# FSA/FSS Risk Management recommendations on applications for four novel foods and three food additives, and an application for the removal of authorisation of twenty-two food flavouring substances from the domestic list

## Summary

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### 1.0 Document subject and purpose

In this document, we publish the Food Standards Agency (FSA)/ Food Standards Scotland (FSS) Risk Management recommendations on applications for four novel foods and three food additives, and an application for the removal of twenty-two food flavouring substances from the approved list. These Risk Management recommendations take into account the safety assessments (which represent the opinion of the FSA and FSS for each application) as well as potential impacts that would result from the authorisation of these novel foods and food additives and

other legitimate factors that Ministers may want to consider before making a decision regarding these applications.  A safety assessment was not required for flavourings removal but potential impacts and other legitimate factors have been considered in developing the recommendations. The final FSA/FSS proposed Risk Management recommendations that are made to Ministers in England, Scotland and Wales, (with the Department of Health Permanent Secretary in Northern Ireland kept informed) will also consider stakeholders' views received from this consultation.

## 2.0 Our safety assessment process

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.

Applications in this consultation have undergone a FSA/FSS safety assessment, including review of the applicants' dossiers. 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. The Committee on Toxicity (COT) also reviewed the AEJEG Committee Advice documents for the food additive applications, agreeing with the conclusions of the AEJEG. The views of the Committees are reflected in the published Safety Assessments which form the opinions of the FSA and FSS on these applications. A safety assessment is not required for an application to remove authorised substances.

The Risk Management recommendations will be considered by Ministers to inform decisions on the authorisation for the novel foods and food additives and the removal of the twenty-two flavouring substances in England, Scotland and Wales. The final FSA/FSS Risk Management Recommendations that are made to Ministers in England and Wales, (with the Department of Health Permanent Secretary in

Northern Ireland kept informed) will also consider stakeholders' views received from this consultation. The Risk Management recommendations are being published in parallel with FSS to inform Ministers' decision in Scotland.

The FSA/FSS Risk Management recommendation for each application is published within a separate annex, including the regulated product ID number and title of the application. A link to the individual safety assessments is provided in each annex.

Annex A: RP19 – Barley Rice Protein (new authorisation of a novel food).

Annex B: RP200 - Cetylated Fatty Acids – (new authorisation of a novel food)
Annex C: RP549 - lacto-N-fucopentaose I (LNFP-I) and 2'-fucosyllactose (2'-FL) - (new authorisation of a novel food)
Annex D: RP1202 - 3-fucosyllactose (3-FL) (from strain of Escherichia coli K-12 DH1) (new authorisation of a novel food)
Annex E: RP217 - polyglycerol polyricinoleate (PGPR, E 476) (extension of use of an authorised food additive)
Annex F RP1084 - Rebaudioside M produced via enzyme modification of steviol glycosides from *Stevia* (new production method of an existing authorised food additive)
Annex G RP1140 - Steviol glycosides produced by *Yarrowia lipolytica* (new production method of an existing authorised food additive)
Annex H RP1737 – Proposed removal of twenty-two flavouring substances from the domestic list

FSA/FSS Risk Management recommendations on applications for four novel foods and three food additives, and an application for the removal of twenty-two flavouring substances from the approved list.

## 3.0 Definition of Terms

When referring to infants and young children, infants describes 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.

## Annex A: RP19 – Barley Rice Protein

RP19 – Barley Rice Protein as a novel food new authorisation.

### Background

FSA/FSS has undertaken a safety assessment of application RP19 for the new authorisation of Barley Rice Protein as a novel food for use in a variety of 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 analogues, 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.

### Safety assessment summary

The application was evaluated by our independent Advisory Committee on Novel Foods and Processes (ACNFP). The FSA/FSS safety assessment was published on 14th August 2023. The assessment of Barley Rice Protein shows that the conditions for authorisation in  of assimilated Regulation 2015/2283 are satisfied. Based on the Committee’s conclusions the FSA and FSS concluded that Barley Rice Protein is safe under the proposed conditions of use, based on the composition and the anticipated intake. Consumption of Barley Rice Protein would not be considered nutritionally disadvantageous if used alone or in combination with other plant sources of protein.  It was considered that although this may be nutritionally disadvantageous if used alone in meal replacement products, as the sole substitute for meat or dairy there were no safety concerns.

### Any relevant provisions of assimilated law

The FSA/FSS has not identified any relevant provisions of assimilated law that would impact authorisation for this product.

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 [for example 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.

## FSA/FSS Risk Management recommendation

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.

## Proposed terms of authorisation

The proposed terms of authorisation are set out below:

## Specification

| General Description | |
|---|---|
| Barley Rice Protein is an off-white powder, produced by concentration of proteins from a mixture of barley and rice from the mash step of beer production using a series of enzymatic hydrolysis and mechanical purification steps. | |
| Specification Parameter | Specification Limit |
| Chemical Parameters | |
| Protein (dry basis) | ≥85% |
| Moisture | <8% |
| Total Carbohydrates | <10% |
| Fat | <2% |
| Ash | <8% |
| Heavy Metals | |

| | |
|---|---|
| Arsenic | <0.1 mg/kg |
| Cadmium | <0.1 mg/kg |
| Lead | <0.2 mg/kg[a] |
| Mercury | <0.1 mg/kg |
| Microbiological Parameters | |
| Aerobic plate count | <30,000 CFU/g |
| Coliforms | <10 CFU/g |
| Yeast and Mould | <50 CFU/g |
| Salmonella | Negative in 25 g |
| Escherichia coli | <10 CFU/g |
| Staphylococcus aureus | <10 CFU/g |
| Listeria spp. | Negative in 25 g |

CFU: Colony Forming Units

[a] The specification limit for lead was established at <0.2 mg/kg to be consistent with the lead limit for cereals and pulses established under the assimilated *Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs.*

## Proposed uses

| Food Category | Maximum Barley Rice Protein levels |
|---|---|
| Bread and similar products | 15 g/100g |
| Fine bakery wares | 15 g/100g |
| Breakfast cereals | 30 g/100g |
| Margarines and similar | 10 g/100g |
| Butter and margarine/oil blends | 10 g/100g |
| Pastas and rice (or other cereal)-based dishes | 30 g/100g |
| Fried or extruded cereal, seed, or root-based products | 30 g/100g |
| Fruit / vegetables spreads and similar | 30 g/100g |
| Confectionery including chocolate | 15 g/100g |

| Food Category | Maximum Barley Rice Protein levels |
|---|---|
| Dairy imitates | 50 g/100 ml(beverages) and 50g/100g (products other than beverages) |
| Milk and dairy products | 50 g/100 ml(beverages) and 50g/100g (products other than beverages) |
| Dessert sauces/toppings | 15 g/100g |
| Syrups (molasses and other syrups) | 15 g/100g |
| Meat analogues | 30 g/100g |
| Soups (marketed as such or reconstituted as instructed by the manufacturer) | 15 g/100g |
| Stock cubes or granules (bouillon base) | 15 g/100g |
| Gravy ingredients | 10 g/100g |
| Savoury sauces | 10 g/100g |
| Condiments (including table-top formats) | 10 g/100g |
| Hummus | 30 g/100g |
| Nut/seeds paste/emulsion/mass | 20 g/100g |
| Energy drinks | 90 g/100ml |
| Carbohydrate-rich energy food products for sports people | 30 g/100g |
| Protein and protein components for sports people | 90 g/100g |
| Meal replacement for weight control | 90 g/100g |

## Labelling

The proposed labelling designation on the labelling of foodstuffs containing barley rice protein shall be ‘partially hydrolysed protein from spent barley and rice’.

The novel food is an allergen and will therefore be labelled in accordance with the UK labelling requirements for allergens and there is therefore no need for any additional labelling requirement to protect those with Coeliac disease or allergy to barley.

## Other legitimate factors

In developing the Risk Management recommendations, the FSA/FSS has had regard to the other legitimate factors (including consumer interests, political, environmental, societal and technical feasibility) that Ministers will consider as part of their decision on authorisation.
The FSA/FSS have not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this novel food. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant Other Legitimate Factors as part of the consultation process.

## Impacts

As part of the risk analysis process, FSA/FSS have assessed the potential impacts that would result from the authorisation of this novel food, should Ministers decide to authorise. No significant impacts were identified. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

Under the Windsor Framework, Barley Rice Protein approved in GB will be able to be placed on the market in Northern Ireland, if it is eligible for, and moved through NIRMS.

## Annex B: RP200 – Cetylated fatty acids

RP200 – Cetylated fatty acids as a novel food new authorisation.

## Background

FSA/FSS has undertaken a safety assessment of application RP200 for the new authorisation of cetylated fatty acids as a novel food for use within the food category: food supplements for people over the age of 18 as per the application.

## Safety assessment summary

The application was evaluated by our independent Advisory Committee on Novel Foods and Processes (ACNFP). The FSA/FSS safety assessment was published on 14th August 2023. The assessment of cetylated fatty acids shows that the conditions for authorisation in Article 7 of Assimilated Regulation 2015/2283 are satisfied. Based on the Committee's conclusions the FSA and FSS concluded that cetylated fatty acids are safe under the proposed conditions of use, based on the composition and the anticipated intake. The anticipated intake levels and the proposed use in food supplements was not considered to be nutritionally disadvantageous.

## Any relevant provisions of assimilated law

The FSA/FSS has not identified any relevant provisions of assimilated law that would impact authorisation for this product.

## FSA/FSS Risk Management recommendation

The FSA/FSS Risk Management recommendation is that cetylated fatty acids, as described in this application, are 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.

## Proposed terms of authorisation

The proposed terms of authorisation are set out below:

## Specification

| Description |
| --- |

| The novel food is a mixture of 70 – 80% cetylated fatty acids which are produced from the reaction of cetyl alcohol with myristic acid and oleic acid. | |
|---|---|
| Characteristics / Composition | - |
| Parameter | Specification |
| Physical status at 25°C | Solid |
| Colour (APHA Colour) | ≤ 600 |
| Acid value (mg KOH/g) | ≤ 5 |
| Iodine value ($I_2$g/100g) | 30 – 50 |
| Saponification value (mg KOH/g) | 130 – 150 |
| Hydroxyl value (mg KOH/g) | ≤ 20 |
| Ester content (%) | 70 – 80 |
| Cetyl oleate (%) | 22 – 30 |
| Cetyl myristate (%) | 41 – 56 |
| Microbiological criteria | - |
| Total aerobic microbial count (CFU/g) | ≤ 1,000 |
| Yeasts and moulds (CFU/g) | ≤ 100 |

CFU: Colony Forming Units

KOH = potassium hydroxide

APHA = American Public Health Association

## Proposed uses

| **Food category** | **Maximum level** |
|---|---|
| Food supplements (as defined in the Food Supplements (England) Regulations 2003 and Food Supplements (Wales) Regulations 2003 for the adult population | 2.1g/day |

## Labelling

The proposed labelling designation on the labelling of foodstuffs containing cetylated fatty acids is ‘cetylated fatty acids preparations’.

## Additional labelling requirements

The labelling of food supplements containing cetylated fatty acids shall bear a statement that:

- those food supplements should not be consumed by persons under 18 years of age.

## Other relevant information (separate to terms of authorisation)

## Other legitimate factors

In developing the Risk Management recommendations, the FSA/FSS has had regard to the other legitimate factors (including consumer interests, political, environmental, societal and technical feasibility) that Ministers will consider as part of their decision on authorisation.

The FSA/FSS have not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this novel food. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant Other Legitimate Factors as part of the consultation process.

## Impacts

As part of the risk analysis process, FSA/FSS have assessed the potential impacts that would result from the authorisation of this novel food, should Ministers decide to authorise. No significant impacts were identified. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

Under the Windsor Framework, cetylated fatty acids approved in GB will be able to be placed on the market in Northern Ireland, if it is eligible for, and moved through NIRMS.

## Annex C: RP549 – lacto-*N*-fucopentaose I (LNFP-l) and 2'-fucosyllactose (2'-FL) – (new authorisation)

RP549 – lacto-*N*-fucopentaose I (LNFP-l) and 2'-fucosyllactose (2'-FL) as a novel food new authorisation.

### Background

FSA/FSS has undertaken a safety assessment of application RP549 for the new authorisation of lacto-*N*-fucopentaose I (LNFP-l) and 2'-fucosyllactose (2'-FL) as a novel food for use in dairy products and analogues, bakery wares, beverages, foods for infants (under 12 months) and young children (children aged 1 year to 3 years), foods for special medical purposes, total diet replacement for weight control, and food supplements. 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. 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.

### Safety assessment summary

The application was evaluated by our independent Advisory Committee on Novel Foods and Processes (ACNFP). The FSA/FSS safety assessment was published on 14th August 2023. The assessment of lacto-*N*-fucopentaose I (LNFP-l) and 2'-fucosyllactose (2'-FL) shows that the conditions for authorisation in Article 7 of assimilated Regulation 2015/2283 are satisfied. Based on the Committee's conclusions the FSA and FSS concluded that lacto-*N*-fucopentaose I (LNFP-l) and 2'-fucosyllactose (2'-FL) is safe under the proposed conditions of use, based on the composition and the anticipated intake. The anticipated intake levels and the proposed use in foods and food supplements was not considered to be nutritionally disadvantageous.

### Any relevant provisions of assimilated law

The FSA/FSS has not identified any relevant provisions of assimilated law that would impact authorisation for this product.

## FSA/FSS Risk Management recommendation

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.

## Proposed terms of authorisation

The proposed terms of authorisation are set out below:

## Specification

| | |
|---|---|
| Description / Definition | LNFP-I /2′-FL mixture is a purified carbohydrate powder or agglomerate obtained from microbial fermentation with a genetically modified strain of *Escherichia coli* K-12 DH1 containing at least 75% of lacto-*N*-fucopentaose I and 2'-fucosyllactose of dry matter, where ≥ 50% is LNFP-l (dry weight) and ≥ 15% is 2'-FL (dry weight). |

| **Characteristics / Composition** | **Specification** |
|---|---|
| Appearance | Powder, agglomerates, powder with agglomerates |
| Colour | White, white to off-white, off-white |
| Assay (water-free)<br>Specified saccharides [a] | ≥ 90.0 w/w % |
| Assay (water-free) – LNFP-I and 2'-FL | ≥75.0 w/w % |
| Assay (water-free) – LNFP-I | ≥ 50.0 w/w % |
| Assay (water-free) – 2'-FL | ≥ 15.0 w/w % |
| Lacto-*N*-tetraose | ≤ 5.0 w/w % |
| 3-fucosyllactose | ≤ 1.0 w/w % |
| Sum of L-Fucose and 2'-fucosyl-lactitol | ≤ 1.0 w/w % |
| D-Lactose | ≤ 10.0 w/w % |

| | |
|---|---|
| Difucosyl-D-lactose | ≤ 2.0 w/w % |
| LNFP-I fructose isomer | ≤ 1.5 w/w % |
| 2'-Fucosyl-D-lactulose | ≤ 1.0 w/w % |
| Sum of other carbohydrates | ≤ 6.0 w/w % |
| pH in 5% solution (20°C) | 4.0–7.0 |
| Water | ≤ 8.0 w/w % |
| Ash, sulphated | ≤ 0.5 w/w % |
| Residual protein by Bradford assay | ≤ 0.01 w/w % |
| Mycotoxins | - |
| Residual endotoxins | ≤ 10 EU/mg |
| Aflatoxin M1 | ≤ 0.025 µg/kg |
| Heavy metals | - |
| Arsenic | ≤0.2 mg/kg |
| Microbiological criteria | - |
| Aerobic mesophilic total plate count | ≤ 1,000 CFU/g |
| Enterobacteriaceae | Absent in 10g |
| *Salmonella* | Absent in 25 g |
| Yeasts | ≤ 100 CFU/g |
| Moulds | ≤ 100 CFU/g |
| *Bacillus cereus* | ≤ 50 cfu/g |
| *Listeria monocytogenes* | Absent in 25g |
| *Cronobacter spp.* | Absent in 10g |

EU: Endotoxin Unit

CFU: Colony Forming Unit

[a] a Sum of specified saccharides includes LNFP-l, 2'-fucosyllactose, lacto-N-tetraose, difucosyl-D-lactose, 3-fucosyllactose, D-lactose, L-fucose and 2’-fucosyl-lactitol, LNFP-I fructose isomer and 2'-fucosyl-D-lactulose.

## Proposed uses

| Food Category Name | Maximum Use Level (expressed as LNFP-I) |
|---|---|
| Unflavoured pasteurised and unflavoured sterilised (including UHT) milk | 1.0 g/L |
| Unflavoured fermented milk-based products | 1.0 g/L (beverages)<br>2.0 g/kg (products other than beverages) |
| Flavoured fermented milk-based products including heat-treated products | 1.0 g/L (beverages)<br>10.0 g/kg (products other than beverages) |
| Cereal bars | 10.0 g/kg |
| Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013 | 1.5 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer |
| Processed cereal-based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013 | 1.0 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer<br>8.33 g/kg (products other than beverages) |
| Milk-based drinks and similar products intended for young children | 1.2 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer<br>10.0 g/kg (products other than beverages) |
| Foods for special medical purposes defined in Regulation (EU) No 609/2013 | In accordance with the particular nutritional requirements of the persons for whom the products are intended |

| Food Category Name | Maximum Use Level (expressed as LNFP-I) |
|---|---|
| Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 | 2.0 g/L (beverages)<br>20.0 g/kg (products other than beverages) |
| Flavoured drinks (excluding cola-type drinks) | 1.0 g/L |
| Food supplements as defined in the Food Supplements (England) Regulations 2003 and the Food Supplements (Wales) Regulations 2003, for infants and young children | 1.5 g/day |
| Food supplements as defined in the Food Supplements (England) Regulations 2003 and the Food Supplements (Wales) Regulations 2003, excluding food supplements for infants and young children | 3.0 g/day |

## Labelling

The proposed labelling designation on the labelling of foodstuffs containing it shall be lacto-*N*-fucopentaose I (LNFP-l) and 2'-fucosyllactose (2'-FL) mixture.

## Additional labelling requirements

The labelling of food supplements containing lacto-*N*-fucopentaose I (LNFP-l) and 2'-fucosyllactose (2'-FL) mixture shall bear a statement that the supplements should not be used if other foods with added lacto-*N*-fucopentaose I (LNFP-l) and/or 2'-fucosyllactose (2'-FL) are consumed on the same day.

The labelling of food supplements containing lacto-*N*-fucopentaose I (LNFP-l) and 2'-fucosyllactose (2'-FL) mixture intended for infants under 12 months or young children aged 1 year to 3 years shall bear a statement that the supplements should not be used if breast milk or other foods with added lacto-*N*-fucopentaose I (LNFP-l) and/or 2'-fucosyllactose (2'-FL) are consumed on the same day.

## Other relevant information (separate to terms of authorisation)

## Supplementary information:

- Consumption of lacto-*N*-fucopentaose I (LNFP-l) and 2'-fucosyllactose (2'-FL) mixture at the proposed use levels is not expected to be nutritionally disadvantageous for consumers.
- The production process uses a GM production microorganism as a processing aid (although this novel food is not considered as a genetically modified product as no GM material is present in the end product).

## Other legitimate factors

In developing the Risk Management recommendations, the FSA/FSS has had regard to the other legitimate factors (including consumer interests, political, environmental, societal and technical feasibility) that Ministers will consider as part of their decision on authorisation.

The FSA/FSS have not identified any applicable other legitimate factors to date that would prevent the authorisation of this novel food. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant Other Legitimate Factors as part of the consultation process.

## Impacts

As part of the risk analysis process, FSA/FSS have assessed the potential impacts that would result from the authorisation of this novel food, should Ministers decide to authorise. No significant impacts were identified. The impacts

considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

Under the Windsor Framework, lacto-N-fucopentaose I (LNFP-l) and 2'-fucosyllactose (2'-FL) approved in GB will be able to be placed on the market in Northern Ireland, if it is eligible for, and moved through NIRMS.

## Annex D: RP1202 - 3-fucosyllactose (3-FL) (from strain of *Escherichia coli* K-12 DH1) (new authorisation)

RP1202 - 3-fucosyllactose (3-FL) (from strain of *Escherichia coli* K-12 DH1). as a novel food new authorisation.

### Background

FSA/FSS has undertaken a safety assessment of application RP1202 for the new authorisation of 3-fucosyllactose (3-FL) (from strain of *Escherichia coli* K-12 DH1) as a novel food for use in dairy products and analogues, bakery wares, foods for special groups, beverages, and as a food supplement. Food supplements should not be used if breast milk or other foods with added lacto-*N*-fucopentaose I (LNFP-l) and/or 2'-fucosyllactose (2'-FL) are consumed on the same day.

### Safety assessment summary

The application was evaluated by our independent Advisory Committee on Novel Foods and Processes (ACNFP). The FSA/FSS safety assessment was published on 14th August 2023. The assessment of 3-fucosyllactose (3-FL) (from strain of *Escherichia coli* K-12 DH1)shows that the conditions for authorisation in Article 7 of assimilated Regulation 2015/2283 are satisfied. Based on the Committee's conclusions the FSA and FSS concluded that 3-fucosyllactose (3-FL) (from strain of *Escherichia coli* K-12 DH1) is safe under the proposed conditions of use, based on the composition and the anticipated intake. The anticipated intake levels and

the proposed use in foods and food supplements was not considered to be nutritionally disadvantageous and does not mislead consumers.

## Any relevant provisions of assimilated law

The FSA/FSS has not identified any relevant provisions of assimilated law that would impact authorisation for this product.

## FSA/FSS Risk Management recommendation

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.

## Proposed terms of authorisation

The proposed terms of authorisation are set out below:

## Specification

| | |
|---|---|
| Description / Definition | 3-fucosyllactose (3-FL) (from strain of *Escherichia coli* K-12 DH1) is a purified carbohydrate powder or agglomerate containing at least 90% of 3-fucosyllactose of dry matter obtained from microbial fermentation with a genetically modified strain of *Escherichia coli* K-12 DH1. |

| **Characteristics / Composition** | **Specification** |
|---|---|
| Appearance | Powder, agglomerates, powder with agglomerates |
| Colour | White, white to off-white, off-white |
| Assay (water-free) – Specified saccharides [a] | ≥ 92.0 w/w % |
| Assay (water-free) – 3-FL | ≥ 90.0 w/w % |
| L-Fucose | ≤ 1.0 w/w % |
| D-Lactose | ≤ 5.0 w/w % |
| 3-fucosyllactulose | ≤ 1.5 w/w % |
| Sum of other carbohydrates | ≤ 5.0 w/w % |
| pH in 5% solution (20°C) | 3.2–7.0 |
| Water | ≤ 6.0 w/w % |
| Ash, sulphated | ≤ 0.5 w/w % |
| Acetic acid [b] | ≤ 1.0 w/w % |
| Residual protein by Bradford assay | ≤ 0.01 w/w % |
| Residual endotoxins | ≤ 10 EU/mg |
| Heavy metals | - |
| Lead | ≤ 0.1 mg/kg |
| Arsenic | ≤ 0.2 mg/kg |
| Mycotoxins | - |
| Aflatoxin M1 | ≤0.025 µg/kg |
| Microbiological criteria | - |
| Aerobic mesophilic total plate count | ≤ 1,000 CFU/g |
| Enterobacteriaceae | Absent in 10g |
| *Salmonella* | Absent in 25 g |
| *Bacillus cereus* | ≤ 50 CFU/g |
| *Listeria monocytogenes* | absent in 25g |

| | |
|---|---|
| *Cronobacter spp.* | absent in 10g |
| Yeasts | ≤ 100 CFU/g |
| Moulds | ≤ 100 CFU/g |

CFU: Colony Forming Units

EU: Endotoxin Units

[a] Specified saccharides include 3-fucosyllactose, D-lactose, L-fucose and 3-fucosyl-lactulose.

[b] Relevant only for crystallised 3-FL

## Proposed uses

| **Food Category Name** | **Proposed Maximum Use Level** |
|---|---|
| Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products | 2.0 g/L |
| Unflavoured fermented milk-based products | 2.0 g/L (beverages)<br>4.0 g/kg (products other than beverages) |
| Flavoured fermented milk-based products including heat-treated products | 2.0 g/L (beverages)<br>12.0 g/kg (products other than beverages) |
| Cereal bars | 25.0 g/kg |
| Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013 | 2.0 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer |
| Milk-based drinks and similar products intended for young children | 2.0 g/L (beverages) in the final product ready for use, marketed as such or reconstituted |

| Food Category Name | Proposed Maximum Use Level |
|---|---|
| | as instructed by the manufacturer<br>12 g/kg (products other than beverages) |
| Foods for special medical purposes as defined in Regulation (EU) No 609/2013 | In accordance with the particular nutritional requirements of the persons for whom the products are intended |
| Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 | 2.0 g/L (beverages)<br>25.0 g/kg (products other than beverages) |
| Flavoured drinks (excluding cola-type drinks) | 1.25 g/L |
| Food supplements as defined in the Food Supplements (England) Regulations 2003 and the Food Supplements (Wales) Regulations 2003, for infants and young children | 2 g/day |
| Food supplements as defined in the Food Supplements (England) Regulations 2003 and the Food Supplements (Wales) Regulations 2003 excluding food supplements for infants and young children | 4 g/day |

## Labelling

The proposed labelling designation on the labelling of foodstuffs containing is '3-fucosyllactose (3-FL)

## Additional labelling requirements

For infants under 12 months and young children aged 1 year to 3 years, food supplements are not intended to be used if other foods with added 3-fucosyllactose or breast milk are consumed on the same day.

## Other relevant information (separate to terms of authorisation)

## Supplementary information:

- Consumption of 3-fucosyllactose (3-FL) (from strain of *Escherichia coli* K-12 DH1) at the proposed use levels is not expected to be nutritionally disadvantageous for consumers.
- It was noted that food supplements are not intended to be used if other foods with the novel food are consumed on the same day, therefore, it is proposed that this is stated on the product label to inform consumers.
- The production process uses a GM production microorganism as a processing aid. The novel food is not considered to be a genetically modified food as no GM material is present in the end product.

## Other legitimate factors

In developing the Risk Management recommendations, the FSA/FSS has had regard to the other legitimate factors (including consumer interests, political, environmental, societal and technical feasibility) that Ministers will consider as part of their decision on authorisation.

The FSA/FSS have not identified any applicable other legitimate factors to date that would prevent the authorisation of this novel food. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant Other Legitimate Factors as part of the consultation process.

## Impacts

As part of the risk analysis process, FSA/FSS have assessed the potential impacts that would result from the authorisation of this novel food, should Ministers decide to authorise. No significant impacts were identified. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

Under the Windsor Framework, 3-fucosyllactose (3-FL) (from strain of Escherichia coli K-12 DH1) approved in GB will be able to be placed on the market in Northern Ireland, if it is eligible for, and moved through NIRMS.

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

RP217 - polyglycerol polyricinoleate (PGPR, E 476) is an emulsifier made from polyglycerol and fatty acids. This application is to allow this food additive in ice creams and frozen yogurts and at a higher level in certain types of sauces. Emulsifiers are generally used in foods that contain fats and water and help create a stable emulsion, for example to stop the oil and water separating. They are used in foods such as mayonnaise and sauces.

## Background

FSA/FSS has undertaken a safety assessment of application RP217 for the extension of use of the authorised additive polyglycerol polyricinoleate (PGPR, E 476) to allow use in edible ices and at a higher level than currently permitted in sauces. 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 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
- 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 level 4000mg/kg)

## Safety assessment summary

The application was evaluated by our independent Joint Expert Group on Additives, Enzymes and other Regulated Products (AEJEG). The Committee on Toxicity (COT) also reviewed the AEJEG assessment agreeing with the conclusions of the AEJEG. The FSA/FSS safety assessment was published on 29th September 2023.

Based on the AEJEG's conclusions the FSA and FSS concluded that the proposed uses and use levels are safe at the anticipated levels of intake, with the provision that the presence of impurities discussed in the safety assessment are monitored both through raw material specifications and during manufacturing.

Changes to the specifications of E 476 and related food additives (E 422 glycerol and E 475 polyglycerol esters of fatty acids) will be considered separately to this application.

## Any relevant provisions of assimilated law

The FSA/FSS has not identified any relevant provisions of assimilated law that would impact authorisation for this product.

## 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.

## Proposed terms of authorisation

The proposed terms of authorisation are set out below:

## Proposed extension of use

The proposed changes to the food additives legislation assimilated Regulation (EC) No 1333/2008 would be to allow:

(1) E 476 in food category 03 (Edible ices) at 4000 mg/kg. As this emulsifier is only needed in specific types of ice-cream and frozen yoghurt, the applicant suggested the restriction of use be "'only fat and oil emulsion of water-in-oil type". The proposed wording was considered not clear enough and could potentially lead to misunderstandings as regards to what products E 476 is authorised for, thus causing difficulties for food business operators and enforcement authorities. The terminology "except sorbets" was deemed as fulfilling the appropriate usages, covering the products in which the direct addition of E 476 to edible ices would perform a technological function, since sorbets do not contain fat for emulsification. Therefore, the applicant agreed the wording "except sorbets" would be clearer and easier to understand by stakeholders and cover the range of products in scope. The EU legislation permitting this extension of use also uses the same wording for this restriction, "except sorbets":
(2) In food category 12.6 (Sauces), a higher level of E476 may be needed to emulsify foods with a higher fat content and therefore, up to 8000mg/kg of E476 should be authorised in emulsified 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.

## Labelling

There will be no change to the current labelling designation.

## Additional labelling requirements

No additional labelling requirements are needed.

## Other legitimate factors

In developing the Risk Management recommendations, the FSA/FSS has had regard to the other legitimate factors (including consumer interests, political, environmental, societal and technical feasibility) that Ministers will consider as part of their decision on authorisation.

The FSA/FSS have not identified any applicable other legitimate factors to date that would prevent the authorisation of this food additive. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant Other Legitimate Factors as part of the consultation process.

## Impacts

As part of the risk analysis process, FSA/FSS have assessed the potential impacts that would result from the extension of use of this food additive, should Ministers decide to authorise. No significant impacts were identified. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of this product should generally result in greater market competition, supporting growth and innovation in the sector. 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.

The same extension of use of polyglycerol polyricinoleate (PGPR, E 476) has already been authorised for Northern Ireland.

## Annex F 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)

RP1084 –Rebaudioside M, AM and D produced via enzymatic conversion of highly purified steviol glycosides from *Stevia* leaf extracts for a new production method of an existing authorised food additive.

### Background

FSA/FSS has undertaken a safety assessment of application RP1084 for a new enzymatic manufacturing method to produce high purity steviol glycosides, mainly rebaudioside AM, M and D. This food additive is a permitted low-calorie, high intensity sweetener. If the new manufacturing method is approved, a new specification for the production method will be included in assimilated Regulation No 231/2012; an amendment to assimilated Regulation No 1333/2008 will not be required as the conditions of use for E 960c are already set out in this legislation as we previously approved E 960c made using a different production method and no changes were requested for the conditions of use.

### Safety assessment summary

The application was evaluated by our independent Joint Expert Group on Additives, Enzymes and other Regulated Products (AEJEG). The Committee on Toxicity (COT) also reviewed the AEJEG assessment agreeing with the conclusions of the AEJEG. The FSA/FSS safety assessment was published on 29th September 2023 and can be found . Based on the AEJEG's assessment, the FSA and FSS concluded that steviol glycosides produced by the proposed production method are safe under the proposed conditions of use and at the anticipated levels of intake.

## Any relevant provisions of assimilated law

The FSA/FSS has not identified any relevant provisions of assimilated law that would impact authorisation for this product.

## 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.

## Proposed terms of authorisation

The proposed terms of authorisation are set out below:

## Specification

In order to allow steviol glycoside made from the new production method to be used in foods, a new specification will need to be added within assimilated Commission Regulation (EU) No 231/2012 to include the new method. If authorised, the specifications for E 960c will need to be subcategorised for each production method used to produce enzymatically produced steviol glycosides: E 960c(i) for the existing method and E 960c(ii) for the new method.

The new specification is set out below.

## Amendment to Current Authorised Food Additive Speculation:

An application for E 960c rebaudioside M produced via enzyme modification of steviol glycosides from *Stevia* was approved in March 2023. The E number remains E 960c for all other purposes but, for the purpose of the specifications only, it will be subcategorised into E 960c(i) the existing method and E 960c(ii) the new method.

## New specification:

E 960c(ii) REBAUDIOSIDE M, AM and D PRODUCED VIA ENZYMATIC CONVERSION OF HIGHLY PURIFIED STEVIOL GLYCOSIDES FROM STEVIA LEAF EXTRACTS

Synonyms -

Definition Steviol glycosides produced via enzymatic conversion of highly purified steviol glycosides (rebaudioside A or stevioside) stevia leaf extracts are composed predominantly of rebaudioside M, rebaudioside D, and rebaudioside AM.

Rebaudiosides D, M and AM are produced via enzymatic conversion of highly purified steviol glycoside (rebaudioside A or stevioside) extracts (95% steviol glycosides) obtained from Stevia rebaudiana Bertoni plant using UDP-glucosyltransferase and sucrose synthase enzymes produced by genetically modified strains of Escherichia coli (pPM294, pFAH170, and pSK041) that facilitate the transfer of glucose from sucrose and UDP-glucose to steviol glycosides via glycosidic bonds. After removal of the enzymes by solid-liquid separation and heat treatment, the purification involves concentration of the steviol glycosides by resin adsorption, followed by recrystallisation of the steviol glycosides resulting in a final product containing not less than 95 % of total steviol glycosides, including one or more of rebaudiosides D, M and AM. Viable cells of E. coli (pPM294, pFAH170, and pSK041) and their DNA shall not be detected in the food additive.

Chemical name Rebaudioside M: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl ester

Rebaudioside D: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl-β-D-glucopyranosyl ester

Rebaudioside AM: 13-[(2-O-β-D-glucopyranosyl-β-Dglucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl ester

| | | | |
|---|---|---|---|
| Molecular formula | Trivial name | Formula | Conversion factor |
| | Rebaudioside M | $C_{56}H_{90}O_{33}$ | 0.25 |
| | Rebaudioside D | $C_{50}H_{80}O_{28}$ | 0.29 |
| | Rebaudioside AM | $C_{50}H_{80}O_{28}$ | 0.29 |
| Molecular weight and CAS No | Trivial name | CAS Number | Molecular weight (g/mol) |
| | | | |
| | Rebaudioside M | 1220616-44-3 | 1,291.30 |
| | Rebaudioside D | 63279-13-0 | 1,129.15 |
| | Rebaudioside AM | 2222580-26-7 | 1,129.15 |
| Assay | Not less than 95 % of steviol glycosides on the dried basis, including one or more of rebaudiosides D, M and AM. | | |
| **Description** | White to light yellow powder, approximately between 200 and 350 times sweeter than sucrose (at 5 % sucrose equivalency). | | |
| **Identification** | | | |
| Solubility | Freely soluble to slightly soluble in water | | |
| pH | Between 4.5 and 7.0 (1 in 100 solution) | | |
| **Purity** | | | |
| Total ash | Not more than 1 % | | |
| Loss on drying | Not more than 6 % (105 °C, 2h) | | |
| Residual solvent | Not more than 5,000 mg/kg ethanol | | |
| Arsenic | Not more than 0.015 mg/kg | | |
| Lead | Not more than 0.2 mg/kg | | |
| Cadmium | Not more than 0.015 mg/kg | | |

| | |
|---|---|
| Mercury | Not more than 0.07 mg/kg |
| Residual protein | Not more than 5 mg/kg |

## Amendment to Current Authorised Food Additive Specification

In the current specification for E 960c any reference to E 960c will be replaced with E 960c(i).

## Proposed uses

The proposed uses and use levels for Rebaudioside AM,D and M,produced via enzymatic conversion of purified Stevia Leaf Extract remain the same as the already authorised food additive Steviol Glycosides (E 960a and E 960c).

## Labelling

There is no need to state (i) or (ii) in ingredients lists, however if used as an ingredient in a product it must be labelled with the technological function and then either the E number or name ie: --either Sweetener E 960c or Sweetener Enzymatically produced steviol glycosides.

## Additional labelling requirements

No additional labelling requirements have been identified.

## Other relevant information (separate to terms of authorisation)

## Supplementary information:

An application for E 960c rebaudioside M produced via enzyme modification of steviol glycosides from *Stevia* was approved in March 2023. If RP1084 is authorised, the specifications for E 960c will need to be subcategorised for each production method used to produce enzymatically produced steviol glycosides: E 960c(i) for the existing method and E 960c(ii) for the new method.

## Other legitimate factors

In developing the Risk Management recommendations, the FSA/FSS have had regard to the other legitimate factors (including consumer interests, political,

environmental, societal and technical feasibility) that Ministers will consider as part of their decision on authorisation.

The FSA and FSS have not identified any applicable other legitimate factors to date that would prevent the authorisation of this new production method. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant Other Legitimate Factors as part of the consultation process.

### Impacts

As part of the risk analysis process, FSA/FSS have assessed the potential impacts that would result from the authorisation of this new production method, should Ministers decide to authorise. No significant impacts were identified. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of this product should generally result in greater market competition, supporting growth and innovation in the sector.

A similar such authorisation is already in place in Northern Ireland.

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

RP1140 - Steviol glycosides produced by *Yarrowia lipolytica* for a new production method of an authorised food additive.

### Background

FSA/FSS has undertaken a safety assessment of application RP1140 for a new production method to produce steviol glycosides using a fermentation process. The application is for a new production method for steviol glycosides (steviol glycosides from fermentation). The proposed new production method would result in a new additive, which would be E number E 960b, steviol glycosides from fermentation. The approved list of food additives in the Annexes to assimilated

Regulation 1333/2008 will need to be amended accordingly. The steviol glycosides are intended for use in the same food categories and at the same use levels currently authorised for E960a and E960c. There are no proposed changes to the conditions of use of steviol glycosides. This food additive is a low-calorie, high intensity sweetener.

## Safety assessment summary

The application was evaluated by our independent Joint Expert Group on Additives, Enzymes and other Regulated Products (AEJEG). The Committee on Toxicity (COT) also reviewed the AEJEG assessment agreeing with the conclusions of the AEJEG. The FSA/FSS safety assessment was published 16th November 2023 and can be found here Based on the AEJEG conclusions, the FSA/ FSS concluded that steviol glycosides manufactured by the proposed production method is safe under the proposed conditions of use and at the anticipated levels of intake

## Any relevant provisions of assimilated law

The FSA/FSS has not identified any relevant provisions of assimilated law that would impact authorisation for this product.

## FSA/FSS Risk Management recommendation

The FSA/FSS Risk Management recommendation is that steviol glycosides produced by *Y. lipolytica*n, 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.

## Specifications

The proposed authorisation would result in a specification for E 960b being added to assimilated Commission Regulation 231/2012, which is detailed below:

E 960b STEVIOL GLYCOSIDES FROM FERMENTATION (YARROWIA LIPOLYTICA)

| | |
|---|---|
| **Synonyms** | - |
| **Definition** | Steviol glycosides from *Yarrowia lipolytica* consist of a mixture predominantly composed of rebaudioside M, with some |

<table>
<tr><td></td><td colspan="3">rebaudioside D, and smaller amounts of rebaudioside A and rebaudioside B. The manufacturing process comprises two main phases. The first phase involves fermentation of a non-toxigenic non-pathogenic strain of Y. lipolytica (VRM) that has been genetically modified with heterologous genes to overexpress steviol glycosides. Removal of biomass by solid-liquid separation and heat treatment is followed by concentration of the steviol glycosides. The second phase involves purification by employing ion-exchange chromatography, followed by recrystallisation of the steviol glycosides resulting in a final product containing not less than 95% of rebaudiosides M, D, A, and B. Viable cells of Y. lipolytica or DNA from the production organism shall not be detected in the food additive.</td></tr>
<tr><td>Chemical name</td><td colspan="3">Rebaudioside A: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester Rebaudioside B: 13-[(2-O-β–D-glucopyranosyl-3-O-β– D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid<br>Rebaudioside D: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl-β-D-glucopyranosyl ester<br>Rebaudioside M: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl ester</td></tr>
<tr><td rowspan="5">Molecular formula</td><td>Trivial name</td><td>Formula</td><td>Conversion factor</td></tr>
<tr><td>Rebaudioside A</td><td>$C_{44}$ $H_{70}$ $O_{23}$</td><td>0.33</td></tr>
<tr><td>Rebaudioside B</td><td>$C_{38}$ $H_{60}$ $O_{18}$</td><td>0.40</td></tr>
<tr><td>Rebaudioside D</td><td>$C_{50}$ $H_{80}$ $O_{28}$</td><td>0.29</td></tr>
<tr><td>Rebaudioside M</td><td>$C_{56}$ $H_{90}$ $O_{33}$</td><td>0.25</td></tr>
</table>

| | | | |
|---|---|---|---|
| Molecular weight and CAS No | Trivial name | CAS Number | Molecular weight (g/mol) |
| | Rebaudioside A | 58543-16-1 | 967.01 |
| | Rebaudioside B | 58543-17-2 | 804.88 |
| | Rebaudioside D | 63279-13-0 | 1,129.15 |
| | Rebaudioside M | 1220616-44-3 | 1,291.30 |
| **Assay** | Not less than 95% of rebaudioside M, rebaudioside D, rebaudioside A, and rebaudioside B on the dried basis. | | |
| **Description** | White to light-yellow powder, approximately between 200 and 350 times sweeter than sucrose (at 5% sucrose equivalency). | | |
| **Identification** | | | |
| Solubility | Freely soluble to slightly soluble in water | | |
| pH | Between 4.5 and 7.0 (1 in 100 solution) | | |
| **Purity** | | | |
| Total ash | Not more than 1 % | | |
| Loss on drying | Not more than 6 % (105 °C, 2h) | | |
| Residual solvent | Not more than 5,000 mg/kg ethanol | | |
| Arsenic | Not more than 0.1 mg/kg | | |
| Lead | Not more than 0.1 mg/kg | | |
| Cadmium | Not more than 0.01 mg/kg | | |
| Mercury | Not more than 0.05 mg/kg | | |
| Residual protein | Not more than 20 mg/kg | | |
| | | | |
| **Microbiological criteria** | | | |
| Total (aerobic) plate count | Not more than 1,000 CFU/g | | |
| Yeast | Not more than 100 CFU/g | | |
| Moulds | Not more than 100 CFU/g | | |
| *Escherichia coli* | Negative in 1g | | |

| | |
|---|---|
| *Salmonella* spp. | Negative in 25g |

## Labelling

The proposed labelling designation is E 960b or Steviol glycosides from fermentation

## Additional labelling requirements

It is proposed that no additional labelling requirements are required.

## Other relevant information (separate to terms of authorisation)

## Other legitimate factors

In developing the Risk Management recommendations, the FSA/FSS have had regard to the other legitimate factors (including consumer interests, political, environmental, societal and technical feasibility) that Ministers will consider as part of their decision on authorisation.

The FSA/FSS have not identified any applicable other legitimate factors to date that would prevent the authorisation of this new production method. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant Other Legitimate Factors as part of the consultation process.

## Impacts

As part of the risk analysis process, FSA/FSS have assessed the potential impacts that would result from the authorisation of this food additive, should Ministers decide to authorise. No significant impacts were identified. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of this product should generally result in greater market competition, supporting growth and innovation in the sector.

Under the Windsor Framework, stevia glycosides produced by Yarrowia lipolytica, approved in GB will be able to be placed on the market in Northern Ireland, if it is eligible for, and moved through NIRMS.

## Annex H RP1737 – Proposed removal of twenty-two flavouring substances from the approved list

RP1737 - Proposed removal of twenty-two flavouring substances from the approved list

### Background

When the list of permitted flavouring substances was established in 2012 (Regulation (EU) No 872/2012), it contained flavouring substances for which the evaluation was completed (evaluated flavouring substances) and those for which the evaluation was still ongoing (flavouring substances under evaluation). The definitions for these flavourings are given below:

- 'evaluated flavouring substances' means substances for which the evaluation and approval have been completed. Those substances are assigned no footnotes in Part A of the domestic list of flavourings and source materials;
- 'flavouring substances under evaluation' means substances for which the risk assessment had not been completed at the time of the entry into force of this Regulation. Those substances are assigned footnotes 1 to 4 in Part A of the domestic list of flavourings and source materials.

In 2020, the International and European Flavouring Trade Associations (IOFI/EFFA) identified 22 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 market as set out in Regulation (EU) 2022/1466.

The UK Flavour Association (UKFA) has submitted an application to remove the same 22 flavouring substances from the domestic list. UKFA have advised that these flavourings are not widely used by the UK flavourings industry and the

flavourings industry has decided not to provide the additional information which would be required to complete the evaluation of these flavouring substances.

## Safety assessment summary

As the application is to remove flavourings from the domestic list, a safety assessment was not conducted.

## Any relevant provisions of assimilated law

The FSA/FSS has not identified any relevant provisions of assimilated law that would impact the removal of these products from the domestic list.

## 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. 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.

## Proposed removals

The twenty-two flavouring substances included in the application (RP1737) for removal from the domestic list (Part A of Annex I to assimilated Regulation (EC) No 1334/2008) 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)

## Other legitimate factors

In developing the Risk Management recommendations, the FSA has had regard to the other legitimate factors (including consumer interests, political, environmental, societal and technical feasibility) that Ministers will consider as part of their decision on authorisation.

As the proposal is to remove 22 flavouring substances which are not widely used in foods or drink sold on the GB market, the FSA/FSS consider there are no relevant other legitimate factors that need to be taken into consideration.

## Impacts

As part of the risk analysis process, FSA/FSS have assessed the potential impacts that would result from the removal of the flavouring substances, should Ministers decide to remove these from the domestic list. No significant impacts were identified as the flavourings industry have stated these flavourings are not used anymore. 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).

This approach will bring GB in line with Northern Ireland, where these flavourings are already unavailable.