-two flavouring substances, is considered within a separate annex, including the regulated product ID number and title of the application:

- Annex B: RP19 – Barley Rice Protein (new authorisation of a novel food).
- Annex C: RP200 - Cetylated Fatty Acids – (new authorisation of a novel food)
- Annex D: RP549 - lacto-N-fucopentaose I (LNFP-I) and 2'-fucosyllactose (2'-FL) - (new authorisation of a novel food)?
- Annex E: RP1202 - 3-fucosyllactose (3-FL) (from strain of Escherichia coli K-12 DH1) (new authorisation of a novel food)
- Annex F: RP217 polyglycerol polyricinoleate (PGPR, E476) extension of use of an authorised food additive)
- Annex G RP1084 - Rebaudioside M, AM and D produced via enzymatic conversion of highly purified steviol glycosides from stevia leaf extracts(new production method of an existing authorised food additive)
- Annex H RP1140 - Steviol glycosides produced by Yarrowia lipolytica ((new production method of an existing authorised food additive)
- Annex I RP1737 – Proposed removal of twenty-two flavouring substances from the domestic list

8.0 Ethylene oxide

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 (assimilated law) to set a maximum residue level at what is deemed to be a level that can be consistently quantified. The level of 0.1 mg/kg has been proposed for incidents and is considered low risk by toxicologists. It is the limit 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. 0.1mg/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 and reflects the approach already adopted by the EU.

The proposal for setting a limit for ethylene oxide in all food additives is considered in a separate annex:

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

9.0 Impacts

Regulated products

As part of the risk analysis process, the FSA/FSS 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 so 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, 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.

10.0 Ethylene oxide

The FSA/FSS 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. The FSA and FSS 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.

11.0 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.

12.0 Trade Impacts

13.0 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-I) 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.

14.0 Ethylene oxide:

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

15.0 Engagement and Consultation Process

Regulated Products:

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

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

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

16.0 Ethylene oxide:

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 particular in a number of food additives. 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.

The FSA/FSS has been engaging with a number of stakeholders in industry affected by these issues. The FSA/FSS 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 some food additives that have resulted in unavoidable contamination, not as a result of deliberate misuse. Given the EU's approach, and the de-facto acceptance of a 0.1 mg/kg 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 has a knock-on effect on food supply.

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

17.0 Questions asked in this consultation:

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 and, if in favour of authorisation, the terms on which the novel foods is authorised (as outlined in the FSA and 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).

Food additives:

1. Do you have any concerns on the safety of the food additives which have not been considered in the FSA/FSS opinions with respect to the intended consumers?
2. Do you have any comments or concerns on the impacts in consideration of authorising or not authorising these food additives, and if in favour of authorisation, the terms on which these food additives is authorised (as outlined in the FSA and FSS risk management recommendations)?
3. Do you have any comments or concerns on other impacts if authorised? (e.g. political, environmental, societal, technological, legal or economic)
4. Are there any other factors that should be considered by Ministers that have not already been highlighted?
5. 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?
7. 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 to the economy?
8. 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).

Flavouring removals:

1. Do you agree with the FSA and FSS’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? Therefore, the only impact would be on third country imports.
2. Do you believe that transition 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 FSA and FSS’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 any of the twenty-two 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 flavourings association (IOFI) considers there will not be any impacts as they are not widely used across the global market. 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 World Trade Organisation (WTO) notification.
6. Would you be willing to be contacted by FSA 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, and if 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
- E 1521 polyethylene glycol.

Does the reduction in ethylene oxide limit for these 8 food additives raise any comments or concerns?

4. Do you have any comments or concerns on other impacts of this proposal? (e.g. political, environmental, societal, technological, legal or economic)?

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

6. Do you have any other feedback?

18.0 Responses

This consultation will run for 8 weeks. Responses are required by close of Friday 29 March 2024.

19.0 How to respond

Please respond to the consultation via the online survey. If this is not possible, you can email a response to: RPconsultations@food.gov.uk

Please indicate which application(s)/product(s) you are responding about by using the following subject line for your response:

Response to [insert RP number(s) if relevant] and the subject of the consultation [novel foods/ food additives/ flavouring removals/ ethylene oxide limit].

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

Responses from Wales should also be sent using the steps outlined above, as all comments received will be shared with FSA in Wales.

We aim to publish a summary of responses to this consultation within 12 weeks of the consultation closing.

For information on how the FSA handles your personal data, please refer to the Consultation privacy notice.

Responses will be shared with Ministers in England, Scotland, Wales and the Department of Health Permanent Secretary in Northern Ireland.

20.0 Further information

If you require a more accessible format of this document, please send details to the named contact for responses to this consultation and your request will be considered.

This consultation has been prepared in accordance with HM Government consultation principles.

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

Yours,
Regulated Products Approvals Team, Regulated Services

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 food additives, novel foods or flavourings 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 (Evergrain LLC, USA) (new authorisation of a novel food.)

Background

In accordance with assimilated 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.

FSA/FSS Risk Management recommendations

The FSA/FSS 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 FSA/FSS risk management recommendations, which includes a link to the safety assessment and details of the proposed terms of use of the novel foods, can be found on the Food Standards Agency website:

- FSA/FSS risk management recommendation
- FSA/FSS safety assessment: RP19 Barley Rice Protein (novel food)

Annex C: RP200- Cetylated Fatty Acids (Pharmaneutra S.p.a., Italy) (new authorisation of a novel food)

Background

In accordance with assimilated 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 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 showsthat 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.

FSA/FSS Risk Management recommendations

The FSA/FSS 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 FSA/FSS risk management recommendations, which includes a link to the safety assessment and details of the proposed terms of use of the novel foods, can be found on the Food Standards Agency website:

- FSA/FSS risk management recommendation
- Safety assessment: RP200 cetylated fatty acids (novel food)

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 assimilated 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 (the third most represented component in breast milk). 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 for a new authorisation 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 on the same day.

FSA/FSS Risk Management recommendations

The FSA/FSS 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 FSA/FSS risk management recommendations, which includes a link to the safety assessment and details of the proposed terms of use of the novel foods, can be found on the Food Standards Agency website:

- FSA/FSS Risk Management recommendation
- Safety assessment: RP549 lacto-N-fucopentaose I (LNFP-I) and 2'-fucosyllactose (2'-FL) (novel food)

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

Background

In accordance with assimilated 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 following food 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 on the same day.

FSA/FSS 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 FSA/FSS risk management recommendations, which includes a link to the safety assessment and details of the proposed terms of use of the novel foods, can be found on the Food Standards Agency website:

- FSA/FSS Risk Management recommendations
- Safety assessment: RP1202 3-fucosyllactose (3-FL) (novel food)

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

Background

In accordance with assimilated Regulation 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 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.

FSA/FSS Risk Management recommendation

The FSA/FSS 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 FSA/FSS 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 Food Standards Agency website:

- FSA/FSS Risk Management recommendation
- Safety assessment: RP217 Extension of use of Polyglycerol Polyricinoleate (E 476) (food additive)

Annex G RP1084 - Rebaudioside M, AM and D produced via enzymatic conversion of highly purified steviol glycosides from stevia leaf extracts

Background

In accordance with assimilated Regulation1331/2008 which establishes a common authorisation procedure for food additives, food enzymes and 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 authorised 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, yoghurts 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.

FSA/FSS Risk Management recommendation

The FSA/FSS 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 FSA/FSS 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 Food Standards Agency website:

- FSA/FSS Risk Management recommendation
- Safety assessment: RP1084 Steviol Glycosides (E 960) from Stevia Leaf Extract (food additive)

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

Background

In accordance with assimilated Regulation 1331/2008 which establishes a common authorisation procedure for food additives, food enzymes and 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, yoghurts, 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.

FSA/FSS Risk Management recommendation

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

The FSA/FSS 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

Food Standards Agency website:

- FSA/FSS Risk Management recommendation
- Safety assessment: RP1140 Steviol Glycosides (E 960) produced by Yarrowia lipolytica (food additive)

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 assimilated Regulation 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 support due to limited use by the flavourings industry. From 26 September 2022, these flavourings were not allowed on the EU as set out in Commission Regulation (EU) 2022/1466.

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.

FSA/FSS Risk Management recommendation

The evaluation is still ongoing for these flavourings and cannot be completed as the flavourings industry has decided not to provide any new information as they have withdrawn their applications for these substances. 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:

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.

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.

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.

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 FSA/FSS risk management recommendations can be found on the Food Standards Agency website:

- FSA/FSS Risk Management recommendation

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

Background

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 a 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 can be harmful and is not approved for use in food. When it is detected, the FSA and FSS 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.

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 limit 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 and reflects the approach already adopted by the EU.

The Annex to assimilated 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 assimilated Regulation No 231/2012 as regards to 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 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 assimilated Regulation No 1333/2008 will be amended to reflect that ethylene oxide (including the 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 assimilated Regulation 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 a limit of 0.1 mg/kg for ethylene oxide in all food additives in September 2022.

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 is classified a hazardous substance as it is carcinogenic, mutagenic and toxic for reproduction and is therefore subject to specific rules in assimilated Regulation No 1272/2008 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 then used in low levels within food products, it is not liable to have any negative effect on human health at levels 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, the FSA, FSS 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 forwards.

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 assimilated Regulation 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

The FSA/FSS will continue to manage the risks associated with products containing unacceptably high levels of ethylene oxide (above the new limit). A product withdrawal would be required for any non-compliant product with levels above 0.1 mg/kg. The FSA and FSS 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 remove divergence with the EU and also provides clarity and consistency to industry, something key stakeholders have been calling for. Furthermore, a consistent approach would aid the food industry selling the same products to GB and EU markets.