Consultation pack on applications for authorisation of miscellaneous regulated products: two novel foods, one flavouring and one food additive

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

Launch date: 17 October

Respond by: 11 December 2022

This consultation will be of most interest to:

- Food industry trade associations
- Food business operators in the UK wishing to use the novel foods, flavouring or food additive
- Enforcement Authorities, including Local Authorities, Port Health Authorities and District Councils
- Consumers and wider stakeholders

A list of interested parties is included in Annex A.

Consultation subject and purpose

This consultation seeks stakeholders' views, comments and feedback in relation to the regulated product applications considered in this document, which have been submitted for authorisation (either as new authorisations or for extension of use / modification). We ask stakeholders to consider any relevant provisions of retained EU law and other legitimate factors (other evidence further supporting clear, rational and justifiable risk analysis, such as consumer interests, technical feasibility and environmental factors), including those that the Food Standards Agency (FSA) and Food Standards Scotland (FSS) have identified as relevant to these applications. This is stakeholders' opportunity for input on the advice given to Ministers to inform decision making.

The consultation concerns the following regulated products:

- RP1158 Vitamin D2 mushroom powder - novel food
- RP1292 UV-treated baker's yeast (Saccharomyces cerevisiae) – novel food
- RP1382 3-(1-((3,5-dimethylisoxazol-4-yl)methyl)-1H-pyrazol-4-yl)-1-(3-hydroxybenzyl)imidazolidine-2,4-dione – flavouring
- RP1194 Rebaudioside M – food additive

The FSA/FSS opinions, and the views gathered through this consultation, will be considered and included alongside those of officials across the FSA, FSS and, for novel foods, UK Government Departments other than the FSA to inform Ministers' decision-making on whether to authorise the individual regulated products for use in Great Britain (GB).

The FSA/FSS opinion comprised in this document (including the proposed terms of authorisation) takes into account the FSA/FSS scientific opinion documents. The views gathered through this consultation will be considered and included alongside those of officials across the FSA, FSS and, for novel foods, UK Government Departments other than the FSA to inform Ministers' decision-making on whether to authorise the individual regulated products for use in Great Britain (GB).

A parallel consultation is being published by FSS.

How to respond

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

Email: RPconsultations@food.gov.uk
Name: Regulated Products Approvals Team
Division/Branch: Regulated Services

Details of consultation

Introduction

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

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

In Northern Ireland, EU Food Law on novel foods, food additives and flavourings continues to apply under the current terms of the Protocol on Ireland/Northern Ireland (NIP). This means that these products require authorisation under the EU's authorisation procedures before being placed on the market in Northern Ireland.

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. Where the European Food Safety Authority (EFSA) had commenced an assessment of an application prior to the end of the transition period for the UK exiting the European Union (EU), the FSA/FSS' risk assessors will take the EFSA opinion into account as part of its risk assessment, where it has been published by EFSA. For the applications in this consultation, the FSA/FSS have had access to all supporting documentation that was provided to EFSA for forming its opinion as this information was provided to the FSA/FSS by the applicant. After evaluation, the FSA/FSS have agreed with EFSA's conclusions in its opinions.

Following risk assessment, this consultation seeks to gather stakeholders' views on the proposed regulated product authorisations.

Ministers in all four nations have agreed to a provisional common framework for Food and Feed Safety and Hygiene. 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 relevant cross-government forums with the Department of Health and Social Care (DHSC), Welsh Government and Scottish Government. Final advice will be agreed on a four-nation basis before being presented to Ministers.

The content of this consultation presents the views of the FSA/FSS and the factors that the FSA/FSS have identified as relevant to these applications, including the impact of any decision made by Ministers, whether this is to authorise or not. 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 feedback on opinions and responses to the consultation, the next step of the authorisation process is for relevant Ministers in England, Scotland and Wales to make decisions on authorisation (with Ministers in Northern Ireland kept informed), taking into account the FSA/FSS opinion, any relevant provisions of retained EU law and any other legitimate factors, including those raised during the consultation process.

Subject of this consultation

In accordance with Retained EU Regulation 2015/2283 on novel foods and Retained EU Regulation 1331/2008 which establishes a common authorisation procedure for food additives, food enzymes and flavourings, the products included in this consultation have been submitted for authorisation or extension of use.

This consultation concerns two novel foods, one new flavouring substance, and one food additive that have been submitted for authorisation in each nation of GB, where the decision on authorisation is made by the respective Ministers in England, Scotland and Wales.

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 Retained EU Regulation 2015/2283. 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.
In order to be approved for use, food additives must be authorised in accordance with Retained EU Regulation 1331/2008, which established a common authorisation procedure for food additives, food enzymes and food flavourings.

Retained EU Regulation 1333/2008 defines food additives as “any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods…”.

Retained EU 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.”

Details of the individual regulated products are given in the annexes. Each application is considered within a separate annex, including the regulated product ID number and title of the application (Ctrl+Click to follow link):

- Annex B: RP1158 – Novel food, new authorisation: Vitamin D2 mushroom powder
- Annex C: RP1292 – Novel food, extension of use: UV treated baker's yeast (Saccharomyces cerevisiae)
- Annex D: RP1194 – Food additive, modification: Rebaudioside M382
- Annex E: RP1382 – Flavouring, new authorisation: 3-(1-((3,5-dimethylisoxazol-4-yl)methyl)-1H-pyrazol-4-yl)-1-(3-hydroxybenzyl)imidazolidine-2,4-dione

Impacts

As part of the risk analysis process, FSA/FSS have assessed the potential impacts that would result from authorisation of these regulated products, should Ministers decide to authorise/extend use. Our collective assessment of the proposals did not identify any significant impacts. The impacts considered included those most frequently identified as potential impacts when introducing or amending food law (i.e., local authority delivery, health, environment, growth, innovation, trade, competition, consumer interests or small and micro businesses). The authorisation/modiciation/extension of use 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. The regulated products included within this consultation, both new authorisations and extensions of use, are authorised for use in Northern Ireland, in line with legislation that applies in Northern Ireland, under the NIP. Therefore, authorising in England, Scotland and Wales would not result in divergence within the UK.

Other legitimate factors

We have considered a range of other legitimate factors that Ministers may consider in making decisions about these regulated products, including political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours.

Our collective assessment of the other legitimate factors Ministers may consider in making decisions did not identify anything of significance, except for the recent EU authorisation and extensions of use of these regulated products.

Taking into account the FSA/FSS opinions, Ministers could decide to authorise the products. As the opinions have concluded that the products are safe to be used on the proposed terms, FSA/FSS views are that there are no reasons for Ministers to refuse authorisation/modification/extension of use unless there are other legitimate factors that might indicate otherwise.

Requirements in retained EU legislation

Requirements in retained EU legislation are given within the annexes.

Options for authorisation

The next step of the authorisation process is for Ministers to make decisions on authorisation. In presenting advice and assisting Ministers?the FSA and FSS?are acting pursuant to their

functions?under the?Food Standards Act?1999?and Food (Scotland) Act 2015.?

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

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

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

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

Engagement and consultation process

Details of all validated applications for regulated products are published on the Register of Regulated Product Applications on the Food Standards Agency website.

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

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

Questions asked in this consultation:

1. Do you have any concerns on the safety of the novel foods, flavouring or food additive which have not been considered below with respect to the intended consumers?
2. Do you have any comments or concerns on the impacts in consideration of authorising or not authorising the individual novel foods, flavouring or food additive, and if in favour of authorisation, the terms on which these are authorised (as outlined in the FSA/FSS opinions)?
3. With respect to the food additive application RP1194 and the label change from E960 to E960a, do you consider a transition period would be appropriate and, if so, how long should this be?
4. Are there any other factors that should be considered by Ministers that have not been highlighted?
5. Do you have any other feedback?

Responses

This consultation will run for 8 weeks. Responses are required by close of 11 December 2022.

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)] Miscellaneous regulated products consultation.

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.

All responses to this consultation will be published by the Food Standards Agency 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 FSS.

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,
Dr Helen Kardos-Stowe
Regulated Products Policy Advisor,
Regulated Services

Annex A: List of stakeholders

Key stakeholder trade associations which are represented across all four nations of the UK who have a strong interest in novel foods, flavourings or food additives 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
- British Soft Drinks Association
- British Specialist Nutrition Association
- Business Wales
- Baby Milk Action
- Campden BRI
- Cereal Ingredient Manufacturers' Association
- Council for Responsible Nutrition UK
- Dairy UK
- Federation of Bakers
- Federation of Small Businesses (Wales)
- Federation of Small Businesses (Northern Ireland)
- Food & Drink Federation (England)
- FDF Sector Group: Biscuit, Cake, Chocolate and Confectionery
- FDF Sector Group: Food additives
- Food & Drink Federation (Wales)
- Food Additives Industry Association (FAIA)
- Health Food Manufacturers' Association

- Leatherhead Food International
- Northern Ireland Food and Drink Association
- Northern Ireland Retail Consortium
- Provision Trade Federation
- Scientific Advisory Committee on Nutrition
- Snack, Nut and Crisp Manufacturers' Association
- UK Flavour Association
- UK Flour Millers
- Welsh Retail Consortium
- Which?

This is not an exhaustive list.

Annex B: RP1158 RP1158 – Vitamin D2 Mushroom (Agaricus bisporus) Powder (new authorisation)

Background

This application was submitted as set out in Retained EU Regulation 2015/2283. The novel food which is the subject of the application is an Agaricus bisporus mushroom powder that has been exposed to UV irradiation to induce the conversion of provitamin D2 (ergosterol) to vitamin D2 (ergocalciferol). The novel food contains levels of vitamin D in the form of vitamin D2 in the range of 580–595 ?g/g.

The applicant intends the novel food to be used in a variety of foods and beverages, foods for special medical purposes (FSMPs), and in food supplements. The proposed target population was the general population, except for food supplements and FSMPs, for which the target population was individuals above one year of age.

Risk assessment outcomes

Following the principles outlined in the main text of this document for making use of the EFSA opinion, the FSA/FSS opinion is that vitamin D2 mushroom powder, containing vitamin D2 in the ranges of 580 – 595 µg/g, is safe under the proposed conditions of use and is not liable to have an adverse effect on human health.

During the application process, the applicant agreed to exclude children under 3 years of age from the request for authorisation of the novel food in food supplements.

Proposed terms for entry to the list of authorised novel foods

The FSA/FSS scientific opinion is in favour of the authorisation of this novel food, based on risk assessment and safety conclusions. The proposed terms for entry to the list of authorised novel foods are given in Table 1.

This product was authorised for placing on the market in the EU and Northern Ireland, under the current terms of the Northern Ireland Protocol (NIP) and the proposed food categories and intended use levels for this novel food in GB are the same as specified in Commission Implementing Regulation (EU) 2021/2079 of 26 November 2021.

Specification

1. Description / Definition

The novel food is mushroom powder produced from dried whole Agaricus bisporus mushrooms. The process includes drying, milling and the controlled exposure of the mushroom powder to UV irradiation.

UV radiation: A process of radiation in ultraviolet light within a range of wavelength similar to those UV-treated novel foods authorised under Retained EU Regulation 2015/2283.

2. Characteristics / Composition:

- Vitamin D2 content: 580-595 µg/g of mushroom powder
- Ash: ? 13.5%
- Water activity: < 0.5
- Moisture content: ? 7.5%
- Carbohydrates: ? 35.0%
- Total dietary fibre: ? 15%
- Crude protein (N x 6.25): ? 22%
- Fat: ? 4.5%

3. Heavy metals:??

- Lead: ? 0.5 mg/kg
- Cadmium: ? 0.5 mg/kg
- Mercury: ? 0.1 mg/kg
- Arsenic: ? 0.3 mg/kg

4. Mycotoxins:?

- Aflatoxin B1: ? 0.10 µg/kg
- Aflatoxins (sum of B1 + B2 + G1 + G2): < 4 µg/kg

5. Microbiological?criteria:??

- Total?plate?count: ? 5000 CFU
- Total yeast and mould count: ? 100 CFU/g??
- E. coli: < 10 CFU/g
- Salmonella?spp.:?Absence?in 25 g??
- Staphylococcus aureus: ? 10 CFU/g
- Coliforms: ? 10 CFU/g
- Listeria spp.: Absence in 25 g
- Enterobacteriaceae: < 10 CFU/g

Labelling

The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘UV-treated mushroom powder containing vitamin D2’.

The labelling of food supplements, as defined by Directive 2002/46/EC, containing vitamin D2 mushroom powder shall bear a statement that they should not be consumed by infants and children under 3 years of age.

Table 1 Proposed uses

Specified food category	Proposed maximum level of Vitamin D2

Breakfast cereals	2.1 µg/100 g
Yeast leavened bread and similar pastries	2.1 µg/100 g
Grain products and pasta and similar products	2.1 µg/100 g
Fruit/vegetable juices and nectars	1.1 µg/100ml (marketed as such or reconstituted as instructed by the manufacturer)
Dairy products and analogues other than beverages	2.1 µg/100 g (marketed as such or reconstituted as instructed by the manufacturer)
Milk and dairy products	1.1 µg/100ml (marketed as such or reconstituted as instructed by the manufacturer)
Meat analogues	2.1 µg/100 g
Soups	2.1 µg/100ml (marketed as such or reconstituted as instructed by the manufacturer)
Extruded vegetable snack	2.1 µg/100 g
Meal replacement for weight control	2.1 µg/100 g
Food for special medical purposes as defined under retained EU regulation 609/2013 excluding those intended for infants	In accordance with the particular nutritional requirements of the persons for whom the products are intended
Food supplements as defined in EU Directive 2002/46/EC excluding food supplements for infants and young children	15 µg of vitamin D2 / day

Any relevant provisions of retained EU law

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

Other legitimate factors identified that Ministers may consider in making decisions

FSA/FSS have not identified any other legitimate factors that would prevent authorisation taking place, so unless the responses to this consultation identify any other legitimate factors Ministers must take into account in making decisions on authorisation, the FSA/FSS advice to Ministers will be to authorise on the proposed terms.

Annex C: RP1292 – UV-treated Baker's Yeast (*Saccharomyces cerevisiae)* (extension of use)

Background

This application was submitted as set out in Retained EU Regulation 2015/2283. The novel food which is the subject of the application is baker's yeast (*Saccharomyces cerevisiae*) which has been treated with ultraviolet light to induce the conversion of ergosterol to vitamin D2 (ergocalciferol).

The yeast concentrate is blended with regular baker's yeast in order not to exceed the maximum level in the pre-packed fresh or dry yeast for home baking. The new intended food uses concern only inactivated UV-treated yeast, which is inactivated by heat treatment.

Vitamin D2 content in the yeast concentrate varies between 800,000 – 3,500,000 IU vitamin D/100 g (200-875 ?g/g).

The novel food is already authorised for use in yeast-leavened breads, rolls and fine bakery at a usage level that would not exceed a maximum concentration of 5 µg vitamin D2 per 100 g and in fresh or dry yeast for home baking with maximum use levels of 45 µg/100 g and 200 µg/100 g for fresh and dried yeast, respectively.

Risk assessment outcomes

Following the principles outlined in the main text of this document for making use of the EFSA opinion, the FSA/FSS opinion is that the novel food described in this application is safe under the proposed conditions of use and is not liable to have an adverse effect on human health.

The FSA/FSS is satisfied that the applicant has suitably demonstrated the relevant safety data for the proposed uses of the substance and its conditions of use.

The uses proposed by the applicant have been varied to inactivate the UV-treated baker's yeast for use in infant formula and follow-on formula, processed cereal-based foods and foods for special medical purposes (FSMPs).

Proposed terms for entry to the list of authorised novel foods

The FSA/FSS scientific opinion is in favour of the authorisation of the extension of use of this novel food, based on risk assessment and safety conclusions. The proposed terms for entry to the list of authorised novel foods are given in Table 1.

The extension of use for this novel food was authorised for placing on the market in the EU and Northern Ireland, under the current terms of the Northern Ireland Protocol (NIP) and the proposed food categories and maximum levels of use for this novel food in GB are the same as specified in Commission Implementing Regulation (EU): C(2022)723 on 11 February 2022.

Specification

1. Description / Definition

Baker's yeast (Saccharomyces cerevisiae) is treated with ultraviolet light to induce the conversion of ergosterol to vitamin D2 (ergocalciferol). Vitamin D2 content in the yeast concentrate varies between 800 000 – 3 500 000 IU vitamin D/100 g (200-875 ?g/g).

The yeast shall be inactivated for use in infant formula and follow-on formula, processed cereal-based food and foods for special medical purposes as defined by Regulation (EU) No 609/2013, while for use in other foods the yeast may or may not be inactivated.

The yeast concentrate is blended with regular baker's yeast in order not to exceed the maximum level in the pre-packed fresh or dry yeast for home baking.
Tan-coloured, free-flowing granules

2. Vitamin D2:

- Chemical formula: (5Z,7E,22E)-(3S)-9,10-secoergosta-5,7,10(19),22-tetraen-3-ol
- Synonym: Ergocalciferol?
- CAS No.: 50-14-6
- Molecular weight: 396.65 g/mol

3. Microbiological?criteria for the yeast concentrate:??

- Coliforms: ? 10 CFU/g
- E. coli: ? 10 CFU/g
- Salmonella: Absence?in 25 g??

Labelling

The designation of the novel food on the labelling of the foodstuffs containing it, or when sold as pre-packed fresh or dry yeast for home baking, shall be 'vitamin D yeast' or 'vitamin D2 yeast'.

When sold as pre-packed fresh or dry yeast for home baking, the labelling of the novel food shall bear a statement that the foodstuff is only intended for baking and that it should not be eaten raw. The labelling of the novel food shall bear instructions for use for the final consumers so that a maximum concentration of 5 ?g/100 g of vitamin D2 in final home-baked products is not exceeded.

Table 1 Proposed uses

Specified food category	Proposed maximum level of Vitamin D2
Yeast leavened breads and rolls (1)	5 µg/100 g
Yeast leavened fine bakery wares (1)	5 µg/100 g
Food supplements as defined in EU Directive 2022/46/EC	In accordance with Directive 2002/46/EC

Specified food category	Proposed maximum level of Vitamin D2
Pre-packed fresh or dry yeast for home baking (2)	45 µg/100 g for fresh yeast, 200 µg/100 g for dried yeast
Dishes, including ready-to-eat meals (excluding soups and salads)	3 µg/100 g
Soups and salads	5 µg/100 g
Fried or extruded cereal, seed or root-based products	5 µg/100 g
Infant formula and follow-on formula as defined by Retained EU Regulation No 609/2013 (3)	In accordance with Retained EU Regulation No 609/2013
Processed cereal-based food as defined by Retained EU Regulation No 609/2013 (3)	In accordance with Retained EU Regulation No 609/2013
Processed fruit products	1.5 µg/100 g
Processed vegetables	2 µg/100 g
Bread and similar products	5 µg/100 g
Breakfast cereals	4 µg/100 g
Pasta, doughs and similar products	5 µg/100 g
Other cereal based products	3 µg/100 g
Spices, seasonings, condiments, sauce ingredients, dessert sauces/toppings	10 µg/100 g
Protein products	10 µg/100 g
Cheese	2 µg/100 g
Dairy desserts and similar products	2 µg/100 g

Specified food category	Proposed maximum level of Vitamin D2
Fermented milk or fermented cream	1.5 µg/100 g
Dairy powders and concentrates	25 µg/100 g
Milk based products, whey and cream	0.5 µg/100 g
Meat and dairy analogues	2.5 µg/100 g
Total diet replacements for weight control as defined by Retained EU Regulation 609/2013	5 µg/100 g
Meal replacement for weight control	5 µg/100 g
Food for special medical purposes as defined under Retained EU Regulation 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended.

1 Current authorisation under Retained EU Regulation 2017/2470
2 Current authorisation under Retained EU Regulation 2017/2470
3 The yeast shall be inactivated for use in this product.

Any relevant provisions of retained EU law

FSA/FSS has not identified any relevant provisions of retained EU law that would impact authorisation for the extension of use for this product.

Other legitimate factors identified that Ministers may consider in making decisions

FSA/FSS has not identified any other legitimate factors that would prevent authorisation taking place, so unless the responses to this consultation identify any other legitimate factors Ministers must take into account in making decisions on authorisation, the FSA/FSS advice to Ministers will be to authorise the extension of use on the proposed terms.

This novel food is authorised for use in Northern Ireland, in line with EU legislation that applies in Northern Ireland, under the Northern Ireland Protocol (NIP).

Annex D: RP1194 – Rebaudioside M (modification to specification)

Background

This application?was submitted?as set out in?Retained EU Regulation 1331/2008.

This is a routine application for the amendment of the specifications for the manufacture of the food additive steviol glycosides (E 960) to include a new method for the production of rebaudioside M, for use as an existing permitted low-calorie, high intensity sweetener.

Rebaudioside M is a minor glycoside present at very low levels (< 1%) in the stevia leaf, which has a taste profile that is more reflective of sucrose when compared to the major glycosides (i.e. stevioside and rebaudioside A).

The new process involves the bioconversion of purified stevia leaf extract (?95% steviol glycosides) through a multistep enzymatic process with enzymes prepared at the first stage of the process. The resulting rebaudioside M undergoes a series of purification and isolation steps to produce the final rebaudioside M (? 95%).

See below for proposed amendments, which mirror the legislation which applies in the EU and Northern Ireland, under the current terms of the Northern Ireland Protocol (NIP).

Risk assessment outcomes

Following the principles outlined in the main text of this document for making use of the EFSA opinion, the FSA/FSS opinion is that the food additive described in this application is safe under the proposed conditions of use and is not liable to have an effect on human health.

The FSA/FSS is satisfied that the applicant has suitably demonstrated the relevant safety data for the proposed uses of the substance and its conditions of use.

Proposed terms of authorisation

The FSA/FSS scientific opinion is in favour of the authorisation of the modification of this food additive, based on risk assessment and safety conclusions. It is proposed that Annex II of Retained EU Regulation 1333/2008 is amended as follows:

(a) In part B2:

1. The entry for E 960 (Steviol glycosides) is replaced by the following:

E 960a Steviol glycosides from Stevia

2. And the new following entry is inserted:

E 960c Enzymatically produced steviol glycosides

(b) In point (5) pf Part C, the following new entries are inserted:

E number	Name
E 960a	Steviol glyvosides from Stevia
E 960c	Enzymatically produced steviol glycosides

(c) Part E is amended to replace each entry for E960, with ‘E960a-c’ and to add reference to footnote 1 for all entries other than those under 11.4. The entry in the column indicating maximum levels of use for categories 11.4.1, 11.4.2 and 11.4.3 is corrected from ‘QS’ to

‘quantum satis’ for consistency.

It is proposed that the food additive ‘steviol glycosides’ (E 960) and foods containing it, which are labelled or placed on the market up to 18 months after the entry into force of the implementing legislation and which comply with the requirements of the current legislation, may be marketed until the stocks are exhausted.

Any relevant provisions of retained EU law

In accordance with Retained EU Regulation 1333/2008, a food additive can only be approved for use in foods if:

(a) it does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer at the level of use proposed;
(b) there is a reasonable technological need that cannot be achieved by other economically and technologically practicable means; and
(c) its use does not mislead the consumer.

Other legitimate factors identified that Ministers may consider in making decisions

FSA/FSS?has not identified any other?legitimate?factors that would prevent authorisation taking place, so unless the responses?to this consultation?identify any other?legitimate?factors Ministers must?take into account?in?making decisions on authorisation, the?FSA/FSS advice to Ministers?will be to authorise on the proposed terms.?

The amendment of the existing specification for steviol glycoside was authorised for use in the EU by Regulation (EU) 2021/1156, amending Annex II to Regulation 1333/2008, and is applicable in Northern Ireland under the NIP. This Regulation came into force on 3 August 2021, allowing E 960c to be placed on the market in Northern Ireland and the EU, with an 18-month transition period to allow the necessary labelling changes for E 960 to E 960a to be implemented.

However, foods containing steviol glycosides, produced from Stevia, already labelled and placed on the Northern Ireland and EU market before 2 February 2023 may continue to stay on the market until they reach their date of minimum durability or ‘use by’ date.

Authorising in England, Scotland and Wales will remove the current regulatory divergence within the UK.

Annex E: RP1382 – Flavouring 3-(1-((3,5-dimethylisoxazol-4-yl)methyl)-1H-pyrazol-4-yl)-1-(3-hydroxybenzyl)imidazolidine-2,4-dione (new authorisation)

Background

This application was submitted as set out in Retained EU Regulation 1331/2008. This is a synthetic substance with FL (Flavis) Number 16.127, CAS number 1119831-25-2 and JECFA No 2161.

This flavouring does not impart a new taste/odour to food and so is classed as a flavour modifier. It reduces the bitterness of certain foods e.g. cocoa, green tea. This allows the use of less sugar or sweetener in the final food and also improves the overall flavour profile.

The flavouring is intended to be used to modify the bitter taste in a limited number of foods and the proposed maximum use levels range between 4 mg/kg to 100 mg/kg - which equate to an addition rate of 0.0004 - 0.01%. See Table 1 for the proposed use levels, which mirror the legislation which applies in the EU and Northern Ireland, under the current terms of the Northern Ireland Protocol (NIP).

Risk assessment outcomes

Following the principles outlined in the main text of this document for making use of the EFSA opinion, the FSA/FSS opinion is that the flavouring described in this application is safe under the proposed conditions of use and is not liable to have an effect on human health.

The FSA/FSS is satisfied that the applicant has suitably demonstrated the relevant safety data for the proposed uses of the substance and its conditions of use.

Proposed terms for entry to the list of authorised flavouring substances

The FSA/FSS scientific opinion is in favour of the authorisation of this flavouring, based on risk assessment and safety conclusions. The proposed terms for entry to the list of authorised flavouring substances are given in Table 1.

This product was authorised for placing on the market in the EU and Northern Ireland, under the current terms of the Northern Ireland Protocol (NIP) and the proposed food categories and intended use levels for this flavouring in GB are the same as specified in Regulation (EU) 2021/1532 which came into force on 17 September 2021.

If approved for use with the requested conditions for use, this flavouring substance will be included in Retained EU Regulation 1334/2008. A new entry will be added to Table 1 of Annex I, Part A, Section 2, i.e. the domestic list of flavouring substances, following the entry for FL No. 16.126.

Specification

1. FL no.: 16.127
2. Chemical name: 3-(1-((3,5-dimethylisoxazol-4-yl)methyl)-1H-pyrazol-4-yl)-1-(3-hydroxybenzyl)imidazolidine-2,4-dione
3. CAS NO.: 1119831-25-2
4. JECFA NO.: 2161
5. CoE No.: -
6. Purity of the named substance: At least 99%, assay (HPLC/UV)

Specified food category	Food category number	Maximum level of use
Flavoured fermented milk products, including heat treated products	1.4	4 mg/kg
Dairy analogues, including beverage whiteners	1.8	8 mg/kg

Specified food category	Food category number	Maximumlevel of use
Edible ices	3	4 mg/kg
Cocoa and chocolate products as covered by Directive 2000/36/EC	5.1	15 mg/kg
Other confectionary including breath refreshening micro-sweets	5.2	16 mg/kg
Chewing gum	5.3	30 mg/kg
Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4	5.4	15 mg/kg
Breakfast cereals	6.3	25 mg/kg
Salt and salt substitutes	12.1	75 mg/kg
Herbs, spices and seasonings	12.2	100 mg/kg
Vinegars and diluted acetic acid (diluted with water to 4-30% by volume)	12.3	25 mg/kg
Mustard	12.4	25 mg/kg
Soup and broths	12.5	4 mg/kg
Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)	13.2	4 mg/kg
Dietary foods for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)	13.3	4 mg/kg
Flavoured drinks	14.1.4	4 mg/l for dairy based drinks only

Specified food category	Food category number	Maximumlevel of use
Coffee, tea, herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant, fruit and cereal preparations for infusions, as well as mixes and instant mixes of these products	14.1.5	8 mg/kg
Potato, cereal, flour or starch-based snacks	15.1	20 mg/kg
Desserts (excluding products covered in category 1, 3 and 4)	16	4 mg/l for dairy based drinks only

Any relevant provisions of retained EU law

FSA/FSS has not identified any relevant provisions of retained EU law that would impact authorisation for this product.??
In accordance with retained EU regulations, a flavouring can only be approved for use in foods if:

(a) it does not, on the basis of the scientific evidence available, pose a safety risk to the health of the consumer; and
(b) its use does not mislead the consumer.

No new labelling requirements are planned for this substance and so the general rules on the labelling of flavourings in food as set out in retained EU Regulation 1169/2011 will apply. This states either the term ‘flavouring(s)’ or by a more specific name or description of the flavouring must be present in the ingredients list.
Rules for the labelling of flavourings sold business to business or directly to consumers are set out in retained EU Regulation 1334/2008.

Other legitimate factors identified that Ministers may consider in making decisions

FSA/FSS?has not identified any other?legitimate?factors that would prevent authorisation taking place, so unless the responses?to this consultation?identify any other?legitimate?factors Ministers must?take into account?in?making decisions on authorisation, the?FSA/FSS advice to Ministers?will be to authorise on the proposed terms.?

This flavouring is authorised for use in Northern Ireland, in line with EU legislation that applies in Northern Ireland, under the Northern Ireland Protocol.