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

**Consultation Summary Page**

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| **Date consultation launched:** | **Closing date for responses:** |
| 17 October 2022 | 11 December 2022 |

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| **Who will this consultation be of most interest to?**This consultation will be of most interest to:* Food industry trade associations.
* Food business operators in the UK wishing to use the novel foods, food additive or food flavouring.
* 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. |

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| **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 Food Standards Scotland (FSS) and the Food Standards Agency (FSA) 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
* RP1194 Rebaudioside M – food additive
* RP1382 3-(1-((3,5-[parallel consultation](https://eur03.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.food.gov.uk%2Fnews-alerts%2Fconsultations%2Fconsultation-on-applications-for-authorisation-of-miscellaneous-regulated-products-two-novel-foods-one-flavouring-and-one-food&data=05%7C01%7C%7C5f4f6ecf1f4848daf8ec08daacfac4d5%7C8a1c50f901b74c8aa6fa90eb906f18e9%7C0%7C0%7C638012490298143717%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=wZaCfc0drIH0XIgKJO42uFRTh2pJ48cttBMibIC4zJw%3D&reserved=0)-4-yl)methyl)-1H-pyrazol-4-yl)-1-(3-hydroxybenzyl)imidazolidine-2,4-dione – flavouring
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| The FSS/FSA opinion comprised in this document (including the proposed terms of authorisation) takes into account the [FSS/FSA scientific opinion](https://www.food.gov.uk/research/novel-and-non-traditional-foods-additives-and-processes/assessment-of-two-novel-foods-and-miscellaneous-regulated-products-applications-under-the-relevant-eu-retained-law) documents. The views gathered through this consultation will be considered and included alongside those of officials across FSS, the FSA, 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 have also published their opinion and launched a [parallel consultation](https://eur03.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.food.gov.uk%2Fnews-alerts%2Fconsultations%2Fconsultation-on-applications-for-authorisation-of-miscellaneous-regulated-products-two-novel-foods-one-flavouring-and-one-food&data=05%7C01%7C%7C5f4f6ecf1f4848daf8ec08daacfac4d5%7C8a1c50f901b74c8aa6fa90eb906f18e9%7C0%7C0%7C638012490298143717%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=wZaCfc0drIH0XIgKJO42uFRTh2pJ48cttBMibIC4zJw%3D&reserved=0) for English and Welsh stakeholders. |

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| **Responses to this consultation** |
| If you wish to comment on the applications in this consultation, all responses should be submitted through the Citizen Space entry, where the questions can be answered and other feedback given. | **Contact details**Joshua EvansLabelling, Standards & Regulated ProductsFood Standards Scotland07776 490599joshua.evans@fss.scot | **Postal address**Food Standards ScotlandFourth FloorPilgrim HouseOld Ford RoadAberdeenAB11 5RL |

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

Consultation on the second tranche of regulated product applications for two novel foods, one food additive and one flavouring and legitimate factors

Details of Consultation

In accordance with [retained EU Regulation 2015/2283](https://www.legislation.gov.uk/eur/2015/2283/contents) on novel foods and [retained EU Regulation 1331/2008](https://www.legislation.gov.uk/eur/2008/1331/contents) which establishes a common authorisation procedure for food additives, food enzymes and food flavourings, the products included in this consultation have been submitted for authorisation, or modification or extension of use.

This consultation concerns applications for 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 Scotland, England 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 novel food 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 register of GB Authorised Novel Foods.

In order to be approved for use, food additives and food flavourings 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 A: List of stakeholders 13](#_Toc116639219)

[Annex B: RP1158 – Vitamin D2 Mushroom (*Agaricus bisporus*) Powder (new authorisation) 15](#_Toc116639220)

[Annex C: RP1292 – UV-treated Baker’s Yeast (*Saccharomyces cerevisiae*) (extension of use) 19](#_Toc116639221)

[Annex D: RP1194 – Rebaudioside M (modification to specification) 24](#_Toc116639222)

[Annex E: RP1382 – Flavouring 3-(1-((3,5-dimethylisoxazol-4-yl)methyl)-1*H*-pyrazol-4-yl)-1-(3-hydroxybenzyl)imidazolidine-2,4-dione (new authorisation) 27](#_Toc116639223)

Introduction

In order to be placed on the market, applications for the authorisation of regulated products must be submitted for authorisation in GB, where the decision on authorisation is made by the respective Ministers in Scotland, England and Wales. 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.

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

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, FSS/FSA have had access to all supporting documentation that was provided to EFSA for forming its opinion as this information was provided to the FSA by the applicant. After evaluation, FSS/FSA 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](https://www.gov.uk/government/publications/food-and-feed-safety-and-hygiene-provisional-common-framework). This consultation has been developed under the commitments to collaborative four-nation working set out in this Framework. As such, this consultation has been developed through relevant cross-government forums with the Department of Health and Social Care (DHSC), Scottish Government and Welsh 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 FSS/FSA and the factors that FSS/FSA have identified as relevant to these applications, including the impact of any decision made by Ministers. Stakeholders are invited to use this opportunity to comment on these factors or highlight any additional factors that should be brought to the attention of Ministers before a final decision is made.

Following feedback on opinions and responses to the consultation, the next step of the authorisation process is for relevant Ministers in Scotland, England and Wales to make decisions on authorisation (with Ministers in Northern Ireland kept informed), taking into account the FSS/FSA scientific opinions, any relevant provisions of retained EU law and any other legitimate factors, including those raised during the consultation process.

Impacts

As part of the risk analysis process, FSS/FSA have assessed the potential impacts that would result from authorisation of these regulated products, should Ministers decide to authorise/extend/modify 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, modification or 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, including new authorisations, modifications 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 Scotland, England 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 FSS/FSA 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, FSS/FSA views are that there are no reasons for Ministers to refuse authorisation, modification or 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 FSS and the FSA are acting pursuant to their functions under the  Food (Scotland) Act 2015 and the Food Standards Act 1999.

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

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

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

Stakeholders are invited to consider the questions posed in relation to any relevant provisions of 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, FSS/FSA 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 available at [this link](https://www.food.gov.uk/risk-analysis/register-of-regulated-product-applications).

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.

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| 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 this document)?
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?
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Responses

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

Please state in your response via the questionnaire:

* Whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents)
* Which application(s)/product(s) you are commenting on.
* If you give us permission to quote your name or organisation in the publication of the results

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

All responses should be sent through the Citizen Space entry for this consultation.

Reponses will be shared with the FSA and Ministers.

Further information

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

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

This consultation has been prepared taking account of the Consultation Criteria.

The Consultation Criteria from the [HM Code of Practice on Consultation](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/100807/file47158.pdf) should be included in each consultation and they are listed below:

The Seven Consultation Criteria

Criterion 1 — When to consult

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

Criterion 2 — Duration of consultation exercises

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

Criterion 3 — Clarity of scope and impact

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

Criterion 4 — Accessibility of consultation exercises

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

Criterion 5 — The burden of consultation

*Keeping the burden of consultation to a minimum is essential if consultations are*

*to be effective and if consultees’ buy-in to the process is to be obtained.*

Criterion 6 — Responsiveness of consultation exercises

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

Criterion 7 — Capacity to consult

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

1. Criterion 2 states that *Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible*. This consultation has been shortened to 8 weeks for the following reasons:
* All 4 cases included within these second tranche draft recommendations are considered routine and should not raise undue concern with consumers, industry or businesses.
* Of the 4 cases all have already been ratified into EU legislation.
* FSS risk management recommendations are based on FSS/FSA review of EFSA opinions.
* Consulting for 12 weeks will place undue pressure on adhering to legislative deadlines for authorisations.
* Delivering authorisations efficiently will demonstrate that processes previously completed by the EU can be delivered at pace post EU Exit, aligning processes' timelines to facilitate authorisation processes for GB businesses with stakes in EU markets.
* An 8-week consultation period allows ample time for comments from industries.
* It is important to aim for consistency across the 4 countries wherever possible. All 4 regulated products in this consultation have already been authorised by the European Commission (EC) and by extension approved for use in Northern Ireland.
* With dual applications, regulation of products should keep pace with the EC.
* Any delay could create an uneven playing field for GB businesses and affect GB-NI trade.
1. The Code of Practice states that an Impact Assessment should normally be published alongside a formal consultation. An impact assessment was not required for this consultation.

Queries

1. If you have any queries relating to this consultation please contact the person named on page 1, who will be able to respond to your questions.

GDPR, Publication of personal data and confidentiality of responses

1. The European General Data Protection Regulation (GDPR) replaces the Data Protection Directive 95/46/EC and was developed to harmonize data privacy laws across Europe. The Data Protection Act (the DPA) 2018 applies GDPR standards and  transposes  the EU Data Protection Directive 2016/680 (Law Enforcement Directive) into domestic UK law. In accordance with the GDPR, we are required to provide a privacy notice in relation to this public consultation. Food Standards Scotland will be known as the “Controller” of the personal data provided to us. We need to collect this information to allow us to effectively carry out our official duties of policy development and for the purposes of record keeping. In responding to this consultation, you have consented to provide this information to us but are able to withdraw your consent at any time by getting in touch with us.
2. Personal information will be stored on Scottish Government servers and cloud based services have been procured and assessed against the national cyber security centre cloud security principles. Personal information will not be used for any purpose other than in relation to consultations. Personal information will be stored for as long as necessary to carry out the above functions and for five years from receipt in accordance with our retention policy. No third parties have access to your personal data unless the law allows them to do so.
3. You have a right to see the information we hold on you by making a request in writing to the email address below. If at any point you believe the information we process on you is incorrect you can request to have it corrected. If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data not in accordance with the law you can complain to the Information Commissioner’s Office (ICO). Our Data Protection Officer in the FSS is the Head of Corporate Services who can be contacted at the following email address: dataprotection@fss.scot
4. In accordance with the principle of openness, our office in Pilgrim House in Aberdeen will hold a copy of the completed consultation as per our retention policy. FSS will not publish anything without your consent. If you have any queries please email: dataprotection@fss.scot  or return by post to the address given on page 1.
5. In accordance with the provisions of Freedom of Information Act (Scotland) 2002/Environmental Information (Scotland) Regulations 2004, all information contained in your response may be subject to publication or disclosure. If you consider that some of the information provided in your response should not be disclosed, you should indicate the information concerned, request that it is not disclosed and explain what harm you consider would result from disclosure. The final decision on whether the information should be withheld rests with FSS. However, we will take into account your views when making this decision.
6. Any automatic confidentiality disclaimer generated by your IT system will not be considered as such a request unless you specifically include a request, with an explanation, in the main text of your response.
7. A detailed Privacy Policy is available on our [website](https://www.foodstandards.gov.scot/privacy/privacy-statement), that explains how FSS will safeguard and process any personal identifiable information that we collect from you in relation to this consultation.

Comments on the consultation process itself

1. We are interested in what you thought of this consultation and would therefore welcome your general feedback on both the consultation package and overall consultation process. If you would like to help us improve the quality of future consultations, please feel free to share your thoughts with us by sending an email to openness@fss.scot or return by post to the address given on page 1.

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

Joshua Evans

Policy Advisor

Labelling, Standards & Regulated Products

Food Standards Scotland

# 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

Baby Milk Action

Campden BRI

Cereal Ingredient Manufacturers’ Association

Council for Responsible Nutrition UK

Dairy UK

Federation of Bakers

Federation of Small Businesses (Scotland)

Food & Drink Federation (Scotland)

FDF Sector Group: Biscuit, Cake, Chocolate and Confectionery

FDF Sector Group: Food additives

Food Additives Industry Association (FAIA)

Health Food Manufacturers’ Association

Leatherhead Food International

Scottish Retail Consortium

Provision Trade Federation

Scientific Advisory Committee on Nutrition

Snack, Nut and Crisp Manufacturers’ Association

Scotland Food and Drink

UK Flavour Association

UK Flour Millers

Which?

This is not an exhaustive list.

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# Annex B: 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 μg/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 FSS/FSA 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 of entry to the list of authorised novel foods**

The [FSS/FSA scientific opinion](%E2%80%A2%09https%3A/www.food.gov.uk/research/novel-and-non-traditional-foods-additives-and-processes/assessment-of-the-safety-of-vitamin-d2-mushroom-agaricus-bisporus-powder-as-a-novel-food-ingredient) 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/100 ml (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) |
| Dairy products and analogues as beverages | 1.1 µg/100 ml (marketed as such or reconstituted as instructed by the manufacturer) |
| Milk and dairy powders | 21.3 µg/100 g (marketed as such or reconstituted as instructed by the manufacturer) |
| Meat analogues | 2.1 µg/100 g  |
| Soups | 2.1 µg/100 ml (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**

FSS/FSA 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**

FSS/FSA 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, FSS/FSA advice to Ministers will be to authorise on the proposed terms.

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# 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 μg/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 FSS/FSA 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.

FSS/FSA 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 of entry to the list of authorised novel foods**

The [FSS/FSA scientific opinion](%E2%80%A2%09https%3A/www.food.gov.uk/research/novel-and-non-traditional-foods-additives-and-processes/assessment-of-the-safety-of-the-extended-uses-of-uv-treated-bakers-yeast-s-cerevisiae-as-a-novel-food) 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 concentrate varies between 800 000 – 3 500 000 IU vitamin D/100 g (200-875 μg/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: ≤ 103 CFU/g
* *E. coli*: ≤ 10 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 μg/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 rolls1 | 5 µg/100 g |
| Yeast-leavened fine bakery wares1 | 5 µg/100 g |
| Food supplements as defined in EU Directive 2002/46/EC | In accordance with Directive 2002/46/EC |
| Pre-packed fresh or dry yeast for home baking2 | 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 609/20133 | In accordance with Retained EU Regulation No 609/2013 |
| Processed cereal-based food as defined by Retained EU Regulation No 609/20133 | 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 |
| 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**

FSS/FSA 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**

FSS/FSA 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 FSS/FSA 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).

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# 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 FSS/FSA 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.

FSS/FSA 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 [FSS/FSA scientific opinion](%E2%80%A2%09https%3A/www.food.gov.uk/research/novel-and-non-traditional-foods-additives-and-processes/assessment-for-the-application-for-a-change-in-the-steviol-glycoside-specification-in-great-britain-to-include-a-new) 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) of Part C, the following new entries are inserted:

|  |  |
| --- | --- |
|  **E-number** | **Name** |
|  E 960a |  Steviol glycosides 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:

1. 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;
2. there is a reasonable technological need that cannot be achieved by other economically and technologically practicable means; and
3. its use does not mislead the consumer.

**Other legitimate factors identified that Ministers may consider in making decisions**

FSS/FSA 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 FSS/FSA 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 Scotland, England and Wales will remove the current regulatory divergence within the UK.

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# Annex E: RP1382 – Flavouring 3-(1-((3,5-dimethylisoxazol-4-yl)methyl)-1*H*-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 FSS/FSA 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.

FSS/FSA 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 [FSS/FSA scientific opinion](https://www.food.gov.uk/research/novel-and-non-traditional-foods-additives-and-processes/assessment-of-new-flavouring-substance-3-1-35-dimethylisoxazol-4-ylmethyl-1h-pyrazol-4-yl-1-3-hydroxybenzylimidazolidine-24) 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](https://www.legislation.gov.uk/eur/2008/1334/contents). 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)-1*H*-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)

**Table 1 – Proposed uses**

| **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 |
| Edible ices | 3 | 4 mg/kg |
| Cocoa and chocolate products as covered by Directive 2000/36/EC | 5.1 | 15 mg/kg |
| Other confectionery 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, 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 |
| Soups 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 |
| 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/kg for dairy based desserts only |

**Any relevant provisions of retained EU law**

FSS/FSA 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**

FSS/FSA 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 FSS/FSA 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.

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