A purple text on a black background

Description automatically generated

Consultation on applications for authorisation of regulated products: one food additive, one feed additive (new specification), one food flavouring and the removal of eight permitted food flavourings, one food contact material, two novel foods and three genetically modified organisms for food and feed uses

### Consultation Summary Page

|  |  |
| --- | --- |
| Date consultation launched: | Closing date for responses: |
| 8th January 2025 | 5th March 2025 |

#### Who will this consultation be of most interest to?

This consultation will be of most interest to:

All Scottish food and feed businesses, local and district councils, and other stakeholders with an interest in food and feed safety.

A list of interested parties is included in [Annex A](#_Annex_A:_List_3).

#### What is the purpose of this consultation?

#### This consultation is conducted by Food Standards Scotland (FSS) on behalf of the Minister for Public Health and Women's Health and seeks stakeholders’ views, comments and feedback in relation to the regulated product applications considered in this document.

FSS have recently assessed one food additive application, one feed additive application, one food flavouring application, one application to remove eight permitted food flavourings, one food contact material application, two novel food applications and three genetically modified organism applications (GMOs).

The FSS opinions provided in the annexes to this document (including the proposed terms of authorisation) take into account the FSS/FSA safety assessments. The views gathered through this consultation will be considered and included alongside those of officials across FSS and other Government Departments to inform Ministers’ decision-making on whether to authorise the individual regulated products for use in Scotland.

The FSA have also published their opinions and launched a [parallel consultation](https://www.food.gov.uk/news-alerts/consultations/consultation-on-market-authorisation-of-10-regulated-food-and-feed-products-december-2024) for English and Welsh stakeholders.

FSS is responsible for providing the Minister for Public Health and Women's Health with recommendations on the applications for the authorisation of regulated products in respect of matters connected with food safety or other interests of consumers in relation to food ([Section 3 of the Food (Scotland) Act 2015](https://www.legislation.gov.uk/asp/2015/1/contents) and [sections 6 and 9 of the Food Standards Act 1999](https://www.legislation.gov.uk/ukpga/1999/28/contents)).

#### What is the subject of this consultation?

This consultation seeks stakeholders’ views, comments and feedback in relation to the regulated product applications included and referenced in this document.

The consultation concerns the following applications:

* a new specification of an existing permitted food additive
* a new use for an existing permitted feed additive
* a new authorisation for one food flavouring
* the removal of eight food flavourings (one application covering eight food flavourings)
* a new authorisation for one food contact material (FCM)
* a new authorisation of one novel food and an extension of use of an existing novel food
* three new authorisations for three Genetically Modified Organisms (GMOs) for food and feed uses

We ask stakeholders to consider any relevant provisions of law and other legitimate factors (other evidence further supporting clear, rational and justifiable risk analysis, such as consumer interests, technical feasibility and environmental factors), including those that FSS have identified as relevant to these applications. This is an opportunity for stakeholders to express views on these applications which Scottish Ministers will use to inform their decision making, which we consider crucial to the process of transparent policymaking.

#### 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

[LabellingStandardsandRegulatedProducts@fss.scot](mailto:LabellingStandardsandRegulatedProducts@fss.scot)

#### Postal address

Food Standards Scotland

Fourth Floor

Pilgrim House

Old Ford Road

Aberdeen

AB11 5RL

Is a Business & Regulatory Impact Assessment (BRIA) included with this consultation?

Yes No

### Introduction

In order to be placed on the market in Scotland, applications for the authorisation of regulated products must be submitted to the Great Britain (GB) regulated products process. The decision on authorisation is made by the respective Minister in Scotland, England and Wales, with the Minister in Northern Ireland kept informed.

This is a function that was previously carried out at EU level. Regulated product applications for the GB market, including food additives, feed additives, food flavourings, FCMs, novel foods and GMOs are now subject to the UK’s own risk analysis process.

FSS has been working to ensure that the high standard of food and feed safety and consumer protection in Scotland continues. This is in line with 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 3, Food (Scotland) Act 2015 and Sections 6 &9, Food Standards Act 1999).

Under current operating arrangements for Northern Ireland, businesses seeking a new authorisation for a regulated food and feed products to be placed on the Northern Ireland market will continue to follow EU rules.

FSS 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.

Subject to one exception, the applications within this consultation have undergone a full FSS safety assessment (arrived at in collaboration with FSA and meeting our obligation to carry out a risk assessment), including a full review of the dossiers and supplementary information provided by the applicants. The exception is the application for the removal of eight food flavourings, which does not require a safety assessment.

This consultation seeks to gather Scottish stakeholders’ views on the proposed regulated product applications for authorisations.

[The provisional Food and Feed Safety and Hygiene Common Framework](https://www.gov.uk/government/publications/food-and-feed-safety-and-hygiene-provisional-common-framework) is a non-statutory arrangement between the UK Government and Devolved Administrations to establish common approaches to policy areas where powers have returned from the EU within areas of devolved competence. This consultation has been developed under the commitments to collaborative four-nation working set out in this Framework.

This consultation letter and the FSS Risk Management recommendations document present the opinions of FSS and any legitimate factors that FSS have identified as relevant to these applications, including the potential impact of any decision made by Ministers. Stakeholders are invited to use this opportunity to comment on these factors or highlight any additional factors that should be brought to the attention of Ministers before a final decision is made.

Following the consultation, Scottish Ministers in Scotland will make a decision on authorisation. They will consider the FSS recommendation, any relevant provisions of law and any other legitimate factors, including those raised during the consultation process.

### Detail of Consultation

#### Food Additives

Food additives are substances which are added to food to perform a technological function, exerting an effect on a food. [Regulation (EC) 1333/2008](https://www.legislation.gov.uk/eur/2008/1333/introduction) 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”.

#### Feed Additives

Feed additives are substances, micro-organisms or preparations (other than feed materials and premixtures) which are intentionally added to feed or water to perform, in particular, one or more specific functions. For further information see the 'Supplementary information' section in Annex B of the accompanying Risk Management document. To place new feed additives on the GB market, an application must be submitted in accordance with [Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents). Feed additives are authorised for a ten-year period. Authorisations can be considered for renewal where an application is re-submitted, at the latest, one-year prior to the authorisation’s expiry date. The procedure for each type of application is laid down in Regulation (EC)1831/2003 as follows:

* Article 4, application for a new authorisation or for a new use of a feed additive
* Article 13, application for modification of authorisation
* Article 14, application for a renewal of authorisation

#### Food Flavourings

Food Flavourings are ‘products not intended to be consumed as such, which are added to food in order to impart or modify odour and/or taste’ as defined by [Regulation (EC) 1334/2008](https://www.legislation.gov.uk/eur/2008/1334/body) on flavourings and certain food ingredients with flavouring properties for use in and on foods.

#### FCM

FCMs are materials and articles that come into contact with food during its production, processing, storage, preparation or serving.

#### Novel foods

Novel foods are foods that were not used for human consumption to a significant degree within the UK or EU before 15 May 1997. In Scotland, the procedure for authorising the placing of new novel foods on the GB market, or to change the specifications or conditions of use of authorised novel foods, starts either on the initiative of the Ministers or following the submission of an application by an applicant in accordance with [Regulation (EU) 2015/2283](https://www.legislation.gov.uk/eur/2015/2283). The applications for authorisation of novel foods which are included in this consultation have been made under Article 10 of this Regulation, which outlines the procedure for authorising the placing on the market of novel foods and the updating of the [public list](https://data.food.gov.uk/regulated-products/landing).

In accordance with Regulation (EU) 2015/2283 on novel foods and [Regulation (EC) 1331/2008](https://www.legislation.gov.uk/eur/2008/1331/contents) which establishes a common authorisation procedure for food additives, food enzymes and food flavourings, the novel food and food additive applications included in this consultation have been submitted for new authorisations, modification and change of an existing authorisation, a new production method of an existing authorisation and removal of existing authorisations.

#### GMOs

GMOs are plants and animals with a genetic make-up that has been modified using techniques of biotechnology. Genetic modification allows scientists to produce plants, animals and micro-organisms with specific qualities. Genetically modified food and feed contain or consist of GMOs or are produced from GMOs. For new authorisations, renewals and modifications of existing authorisations for GMOs to be placed on the GB market, an application must be submitted in accordance with [Regulation (EC)1829/2003](https://www.legislation.gov.uk/eur/2003/1829/introduction).

### Terms of reference

#### Assimilated Law and EU Regulations

Directly applicable EU legislation no longer applies in GB. EU legislation, retained when the UK exited the EU, is called assimilated law as of 31 December 2023. References to any legislation with ‘EU’ or ‘EC’ in the title (e.g. Regulation (EU) 2015/2283 or Regulation (EC) 1333/2008) should now be regarded as assimilated law where applicable to GB. Assimilated law is published on [https://www.legislation.gov.uk](https://www.legislation.gov.uk/). References to ‘Retained EU Law’ or ‘REUL’ should now be regarded as references to law.

### Northern Ireland – Windsor Framework

In October 2023, the Windsor Framework was implemented providing a unique set of arrangements to support the flow of agrifood retail food products from GB to Northern Ireland. These goods can meet the same standards applied in the rest of the UK in public health, marketing (including labelling) and organic foods when moving through the Northern Ireland Retail Movement Scheme (NIRMS). Under the NIRMS regulated products which have been authorised in GB will be able to be placed on the market in Northern Ireland.

The scheme extends to some pet food and dog chews. Feed for particular nutritional uses (PARNUTs) and feed additives, whether being used to produce compound feeds or being fed directly to livestock, would not be able to benefit from the scheme. However, if goods remain in Northern Ireland, traders can benefit from the Movement Assurance Scheme to recoup costs associated with certification. In Northern Ireland, feed additives used in qualifying Northern Ireland goods would be able to be placed on the market in GB.

### Impacts

As part of the risk analysis process, FSS have assessed the potential impacts that may result should Ministers decide to authorise these regulated product applications. 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 and feed law (i.e. local authority delivery, health, environment, growth, innovation, trade, competition, consumer interests or small and micro-businesses).

For the applications in this consultation, no significant impacts have been identified. Individual detailed impacts, including trade, Northern Ireland and other legitimate factors for each application are listed in the corresponding risk management (RM) document for each application. The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

### Other legitimate factors

We have considered a range of other legitimate factors that Ministers may wish to consider in making decisions about these regulated product applications including political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours. Our collective assessment of the other legitimate factors did not identify any impacts.

### Engagement and Consultation Process

#### Regulated Products

Details of all valid applications for regulated products are published monthly on the Register of Regulated Product Applications, available [here](https://data.food.gov.uk/regulated-product-applications).

Stakeholders are invited to consider the questions below.

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

### Questions asked in this consultation (for all applications with the exception of RP2184 flavouring removals)

1. Do you have any concerns about the safety of the application with respect to the intended consumers?
2. Do you have any comments or concerns on the impacts of authorising or not authorising the application and, if in favour of authorisation, the terms on which the application is authorised (as outlined in the RM recommendations)?
3. Are there any other factors that should be considered by Ministers that have not already been highlighted?
4. Do you have any other feedback? Including consideration of any relevant provisions of law and other legitimate factors (other evidence further supporting clear, rational and justifiable risk analysis, such as consumer interests, technical feasibility and environmental factors).

#### Additional question for food additive (RP1112) Steviol glycosides from fermentation Rebaudioside M only

1. Do you have any feedback concerning the proposed specification for E 960b(ii) Rebaudioside M from fermentation (*Saccharomyces cerevisiae)?*

#### Additional question for novel food (RP956) Magnesium L-threonate only

1. Do you have any comments about adding magnesium L-threonate to Schedule 2 of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 as a form of magnesium to enable its use in food supplements?

### Questions asked in this consultation for application RP2184 only

1. UK industry has indicated that they no longer use these flavouring substances. Do you agree with our view that there should be no significant impact on UK businesses from removing them from the list?
2. Do you believe that transition arrangements are necessary or should be considered for foods containing these flavourings which are placed on the market before any decision to remove them from the list is processed? Should any such transitional measures also apply for foods dispatched for export to Great Britain? Please explain your answer.
3. If you disagree with the FSS’ view or have particular concern about the removal of any of the eight flavourings, please explain why and provide information to help us understand and evidence the impact. Please include details on which of the flavouring substances (including the relevant FL Number) your feedback relates to and, if applicable, the type of product you are using it in.
4. For any of the eight flavourings to stay on the list, industry will need to commit to providing the necessary safety studies to allow the risk assessment to be completed. If you believe any of the eight flavourings should remain on the list, please identify who would be willing to provide the necessary safety studies and for which flavouring substances (e.g. please provide the FL number)?
5. Impacts on countries outside of the EU need to be considered. The International Organization of the Flavor Industry does not consider there to be any impacts as they are not widely used across the global market. Do you agree with this assessment? If not, please explain your answer.
6. Are there any other factors that should be considered by ministers that have not already been highlighted?
7. Do you have any other feedback? Including consideration of any relevant legal provisions and other legitimate factors (other evidence further supporting clear, rational and justifiable risk analysis, such as consumer interests, technical feasibility and environmental factors).

### Responses

This consultation will run for 8 weeks. Responses are required by close of 5th March 2025.

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 (please also make sure you have read and understood the paragraphs below where we discuss GDPR, publication of personal data and confidentiality of responses) or that of the organisation on whose behalf you are participating in the consultation in the publication of the results. For information on how FSS handles your personal data, please refer to the [Consultation Privacy notice](https://www.foodstandards.gov.scot/privacy/privacy-notices/consultations-privacy-notice).
* Please indicate which application(s)/product(s) you are responding to by using the following subject line for your response: “Response to and the subject of the consultation (novel foods/ food additives/ flavourings/ flavouring removals/ food contact materials/ feed additives/ genetically modified organisms).”

FSS aim to publish all responses to this consultation on Citizen Space 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 information

Criterion 1 — When to consult

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

Criterion 2 — Duration of consultation exercises

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

Criterion 3 — Clarity of scope and impact

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

Criterion 4 — Accessibility of consultation exercises

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

Criterion 5 — The burden of consultation

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

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

Criterion 6 — Responsiveness of consultation exercises

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

Criterion 7 — Capacity to consult

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

Criterion 2 states that *Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible*.

This consultation has been shortened to 8 weeks for the following reasons:

* The regulated product applications are considered routine and should not raise undue concern with users, industry or businesses.
* FSS risk management recommendations are informed by the FSS review of EFSA opinions.
* Consulting for 12 weeks will place undue pressure on adhering to legislative deadlines for authorisations.
* Making decisions on 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.
* It is considered that, in this instance, an 8-week consultation period allows ample time for comments from stakeholders.
* It is important to aim for consistency across the four nations of the United Kingdom wherever possible. All ten of the applications in this consultation have already been approved by the EU 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.

The Code of Practice states that an Impact Assessment should normally be published alongside a formal consultation. An impact assessment was not required for this consultation.

### Queries

If you have any queries relating to this consultation, please contact FSS using the contact details on page 4, and an FSS official will be able to respond to your questions.

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

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 (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. FSS 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.

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.

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](mailto:dataprotection@fss.scot).

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](mailto:dataprotection@fss.scot.) or return by post to the address given on page 4.

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.

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.

A detailed Privacy Policy is available on our [website](https://www.foodstandards.gov.scot/privacy), that explains how FSS will safeguard and process any personal identifiable information that we collect from you in relation to this consultation.

### Comments on the consultation process

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](mailto:openness@fss.scot) or return by post to the address given on page 4.

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

Regulated Products Team

Food Standards Scotland

LabellingStandardsandRegulatedProducts@fss.scot

### List of Annexes

[Annex A: List of interested parties](#Annx_A)

Details of the applications are given in the annexes below and in the FSS risk management recommendation documents which include the FSS opinions.

[Annex B: RP1112](#_Annex_B:_RP16) - Steviol Glycosides (E 960b) produced by Fermentation (new specification of a permitted food additive)

[Annex C: RP694](#_Annex_C:_RP24) – Saccharomyces cerevisiae CNCM I-1079 (new use) (Feed Additive)

[Annex D: RP1466](#_Annex_D:_RP25) - 2-Hydroxy-4-methoxybenzaldehyde (new authorisation) (Flavouring)

[Annex E: RP2184](#Annex_E) - Removal of 8 permitted food flavouring substances from the domestic list

[Annex F: RP1190](#_Annex_F:_RP29) – phosphoric acid, mixed esters with 2-hydroxyethyl methacrylate (HEMAP) (CAS No. 52628-03-2) (new authorisation) (Food Contact Material)

[Annex G: RP956](#Annex_G) – Magnesium L-threonate (new authorisation) (Novel Foods)

[Annex H: RP1033](#_Background) - Isomaltooligosaccharide (IMO) (Extension of use) (Novel Food)

[Annex I: RP1123](#_Annex_G:_RP140) - GMB151 (new authorisation) (Genetically Modified Organisms (GMOs) for food and feed uses)

[Annex J: RP1232](#_Annex_H:_RP141) - GHB811 Cotton (new authorisation) (Genetically Modified Organisms (GMOs) for food and feed uses)

[Annex K: RP1506](#_Annex_I:_RP142) - Genetically Modified maize DP4114 x MON 810 x MIR604 x NK603 and sub-combinations (new authorisation)(Genetically Modified Organisms (GMOs) for food and feed uses)

### Annex A: List of interested parties

Key stakeholder trade associations who have an interest in food and feed across the wider sector will be contacted directly for feedback on this consultation:

Agricultural Industries Confederation

Agricultural Industries Confederation Scotland

British Association of Feed Supplement and Additive Manufacturers

British Equestrian Trade Association

Grain and Feed Trade Association

National Farmers Union of Scotland

Scottish Quality Crops British

Specialist Nutrition Association

British Nutrition Foundation

British Retail Consortium (BRC)

Chilled Food Association (CFA)

Food and Drink Federation FDF (Scotland) British Dietetic Association

Food and Drink Federation FDF Sector Group: Food additives

UK Flavour Association (UKFA)

Food Additives & Ingredients Association (FAIA) Federation of Bakers

Health Food Manufacturers’ Association

Campden BRI

Council for Responsible Nutrition UK

Scottish Retail Consortium

International Organization of the Flavor Industry (IOFI)

BRPPA: British Rubber and Polyurethane Products Association

The Packaging Federation

This is not an exhaustive list.

[Return to top of consultation document.](#_top)

Annex B: RP1112 - Steviol Glycosides (E 960b) produced by Fermentation (new specification of a permitted food additive)

### Background

An application for new specification of steviol glycosides (E 960b) produced by fermentation as a food additive (sweetener) was received from Amyris Inc. Amyris, Inc. has applied for the authorisation of a rebaudioside M that is made by fermenting food grade cane sugar with genetically modified (GM) *Saccharomyces cerevisiae.*

As this application is for rebaudioside M produced using a different microorganism *(S. cerevisiae),* it must be authorised before use as required by Article 12 of Regulation (EC) 1333/2008, which states that any permitted food additive made using a different production method needs to be authorised and a new specification must be set in legislation before the food additive can be used in food or sold.

### FSS RM recommendation

It is the opinion of FSS, as per [Article 5 Regulation (EC) 1331/2008](https://www.legislation.gov.uk/eur/2008/1331/article/5), that rebaudioside M from fermentation *(S. cerevisiae*), as described in this application, is safe and not liable to have an adverse effect on the target population, environmental safety or human health at the intended concentrations of use.

The full FSS risk management recommendation, which includes a link to the safety assessment and details the terms of use of the food additive, can be found in the Risk Management document.

[Return to top of consultation document.](#_top)

Annex C: RP694 - *Saccharomyces cerevisiae* CNCM I-1079 (new use) (Feed Additive)

### Background

An application for the new intended use of feed additive (*Saccharomyces cerevisiae* CNCM I-1079), under the category of ‘zootechnical’ and in the functional groups ‘gut flora stabiliser’ and ‘physiological condition stabiliser’ for its use in calves, and all other ruminants and camelidae, for rearing and fattening, at their correspondent developmental stage, was received from Lallemand Animal Nutrition UK. Since receipt of the application, the applicant has subsequently withdrawn the proposal for the additive to be classified in the ‘physiological condition stabiliser’ functional group.

### FSS RM recommendation

It is the opinion of FSS, as per [Article 4 & 7 Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/chapter/II), that *Saccharomyces cerevisiae* CNCM I-1079, as described in this application, is safe and not liable to have an adverse effect on the target species, environmental safety and or human health in its intended use.

The full FSS risk management recommendation, which includes a link to the safety assessment, can be found in the Risk Management document.

[Return to top of consultation document.](#_top)

Annex D: RP1466 - 2-Hydroxy-4-methoxybenzaldehyde (new authorisation) (Flavouring)

### Background

An application for 2-hydroxy-4-methoxybenzaldehyde as a new flavouring substance to be used in food, was received from Firmenich S.A.

### FSS RM recommendation

It is the opinion of FSS, as per [Article 5 Regulation (EC) 1331/2008](https://www.legislation.gov.uk/eur/2008/1331/article/5), that 2-hydroxy-4-methoxybenzaldehyde, as described in this application, is safe and not liable to have an adverse effect on the target population, environmental safety and human health at the intended concentrations of use.

The full FSS risk management recommendation, which includes a link to the safety assessment and details the proposed terms of use of the flavouring substance, can be found in the Risk Management document.

[Return to top of consultation document.](#_top)

Annex E: RP2184 - removal of eight permitted food flavouring substances from the domestic list

### Background

An application to update the list of flavouring substances to remove eight flavouring substances on the terms below has been submitted.

The eight flavouring substances included in the application that are proposed to be removed from the domestic list are:

• 2-Phenylpent-2-enal (FL No. 05.175)

• 2-Phenyl-4-methyl-2-hexenal (FL No. 05.222)

• 2-(sec-Butyl)-4,5-dimethyl-3-thiazoline (FL No. 15.029)

• 4,5-Dimethyl-2-ethyl-3-thiazoline (FL No. 15.030)

• 2,4-Dimethyl-3-thiazoline (FL No. 15.060)

• 2-Isobutyl-3-thiazoline (FL No. 15.119)

• 5-Ethyl-4-methyl-2-(2-methylpropyl)-thiazoline (FL No. 15.130)

• 5-Ethyl-4-methyl-2-(2-butyl)-thiazoline (FL No. 15.131)

### FSS RM recommendation

It is the opinion of FSS, as per [Article 5 Regulation (EC) 1331/2008](https://www.legislation.gov.uk/eur/2008/1331/article/5), that these eight flavouring substances should be removed from the list of permitted flavouring substances, but with transitional provisions set for the flavourings themselves and foods containing them.

[Return to top of consultation document.](#_top)

Annex F: RP1190 - phosphoric acid, mixed esters with 2-hydroxyethyl methacrylate (HEMAP) (CAS No. 52628-03-2) (new authorisation) (Food Contact Material)

### Background

An application for the new authorisation for phosphoric acid, mixed esters with 2-hydroxyethyl methacrylate (HEMAP) (CAS No. 52628-03-2) intended to be used in plastic Food Contact Materials (FCMs), was received from Keller and Heckman LLP.

### FSS RM recommendation

It is the opinion of FSS, as per [Article 10, Regulation (EC) 1935/2004](https://www.legislation.gov.uk/eur/2004/1935/article/10), that HEMAP, as described in this application, is safe and not liable to have an adverse effect on the target population, environmental safety and or human health in its intended use.

The full FSS risk management recommendation, which includes a link to the safety assessment, can be found in the Risk Management document.

[Return to top of consultation document.](#_top)

Annex G: RP956 – Magnesium L-threonate (new authorisation) (Novel Foods)

### Background

An application for the new authorisation for the use of magnesium L-threonate monohydrate as a novel food in food supplements was received from AIDP, USA. The application also requests that magnesium L-threonate monohydrate is permitted as a form of magnesium to be used in the manufacture of food supplements and added to the table which is set out in ['Schedule 2](https://www.legislation.gov.uk/uksi/2019/651/schedule/2) of [The Nutrition (Amendment etc.) (European Union Exit) Regulations 2019](https://www.legislation.gov.uk/uksi/2019/651/contents).

### FSS RM recommendation

It is the opinion of FSS, as per [Article 11 Regulation (EU) 2015/2283](https://www.legislation.gov.uk/eur/2015/2283/article/11), that Magnesium-L-threonate monohydrate, as described in this application, is safe and not liable to have an adverse effect on the target population, environmental safety and human health at the intended concentrations of use.

The full FSS risk management recommendation which includes a link to the safety assessment and details the proposed terms of use of the novel food, can be found on the consultation page.

[Return to top of consultation document.](#_top)

Annex H: RP1033 - Isomaltooligosaccharide (IMO) (Extension of use) (Novel Food)

### Background

An application for the extension of use of IMO (also known as oligo-isomaltose) as a novel food was received from Bioneutra Incorporated, North America. IMO is currently authorised as a novel food under [Regulation (EU) 2017/2470](https://www.legislation.gov.uk/eur/2017/2470/contents), for use in 12 different food categories. The application proposes the extension of IMO use as an ingredient in 15 further food categories and for use in supplements.

### FSS RM recommendation

It is the opinion of FSS, as per [Article 11 Regulation (EU) 2015/2283,](https://www.legislation.gov.uk/eur/2015/2283/article/11) that IMO, as described in this application, is safe and not liable to have an adverse effect on the target population, environmental safety and human health at the intended concentrations of use.

The full FSS risk management recommendation which includes a link to the safety assessment and details the proposed terms of use of the novel food, can be found on the consultation page.

[Return to top of consultation document.](#_top)

Annex I: RP1123 - GMB151 (new authorisation) (Genetically Modified Organisms (GMOs) for food and feed uses)

### Background

An application for the new authorisation of genetically modified GMB151 soybean for import, processing and food and feed uses, was received from BASF Agricultural Solutions Seed US LLC. The application does not cover cultivation and therefore no GMB151 soybean will be grown in the UK.

### FSS RM recommendation

It is the opinion of FSS, as per [Article 6 Regulation (EC) 1829/2003](https://www.legislation.gov.uk/eur/2003/1829/article/6), that GMB151 soybean, as described in this application, is safe and not liable to have an adverse effect on the target population, environmental safety and or human health at the intended concentrations of use.

The full FSS risk management recommendation which includes a link to the safety assessment and details the proposed terms of use of the GMO, can be found on the consultation page.

[Return to top of consultation document.](#_top)

Annex J: RP1232 - GHB811 Cotton (new authorisation) (Genetically Modified Organisms (GMOs) for food and feed uses)

### Background

An application for the new authorisation of genetically modified GHB811 cotton for import, processing and food and feed uses, was received from BASF Agricultural Solutions Seed US LLC. The application does not cover cultivation and therefore no GHB811 cotton will be grown in the UK.

### FSS RM recommendation

It is the opinion of FSS, as per [Article 6 Regulation (EC) 1829/2003](https://www.legislation.gov.uk/eur/2003/1829/article/6), that Cotton GHB811, as described in this application, is safe and not liable to have an adverse effect on the target population, environmental safety and or human health at the intended concentrations of use.

The full FSS risk management recommendation which includes a link to the safety assessment and details the proposed terms of use of the GMO, can be found on the consultation page.

[Return to top of consultation document.](#_top)

Annex K: RP1506 – Genetically Modified maize DP411 x MON 810 x MIR604 x NK603 and sub-combinations (new authoirsation) (Genetically Modified Organisms (GMOs) for food and feed uses)

### Background

An application for the new authorisation of genetically modified maize DP4114 x MON 810 x MIR604 x NK603 (unique identifier: DP-ØØ4114-3xMONØØ81Ø-6xSYN-IR6Ø4-5xMON-ØØ6Ø3-6) was received from Corteva Agrisciences LLC Represented by Corteva Agriscience UK Limited. The application does not cover cultivation and therefore no GMB151 soybean will be grown in the UK.

### FSS RM recommendation

It is the opinion of FSS, as per [Article 6 Regulation (EC) 1829/2003](https://www.legislation.gov.uk/eur/2003/1829/article/6), that maize DP4114 x MON 810 x MIR604 x NK603, as described in this application, is safe and not liable to have an adverse effect on the target population, environmental safety and or human health at the intended concentrations of use.

The full FSS risk management recommendation which includes a link to the safety assessment and details the proposed terms of use of the GMO, can be found on the consultation page.

[Return to top of consultation document.](#_top)