Consultation Pack on Market Authorisation of 10 Regulated Food and Feed Products December 2024

This consultation seeks stakeholders' views, comments and feedback in relation to regulated product applications considered in this document.

Launch date: 18 December 2024

Respond by: 19 February 2025

This consultation will be of most interest to

All England, Wales, and Northern Ireland food and feed businesses, local and port health authorities, district councils, and other stakeholders with an interest in food and feed safety. A parallel consultation is being published by FSS to inform the Minister in Scotland before they make a decision.

Purpose of the consultation

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

- ?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 8 food flavourings (one application covering eight food flavourings)
- a new authorisation for one Food Contact Material (FCM)
- 3 new authorisations for 3?Genetically Modified Organisms (GMOs) for food and feed uses
- a new authorisation of one novel food and an extension of use of an existing novel food

How to respond

Responses to this consultation should be **submitted via the?online survey**. If this is not possible, you can email a response to:

Email:?RPconsultations@food.gov.uk

Full details on how to respond are given in the 'Reponses' section.

Definitions

The Regulated Product types in this consultation are food and feed additives, flavourings, Food Contact Materials (FCM), Genetically Modified Organisms (GMOs) and novel foods.

The definitions below provide information that may be of use when responding to this consultation.

Regulated Products are certain food and feed products that must go through a risk analysis process and require authorisation before they can be sold in the UK.?You can find out more about the application process, including the risk analysis and risk management processes and ministerial involvement here: Background on placing a regulated product on the market.

Food additives are substances which are added to food to perform a technological function exerting an effect on a food. Assimilated 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’.

Food additives

Food additives authorisation guidance

Feed additives are substances, micro-organisms or preparations (other than feed materials and premixtures) which are intentionally added to feed or water to perform one or more specific functions.?

Feed additives authorisation guidance

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 assimilated Regulation 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods.

Flavourings authorisation guidance

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

Food contact materials authorisation guidance

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 Great Britain market, an application must be submitted in accordance with assimilated Regulation 1829/2003.

Genetically modified foods

Novel foods are foods that were not used for human consumption to a significant degree within the UK or European Union (EU) before 15 May 1997. To place new novel foods on the Great Britain market or to change the specifications or conditions of use of authorised novel foods, applicants must submit an application in accordance with assimilated Regulation 2015/2283.

Novel foods authorisation guidance

Assimilated Regulations - Directly applicable EU legislation no longer applies in Great Britain. EU legislation, retained when the UK exited the EU, was assimilated on 31 December 2023. References to any legislation with ‘EU’ or ‘EC’ in the title should now be regarded as assimilated law where applicable to Great Britain. Assimilated law is published on legislation gov.uk.

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

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

Transitional Periods - Transitional arrangements may be applied, for example, where the criteria of a new authorisation differs from the existing food or feed authorisation, or where authorisations are removed, to allow existing stocks and products on the market to be used up. Transitional arrangements are only referenced where applicable, based on significant change between the existing and new authorisation or for removal of authorisations.

Windsor Framework - For goods eligible for Northern Ireland Retail Movement Scheme (NIRMS):

In October 2023, the Windsor Framework was implemented providing a unique set of arrangements to support the flow of agrifood retail food products from Great Britain 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 Northern Ireland Retail Movement Scheme, regulated products which have been authorised in Great Britain, will be able to be placed on the market in Northern Ireland

The FSA remain committed to ensuring that consumers across the UK can be confident that food is safe and is what it says it is, even where rules applicable to the same type of food may be slightly different

Windsor Framework - feed additives

In October 2023 the Windsor Framework was implemented providing a unique set of arrangements to support the flow of agri-food retail food products from Great Britain 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 NIRMS.

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 form 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 Great Britain in line with the Government’s steadfast commitment to ensuring Northern Ireland’s unfettered access to the Great Britain market.

Safety Assessment – FSA / FSS Risk Assessors deliver the science behind our advice. They are responsible for identifying and characterising hazards and risks to health and assessing exposure levels. Links to the safety assessment can be found in the relevant corresponding Annex below.

Risk Management - Our policy advisors are responsible for the risk management outputs. The FSA risk management recommendations document presents the factors that they have identified as relevant to these applications, including the potential impact of any decision made by ministers, and contains proposed terms of authorisation and other relevant provisions. Links to the risk management recommendations document for each application can be found in the relevant corresponding Annex below.

Details of Consultation

Introduction

This consultation seeks views on the regulated products applications for one food additive, one feed additive, one food flavouring and the removal of 8 permitted flavouring substances, one FCM, 3 GMO (for food and feed uses) and 2 novel foods.

An overview of the details for each of the applications can be found in the below Annexes. For further information, please refer to the technical documents of the FSA/FSS safety assessments and FSA risk management recommendations documents as hyperlinked in the corresponding Annex.

Annexes to applications

Annex 1: RP1112 - Steviol Glycosides (E 960b) produced by Fermentation (new specification of a permitted food additive)

Annex 2: RP694 - Saccharomyces cerevisiae CNCM I-1079 (new use) (Feed Additive)

Annex 3: RP1466 - 2-Hydroxy-4-methoxybenzaldehyde (new authorisation) (Flavouring)

Annex 4: RP2184 - removal of 8 permitted food flavouring substances from the domestic list?

Annex 5: RP1190 - phosphoric acid, mixed esters with 2-hydroxyethyl methacrylate (HEMAP) (CAS No. 52628-03-2) (new authorisation) (Food Contact Material)

Annex 6: RP1123 – GMB151 (new authorisation) (Genetically Modified Organisms (GMOs) for food and feed uses)

Annex 7: RP1232 - GHB811 Cotton (new authorisation) (Genetically Modified Organisms (GMOs) for food and feed uses)

Annex 8: RP1506 - 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 9: RP1033 - Isomaltooligosaccharide (IMO) (Extension of use) (Novel Food)

Annex 10: RP956 – Magnesium L-threonate (new authorisation) (Novel Foods)

In consulting, the FSA is seeking views from stakeholders on the proposed authorisation and the terms on which it is proposed, any transitional period or labelling requirements, and on any other legitimate factors (i.e. social, environmental, economic, etc) as identified. Stakeholders are invited

to use this opportunity to comment on these factors or highlight any additional factors that should be brought to the attention of ministers before a final decision is made.

Following the consultation, the next step is for the FSA to write to ministers in England, Wales and Northern Ireland with their recommendations. This is in line with FSA responsibility to provide recommendations to ministers in respect of matters connected with food safety or other interests of consumers in relation to food (section 6, Food Standards Act 1999). Relevant ministers will then make decisions on authorisation, taking into account the FSA risk management recommendations, any relevant provisions of assimilated law and any other legitimate factors, including those raised during the consultation process.

Impacts

As part of the risk analysis and risk management process, the FSA has assessed the potential impacts that would result from the proposals. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, political, environmental, societal, technical feasibility, and consumer interests).

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 document for each application. The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

Engagement and Consultation Process

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

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

Questions

Questions for the authorisation of applications

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

1a) Do you have any concerns about the safety of the application with respect to the intended consumers?

1b) 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 FSA risk management recommendations)?

1c) Are there any other factors that should be considered by ministers that have not already been highlighted?

1d) Do you have any other feedback? Including consideration of any relevant provisions of assimilated law and other legitimate factors (other evidence further supporting clear, rational and justifiable risk analysis, such as consumer interests, technical feasibility and environmental factors).

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

1e) 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.

1f) 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 for the removal of 8 flavourings (RP 2184 only)

Questions asked in this consultation:

2a) 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?

2b) 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.

2c) If you disagree with the FSA's view or have particular concern about the removal of any of the 8 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.

2d) For any of the 8 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 8 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)?

2e) 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.

2f) Are there any other factors that should be considered by ministers that have not already been highlighted?

2g) Do you have any other feedback? Including consideration of any relevant provisions of assimilated law and other legitimate factors (other evidence further supporting clear, rational and justifiable risk analysis, such as consumer interests, technical feasibility and environmental factors).

Responses

Responses are required by 23:59 on 19 February 2025. Please state in your response whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents).

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

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

‘Response to and the subject of the consultation (novel foods/ food additives/ flavourings/ flavouring removals/ food contact materials/ feed additives/ genetically modified organisms).’

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

We aim to publish a summary of responses to this consultation at around 3 months of the consultation closing.

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

A summary of responses will be shared with ministers in England, Wales and Northern Ireland.

Further Information

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

This consultation has been prepared in accordance with HM Government Consultation Principles.

Thank you on behalf of the FSA for participating in this public consultation.

Regulated Products Service Delivery

Annex 1: RP1112 - Steviol Glycosides (E 960b) produced by Fermentation (new specification of a permitted food additive)

Background

An application for a new specification of steviol glycosides (E 960b) produced by fermentation as a food additive (sweetener) was received by the FSA 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 assimilated Regulation (EC) No.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.?

Trade

Food exported from the UK to other countries/blocs will need to continue to meet the rules of those countries/blocs.

European Union (EU)

No steviol glycosides made by fermentation (E 960b) have been authorised by the EU, and therefore there will be divergence with EU legislation.

Northern Ireland

Steviol glycosides made by fermentation (E 960b) is not currently authorised in Northern Ireland. However, goods authorised in GB can be moved into Northern Ireland through the Northern Ireland Retail Movement Scheme

FSA Risk Management Recommendations

The FSA risk management recommendation is that that rebaudioside M from fermentation (Saccharomyces cerevisiae), as described in this application, is safe and is not liable to have an adverse effect on the target population, environmental safety and human health at the intended concentrations of use.

The FSA risk management recommendations and safety assessment can be found below:

PDF
View Risk Management Recommendations for Market Authorisation of 10 Regulated Food and Feed Products December 2024 as PDF(Open in a new window) (711.79 KB)

FSA/FSS safety assessment: RP1112 Assessment of steviol glycosides produced by fermentation using Saccharomyces cerevisiae

Annex 2: RP694 - Saccharomyces cerevisiae CNCM I-1079 (new use) (Feed Additive)

Background?

An application for the new authorisation of an 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 by the FSA 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.

For feed additives to be placed on the market in Great Britain, an application shall be submitted in accordance with assimilated Regulation (EC) 1831/2003. Article 4 of the regulation is used to authorise applications for a new feed additive or a new use of a feed additive.

Labelling

Feed additives labelling must include details pursuant to Article 16 of assimilated Regulation 1831/2003 (Article 16 1831/2003). As this feed additive falls under the ‘zootechnical’ category it is also subject to additional labelling set out in Annex III of assimilated Regulation 1831/2003 and Annex VI of assimilated Regulation 767/2009.

Trade

Food exported from the UK to other countries/blocs will need to continue to meet the rules of those countries/blocs.

Northern Ireland

Feed additives placed on the Northern Ireland market are assessed by The European Food Safety Authority (EFSA). If there is any difference in approach, this is managed through the relevant provisional Common Frameworks.

FSA Risk Management Recommendations?

The FSA risk management recommendation is that Saccharomyces cerevisiae CNCM I-1079, as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health at the intended concentrations of use.

The FSA risk management recommendations and safety assessment can be found below:?

PDF
View Risk Management Recommendations for Market Authorisation of 10 Regulated Food and Feed Products December 2024 as PDF(Open in a new window) (711.79 KB)

FSA/FSS safety assessment: Safety Assessment RP694 S. Cerevisiae | Food Standards Agency

Annex 3: 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 by the FSA from Firmenich S.A.

Flavourings are used to impart or modify the odour and/or taste of a food. The use of flavourings is controlled by assimilated Regulation No. 1334/2008, which is applicable in England, Wales and Scotland. Assimilated Regulation No. 1331/2008 sets out the process to add, modify or remove flavourings from domestic lists.

Generally, a commercial flavouring consists of a variety of flavourings rather than a single substance.??The domestic list of flavourings is set out in assimilated Regulation No. 1334/2008 which is applicable in England, Wales and Scotland.?This lists which flavourings are permitted for use, purity criteria and any restrictions of use.

Labelling

No specific labelling requirements are planned for this substance and so the general rules on the labelling of flavourings in food as set out in assimilated Regulation No. 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 assimilated Regulation No. 1334/2008.?

Trade

Food exported from the UK to other countries/blocs will need to continue to meet the rules of those countries/blocs.

European Union (EU)

This flavouring substance, 2-hydroxy-4-methoxybenzaldehyde, has already been authorised by the European Commission in February 2023 Commission Regulation (EU) 2023/441. The only difference between the EU and recommended Great Britain authorisation is that we will include the JECFA identification number (2277) for this substance, which has only recently been established.

Northern Ireland

2-hydroxy-4-methoxybenzaldehyde is already authorised for use in Northern Ireland, in line with legislation that applies in there. The FSA's recommendation to authorise aligns with the product authorisation in Northern Ireland.

FSA Risk Management Recommendations?

The FSA risk management recommendation is that 2-hydroxy-4-methoxybenzaldehyde, as described in this application, is safe and use is not liable to have an adverse effect on the target population, environmental safety and human health at the intended concentrations of use.?

The FSA risk management recommendations and safety assessment can be found below:?

PDF
View Risk Management Recommendations for Market Authorisation of 10 Regulated Food and Feed Products December 2024 as PDF(Open in a new window) (711.79 KB)

FSA/FSS safety assessment: Safety Assessment RP1466 2-Hydroxy-4-methoxybenzaldehyde | Food Standards Agency

Annex 4: RP2184 - removal of 8 permitted food flavouring substances from the domestic list?

Background??

An application to update the list of flavouring substances to remove 8 flavouring substances on the terms below has been submitted.

The 8 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)

Flavourings are used to impart or modify the odour and/or taste of a food. The use of flavourings is controlled by assimilated Regulation (EC) No. 1334/2008, which is applicable in England, Wales and Scotland. Assimilated Regulation (EC) No. 1331/2008 sets out the process to add, modify or remove flavourings from domestic lists.

The list of permitted flavouring substances contains flavouring substances for which the evaluation has been completed ('evaluated flavouring substances') and those for which the

evaluation is still ongoing (‘flavouring substances under evaluation’). The application is to remove 8 ‘flavouring substances under evaluation’ as they are not widely used and so the flavourings industry has decided not to provide additional data for the FSA to complete the evaluation.

Safety Assessment Summary

A safety assessment is not required for an application to remove substances from domestic lists.

Trade

European Union (EU)

The EU has removed these 8 flavouring substances from the Union list (Regulation (EU) 2024/234). There are transitional measures so foods containing the flavourings that were lawfully placed on the market before 25 January 2024 could remain on sale until their date of minimum durability or use by date. No transitional measures were set for the flavourings themselves or preparations containing them.

Wider trade considerations

Although these flavouring substances may be permitted for use in non-EU countries, the International Organisation of the Flavor Industry (IOFI) supports their removal based on feedback from the global flavourings industry that they are not widely used in foods. Therefore, it is unlikely there will be significant impacts on trade as they may not be widely used in food exported to the UK.

Northern Ireland

These 8 flavouring substances have already been removed from the permitted list in Northern Ireland, so businesses can no longer use these flavourings in food for the Northern Ireland market. However, foods containing these flavourings can remain on sale under the transitional measures.

The removal of these substances from the UK domestic list will bring Great Britain into alignment with Northern Ireland. There may be a minor difference between the transitional measures set for these flavourings as the proposed transitional measures cover both foods containing these flavourings and the flavouring themselves. However, it remains the case that foods containing these flavourings can be moved to Northern Ireland through the Northern Ireland Retail Movement Scheme subject to the transitional measures proposed.

FSA Risk Management Recommendations??

The FSA risk management recommendation is that these 8 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.???

The FSA risk management recommendations can be found below:??

PDF
View Risk Management Recommendations for Market Authorisation of 10 Regulated Food and Feed Products December 2024 as PDF(Open in a new window) (711.79 KB)

Annex 5: RP1190 - phosphoric acid, mixed esters with 2-hydroxyethyl methacrylate (HEMAP) (CAS No. 52628-03-2) (new authorisation) (Food Contact Material)

Background?

An application 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 by the FSA from Keller and Heckman LLP.

The process to approve substances in FCM for the market in Great Britain is set out in assimilated Regulation 1935/2004.?

Labelling

HEMAP is used in the manufacture of acrylic kitchen worktops and sinks. The final article itself does not need to be labelled as containing HEMAP. As per traceability requirements, supporting documentation does however need to stipulate adequate information relative to substances used for which restrictions and/or specifications are set out in Annex I of assimilated Regulation 10/2011. Any potential user will need to ensure that this and other authorised substances with restrictions and/or specifications are accurately documented for compliance checking purposes.?

Trade

FCMs exported from the UK to other countries/blocs will need to continue to meet the rules of those countries/blocs.

The proposed authorisation mirrors the EU authorisation in respect of ID (FCM substance number) and substance name, thus minimising barriers to trade.

Northern Ireland

This product is already authorised for use in Northern Ireland, in line with legislation that applies in there. The FSA's recommendation to authorise aligns with the product authorisation in Northern Ireland.??

FSA Risk Management Recommendations?

The FSA risk management recommendation is that HEMAP, as described in this application, is safe and is not liable to have an adverse effect on the target population, environmental safety and human health in its intended use.

The FSA risk management recommendations and safety assessment can be found below:?

PDF
View Risk Management Recommendations for Market Authorisation of 10 Regulated Food and Feed Products December 2024 as PDF(Open in a new window) (711.79 KB)

FSA/FSS safety assessment: Safety Assessment: Outcome of the Assessment of 2-Hydroxyethyl Methacrylate Phosphate as a Monomer for use in the Manufacture of Plastic Food Contact Materials and Articles

Annex 6: 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 by the FSA from BASF Agricultural Solutions Seed US LLC. The application does not cover cultivation and therefore no GMB151 soybean will be grown in the UK.

For new GMOs for food and feed uses to be placed on the market in Great Britain, an application shall be submitted in accordance with assimilated Regulation (EC) No. 1829/2003. Article 5 of the regulation is used to authorise new Genetically Modified Food and Article 17 of the regulation is used to authorise new Genetically Modified Feed.

Labelling

In accordance with assimilated Regulation (EC) No. 1830/2003, concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from GMOs, there is a traceability and labelling requirement for food and feed products derived from genetically modified sources regardless of the presence of detectable novel genetic material in the final product, or of the quantity of intentionally used genetically modified ingredient present.

In the case of pre-packaged genetically modified food/feed products, the words ‘This product contains genetically modified organisms’ or ‘This product contains genetically modified soybean’ must appear on a label. In the case of products without packaging, these words must still be clearly displayed immediately next to the product.

Operators shall ensure the Unique Identifier BCS-GM151-6 is accompanied with a written declaration of GMO presence for traceability functions, starting at the initial stages of placing on the market including in bulk quantities.

Food products derived from animals fed with feed containing GMOs do not fall within the scope of the specific GM labelling requirements.

Trade

Food exported from the UK to other countries/blocs will need to continue to meet the rules of those countries/blocs.

European Union (EU)

GMB151 soybean is already approved for use in the EU. Our recommendation to authorise this product aligns with the EU with regards to the following: the unique identifier, the terms of authorisation for foods and food ingredients, feed, products, labelling and method of detection.

Northern Ireland

GMB151 soybean is already authorised for use in Northern Ireland, in line with legislation that applies in there. The FSA’s recommendation to authorise aligns with the product authorisation in Northern Ireland.

FSA Risk Management Recommendations?

The FSA risk management recommendation is that that GMB151 soybean, as described in this application, is safe and are not liable to have an adverse effect on the target population, environmental safety and or human health at the intended concentrations of use.

The FSA risk management recommendations and safety assessment can be found below:?

PDF
View Risk Management Recommendations for Market Authorisation of 10 Regulated Food and Feed Products December 2024 as PDF(Open in a new window) (711.79 KB)

FSA/FSS safety assessment: Assessment of the safety of genetically modified GMB151 soybean for food and feed uses under assimilated Regulation (EC) No. 1829/2003

Annex 7: 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 by the FSA from BASF Agricultural Solutions Seed US LLC. The application does not cover cultivation and therefore no GHB811 cotton will be grown in the UK.

For new GMOs for food and feed uses to be placed on the market in Great Britain, an application shall be submitted in accordance with assimilated Regulation (EC) No. 1829/2003. Article 5 of the regulation is used to authorise new Genetically Modified Food and Article 17 of the regulation is used to authorise new Genetically Modified Feed.

Labelling

In accordance with assimilated Regulation (EC) No. 1830/2003, concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from GMOs, there is a traceability and labelling requirement for food and feed products derived from genetically modified sources regardless of the presence of detectable novel genetic material in the final product, or of the quantity of intentionally used genetically modified ingredient present.

In the case of pre-packaged genetically modified food/feed products, the words ‘This product contains genetically modified organisms’ or ‘This product contains genetically modified cotton’ must appear on a label. In the case of products without packaging, these words must still be clearly displayed immediately next to the product.

Operators shall ensure the Unique Identifier BCS-GH811-4 is accompanied with a written declaration of GMO presence for traceability functions, starting at the initial stages of placing on the market including in bulk quantities.

Food products derived from animals fed with feed containing GMOs do not fall within the scope of the specific GM labelling requirements.

Trade

Food exported from the UK to other countries/blocs will need to continue to meet the rules of those countries/blocs.

European Union (EU)

GHB811 cotton is already approved for use in the EU. Our recommendation to authorise this product aligns with the EU with regards to the following: unique identifier, the terms of authorisation for foods and food ingredients, feed, products, labelling and method of detection.

Northern Ireland

GHB811 cotton is already authorised for use in Northern Ireland, in line with legislation that applies there. The FSA's recommendation to authorise aligns with the product authorisation in Northern Ireland.

FSA Risk Management Recommendations?

The FSA risk management recommendation is 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 FSA risk management recommendations and safety assessment can be found below:?

PDF
View Risk Management Recommendations for Market Authorisation of 10 Regulated Food and Feed Products December 2024 as PDF(Open in a new window) (711.79 KB)

FSA/FSS safety assessment: RP1232 Assessment of the safety of genetically modified GHB811 cotton for food and feed uses under assimilated Regulation (EC) No. 1829/2003

Annex 8: RP1506 - 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)

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 by the FSA from Corteva Agrisciences LLC Represented by Corteva Agriscience UK Limited.

For new GMOs for food and feed uses to be placed on the market in Great Britain, an application shall be submitted in accordance with assimilated Regulation (EC) No. 1829/2003. Article 5 of the regulation is used to authorise new Genetically Modified Food and Article 17 of the regulation is used to authorise new Genetically Modified Feed.

Labelling

In accordance with assimilated Regulation (EC) No. 1830/2003, concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from GMOs, there is a traceability and labelling requirement for food and feed products

derived from genetically modified sources regardless of the presence of detectable novel genetic material in the final product, or of the quantity of intentionally used genetically modified ingredient present.

In the case of pre-packaged genetically modified food/feed products, the words ‘This product contains genetically modified organisms’ or ‘This product contains genetically modified maize’ must appear on a label. In the case of products without packaging, these words must still be clearly displayed immediately next to the product.

Operators shall ensure the Unique Identifier DP-ØØ4114-3 x MON-ØØ81Ø-6 x SYN-IR6Ø4-5 x MON-ØØ6Ø3-6 or of a sub-combination combining two, three, four or five of the single events is accompanied with a written declaration of GMO presence for traceability functions, starting at the initial stages of placing on the market including in bulk quantities.

Food products derived from animals fed with feed containing GMOs do not fall within the scope of the specific GM labelling requirements.

Trade

Food exported from the UK to other countries/blocs will need to continue to meet the rules of those countries/blocs.

European Union (EU)

Maize DP4114 x MON 810 x MIR604 x NK603 is already approved for use in the EU. Our recommendation to authorise this product aligns with the EU with regards to the following: - unique identifier, the terms of authorisation for foods and food ingredients, feed, products, labelling and method of detection.

Northern Ireland

Maize DP4114 x MON 810 x MIR604 x NK603 is already authorised for use in Northern Ireland, in line with legislation that applies there. The FSA’s recommendation to authorise aligns with the product authorisation in Northern Ireland.

FSA Risk Management Recommendations?

The FSA risk management recommendation is that that maize DP4114 x MON 810 x MIR604 x NK603, as described in this application, are safe and are not liable to have an adverse effect on the target population, environmental safety and or human health at the intended concentrations of use.

The FSA risk management recommendations and safety assessment can be found below:?

PDF
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FSA/FSS safety assessment: RP1506 Assessment of the safety of genetically modified DP4114xMON810xMIR604xNK603 Maize and sub-combinations for food and feed uses under assimilated Regulation (EC) No. 1829/2003

Annex 9: 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 by the FSA from Bioneutra Incorporated, North America. IMO is currently authorised as a novel food under assimilated Commission Implementing Regulation (EU) 2017/2470, 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.

Labelling

In the case of this novel food, its designation on the labelling of food containing it shall be 'Isomaltooligosaccharide'.

Foods containing the novel food must be labelled as 'a source of glucose'.

Where supplements contain IMO, they should not be consumed by children under 10 years of age.

Wheat is one of the ingredients that IMO is derived from and is listed in Annex II of assimilated Regulation (EU) No 1169/2011. When made from wheat, Isomaltooligosaccharide must be labelled in accordance with the labelling requirements set out in Article 21 of assimilated Regulation (EU) No 1169/2011.

Trade

Food exported from the UK to other countries/blocs will need to continue to meet the rules of those countries/blocs.

A similar application has been received in the EU. If this extension of use is subsequently authorised in both Great Britain and EU, there may be some divergence depending on categories and conditions of use including maximum levels ultimately agreed by the EU.

Northern Ireland

This extension of use is not currently authorised in Northern Ireland. However, goods authorised in Great Britain can be moved into Northern Ireland through the Northern Ireland Retail Movement Scheme.

FSA Risk Management Recommendations?

The FSA risk management recommendation is that IMO, as described in this application, is safe and is not liable to have an adverse effect on the target population, environmental safety and human health at the intended concentrations of use.

The FSA risk management recommendations and safety assessment can be found below:?

PDF
View Risk Management Recommendations for Market Authorisation of 10 Regulated Food and Feed Products December 2024 as PDF(Open in a new window) (711.79 KB)

FSA/FSS safety assessment: Safety Assessment: Change of conditions of use for the novel food, Isomaltooligosaccharide | Food Standards Agency

Annex 10: RP956 – Magnesium L-threonate (new authorisation) (Novel Foods)

Background?

An application for the use of magnesium L-threonate monohydrate as a novel food in food supplements was received by the FSA 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 of The Nutrition (Amendment etc.) (European Union Exit) Regulations 2019.

Labelling

- Intended as a food supplement for adults (18 years and over)
- Not for lactating and pregnant women
- Not for children under the age of 18
- A warning not to exceed the stated recommended daily dose (per standard supplements requirements)
- Will be labelled as ‘magnesium L-threonate'

Impacts

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

Trade

Food exported from the UK to other countries/blocs will need to continue to meet the rules of those countries/blocs.

Magnesium-L-threonate has been authorised by the EU. There is no significant divergence to the FSA’s proposed terms of authorisation.

Northern Ireland

This product is already authorised for use in Northern Ireland, in line with legislation that applies in there. There is no significant difference from the FSA’s proposed terms of authorisation.

FSA Risk Management Recommendations?

The FSA risk management recommendation is that Magnesium-L-threonate monohydrate, as described in this application, is safe and is not liable to have an adverse effect on the target population, environmental safety and human health at the intended concentrations of use.

The FSA risk management recommendations and safety assessment can be found below:?

PDF
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FSA/FSS safety assessment: RP956 Magnesium L-threonate as a novel food for use in food supplements