Risk Management Recommendations on Market Authorisation of 10 Regulated Food and Feed Products December 2024

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Document subject and purpose

In this document we publish the Food Standards Agency (FSA) risk management recommendations for one food additive, one feed additive, one food flavouring and the removal of 8 permitted flavouring substances, one food contact material, 3 genetically modified organisms (for food and feed uses) and 2 novel foods.

Our risk assessors deliver the science behind our advice and publish their safety assessments, links to which are available within each recommendation annex. Risk assessors are responsible for identifying and characterising hazards and risks to health and assessing levels of exposure.

The risk management recommendations consider any safety assessments as well as potential impacts that may result from the authorisation of these applications. They also consider other legitimate factors that ministers may want to consider before making a decision on authorisation of these applications.

The final FSA recommendations that are made to ministers in England, Wales and Northern Ireland will consider stakeholders' views received from this consultation.

Annexes to Risk Management Recommendations

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

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

An application for authorisation in Great Britain, of this food additive, on the terms below has been submitted. It is for ministers in England, Wales and Scotland to decide whether to authorise the additive.

Introduction

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

Safety Assessment Summary

The FSA and Food Standards Scotland (FSS) considered that the proposed change in the steviol glycoside specification, to include a production method using *S. cerevisiae* to convert sugar into rebaudioside M via fermentation, is safe under the proposed conditions of use and at the anticipated levels of intake. Therefore, there were no concerns over safety of the proposed process.

Safety assessment: RP1112 Assessment of steviol glycosides produced by fermentation using Saccharomyces cerevisiae

Relevant legislation

Assimilated Regulation (EC) No. 1333/2008 sets out a list of approved food additives and their conditions of use. Specifications for food additives are set out in assimilated Regulation (EU) No. 231/2012. The process to authorise food additives is set out in assimilated Regulation (EC) No. 1331/2008.

Terms of Authorisation

There are no requested changes to conditions of use for E 960b, so this sweetener must comply with the conditions of use as set out for steviol glycosides in assimilated Regulation (EC) No. 1333/2008.

Specification

The proposed specification for E 960b(ii) is set out below. For the specification of E 960b Steviol Glycosides from Fermentation (*Yarrowia lipolytica),* the E number needs to be subcategorised to E 960b(i).

E 960b(ii) REBAUDIOSIDE M FROM FERMENTATION (*SACCHAROMYCES CEREVISIAE*)

Synonyms

Category	Information
Definition	Rebaudioside M is a steviol glycoside composed predominantly of rebaudioside M with minor amounts of other steviol glycosides such as rebaudioside A, rebaudioside D, rebaudioside E, stevioside, rubusoside, rebaudioside B, and steviolbioside. Rebaudioside M is obtained by fermentation of food grade cane sugars with Saccharomyces cerevisiae. The manufacturing process comprises two main phases. The first phase involves fermentation of a non-toxigenic non-pathogenic strain of Saccharomyces cerevisiae that has been genetically modified with heterologous genes from multiple donor organisms to overexpress steviol glycosides. The GM strain is 40426556XX. Removal of biomass by solid-liquid separation and heat treatment is followed by concentration of rebaudioside M. The second phase involves purification by employing ultra-, nano-, and press-filtration. Optional recrystallisation of rebaudioside M from aqueous ethanol and carbon treatment resulting in a final product containing not less than 95% of rebaudioside M. Viable cells or the DNA of Saccharomyces cerevisiae must not be detected in the food additive.
Chemical Name	Rebaudioside M: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl ester

Molecular formula

Category	Information
Trivial name	Rebaudioside M
Formula	C56H90O33
Conversion factor	0.25
Molecular weight and CAS No.	
Trivial name	Rebaudioside M
CAS Number	1220616-44-3
Molecular weight (g/mol)	1291.29
Assay	Not less than 95% of rebaudioside M on the dried basis.
Description	White to light yellow powder, approximately between 200 and 350 times sweeter than sucrose (at 5% sucrose equivalency).

Identification

Category	Information
Solubility	Freely soluble to slightly soluble in water.
pH	Between 4.5 and 7.0 (1 in 100 solution)

Purity

Category	Information
Total ash	Not more than 1%
Loss on drying	Not more than 6% (105 °C, 2h)
Kaurenoic acid	Not more than 300 mg/kg
Residual solvent	Not more than 5000 mg/kg ethanol
Arsenic	Not more than 0.1 mg/kg
Lead	Not more than 0.1 mg/kg
Cadmium	Not more than 0.01 mg/kg
Mercury	Not more than 0.05 mg/kg
Residual protein	Not more than 20 mg/kg

Microbiological Criteria

Category	Information
Total (aerobic) plate count	Not more than 1000 CFU/g
Yeast	Not more than 100 CFU/g

Category	Information
Moulds	Not more than 100 CFU/g
Escherichia coli	Negative in 1g
Salmonella spp.	Negative in 25g

Proposed uses

The current application is for an already authorised sweetener, rebaudioside M, and the applicant has not requested any changes to the current conditions of use for steviol glycosides as set out in assimilated Regulation No. 1333/2008.

Supplementary information

N/A

Labelling

N/A

Transitional requirements/ provisions

N/A

Further explanation/ Rationale

N/A

Post market monitoring

N/A

Definitions

N/A

Other Legitimate Factors

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

The authorisation of rebaudioside M made by fermentation should generally result in greater market competition, supporting growth and innovation in the sector.

Impacts

As part of the risk analysis process, the FSA has assessed the potential impacts that would result from the authorisation of this food additive (new production method) should ministers decide to authorise. No significant impacts were identified. The impacts considered included those most

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

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.

Risk Management Recommendation

The FSA risk management recommendation is 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.

Annex 2
FSA Risk Management Recommendation
RP694 - *Saccharomyces cerevisiae* CNCM I-1079 (new use) (Feed Additive)

An application for authorisation in Great Britain of this feed additive on the terms below has been submitted. It is for ministers in England, Wales and Scotland to decide whether to authorise the additive.

Introduction

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.

Safety Assessment Summary

The FSA and FSS have undertaken a safety assessment of application RP694 for the new use of *Saccharomyces cerevisiae* (CNCM I-1079) as a feed additive for calves, and all other ruminants and camelidae, for rearing and fattening, at their correspondent developmental stage.

The assessment of *Saccharomyces cerevisiae* (CNCM I-1079) shows that the conditions for authorisation in Article 5 of assimilated Regulation (EC) 1831/2003 are satisfied.

The FSA and FSS have accepted the European Union Reference Laboratory (EURL) analytical method evaluation report and determined the analytical methods as appropriate for official controls for this feed additive. The FSA and FSS have concluded that *Saccharomyces cerevisiae* (CNCM I-1079) is correctly identified and characterised with no causes for concern raised in this section of the application.

The additive, 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 under the proposed conditions of use. However, the additive should be considered a potential respiratory sensitiser.

Safety assessment: RP694 Assessment of the safety and efficacy of an additive of Saccharomyces cerevisiae CNCM I-1079 as a feed additive

Relevant Legislation

Legislation in respect of feed additives applies to this application. In particular, it is noted that this application must meet the requirements of assimilated Regulation (EC) 1831/2003 ('Regulation (EC) 1831/2003') on additives for use in animal nutrition including:

- Article 4 and 7: Application for authorisation of a new or new use of a feed additive
- Article 5: Conditions for authorisation
- Article 6 and Annex I: Categories of feed additives and functional groups
- Article 16 and Annex III: Labelling and packaging requirements apply, if authorised
- Article 17: Register of feed additives – An entry will be required
- Article 21 and Annex II: Analytical methods have been verified by the European Reference Laboratory as used for the control of *Saccharomyces cerevisiae* CNCM I-1079 in animal feed as detailed in the EURL analytical method evaluation report FAD-2010-0121. Valid methods exist for:
  1. Identification of the bacterial strain *Saccharomyces cerevisiae* CNCM I-1079.
- Annex IV: The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

In addition to the requirements set out in assimilated Regulation (EC) 1831/2003 there are additional labelling requirements required by Annex VII of assimilated Regulation (EC) No 767/2009.

Terms of Authorisation

The proposed terms of authorisation are set out below.

The applicant has adequately and sufficiently demonstrated that the additive has the characteristic of favourably affecting animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feedingstuffs.

The assessment of the preparation of the new authorisation of an additive (*Saccharomyces cerevisiae* CNCM I-1079), under the category of 'zootechnical' and functional group 'gut flora stabiliser' for its use in calves, all other ruminants and camelidae for rearing and fattening has demonstrated that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, has been satisfied.

Additive	Saccharomyces cerevisiae CNCM I-1079
Identification number	4d1703
Authorisation holder	Danstar Ferment AG (Switzerland)
Additive category	Zootechnical additives
Functional group	Gut flora stabilisers
Additive composition	Solid preparation of Saccharomyces cerevisiae CNCM I-1079 containing a minimum of: • 2.0×10^{10} CFU/g (Non-coated/encapsulated preparations) • 1.0×10^{10} CFU/g (Coated/encapsulated preparations)
Characterisation of the active substance(s)	Viable cells of Saccharomyces cerevisiae CNCM I-1079
Analytical methods[4]	
Identification:	Polymerase chain reaction (PCR) method (DD CEN/TS 15790:2008)[5]
Enumeration:	pour plate method using chloramphenicol glucose yeast extract agar (BS EN 15789:2021)[6]
Species or category of animal	Calves, all other ruminant species (for rearing and fattening), and Camelidae (for rearing and fattening)
Maximum age	Not applicable
Colony-forming units (CFU) of the additive) /kg of complete feed with a moisture content of 12%.	
Minimum content	1×10^9
Maximum content	Not applicable

Category	Information
Other provisions	The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture.

Proposed uses

This application is to place on the market a preparation of *Saccharomyces cerevisiae* CNCM I-1079 as a feed additive under the category of 'zootechnical' functional group 'gut flora stabiliser' for its use in calves, and all other ruminants (lambs, goat kids, buffalo calves, calves/kids of species in the family Cervidae and other species of ruminants) and C*amelidae*, for rearing and fattening, at their correspondent developmental stage.

Supplementary information

- Feed additives are subject to UK health and safety legislation. The safety assessment identified that particular consideration should be given to hazards as a:
  - Potential respiratory sensitiser
- Health and Safety Legislation includes:
  - The Personal Protective Equipment at Work Regulations 1992 (legislation.gov.uk)
  - The Control of Substances Hazardous to Health Regulations 2002 (legislation.gov.uk)
- Main animal species and their subgroups are defined in Annex IV of assimilated Regulation (EC) 429/2008. [DN: although Camelidae are not defined here]
- The FSA considers there is no basis to propose specific requirements for post-market monitoring.

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.

Transitional Requirements/ Provisions

N/A

Further Explanation/ Rationale

N/A

Post Market Monitoring

The FSA do not propose a requirement for post market monitoring other than those established in the Feed Hygiene Regulation and Good Manufacturing Practice is required.

Definitions

- Camelidae species include camels, alpacas, llamas. There is precedent of authorisation for use in Camelidae in Commission Implementing Regulation (EU) 2020/1374 of 1 October 2020 concerning the authorisation of the preparation of *Saccharomyces cerevisiae* CNCM I-1077 as a feed additive for calves, all minor ruminant species (for rearing) other than lambs and camelidae (for rearing) (holder of authorisation Danstar Ferment AG represented by Lallemand SAS) (Text with EEA relevance) (legislation.gov.uk). Article 1 of 429/2008 indicates this should be classified as a minor species.
- Ruminants
- Minor species
- Zootechnical category and function

Other Legitimate Factors

In developing the risk management recommendations, the FSA has had regard to the other legitimate factors (including consumer interests, political, environmental, societal and technical feasibility) that ministers will consider as part of their decision on authorisation. The FSA has not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this feed additive. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant other legitimate factors as part of the consultation process.

The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector as well as contributing to the health of the target species within farming practices.

Impacts

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

Northern Ireland

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

Risk Management Recommendation

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.

Annex 3
FSA Risk Management Recommendation
RP1466 - 2-Hydroxy-4-methoxybenzaldehyde (new authorisation) (Flavouring)

An application for authorisation in Great Britain of this flavouring on the terms below has been submitted. It is for ministers in England, Wales and Scotland to decide whether to authorise the flavouring.

Introduction

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.

Safety Assessment Summary

The FSA and FSS are satisfied that the use for 2-hydroxy-4-methoxybenzaldehyde is safe under the proposed conditions and at the anticipated levels of intake and is not liable to have an effect on human health.

Safety assessment: Safety Assessment RP1466 2-Hydroxy-4-methoxybenzaldehyde | Food Standards Agency

Relevant Legislation

The process to authorise new flavouring substances in line with Article 9 of assimilated Regulation No. 1334/2008 is set out in the common authorisation procedure for food additives, food enzymes and food flavourings – assimilated Regulation No. 1331/2008.
In particular:

- Article 3 - Main stages of the common procedure
- Article 7 - Updating the domestic list

Assimilated Regulation No. 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods:

- Article 11(3) – Inclusion of flavourings and source materials in the domestic list

Terms of Authorisation

Category	Information
FL No	05.229
Chemical name	2-Hydroxy-4-methoxybenzaldehyde
CAS No.	673-22-3
JECFA No.	2277
CoE No.	
Purity of the named substance at least 95% unless otherwise specified	Isolated from Periploca sepium
Restrictions of Use	None
Footnote	
Reference	The Authority

In legislation 'The Authority' is defined as the FSA. There is also no Council of Europe number for this flavouring and, as it is a new flavouring substance, it does not need a footnote. Restrictions of use are only required for flavouring substances if they have a different function (e.g. food additive, physiological effect) when used above a certain level, or if restrictions are needed for safety reasons. No restrictions of use are required for this flavouring substance.

Supplementary Information

N/A

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.

Transitional Requirements/ Provisions

N/A

Further Explanation/ Rationale
N/A

Post Market Monitoring
N/A

Definitions
N/A

Other Legitimate Factors
In developing the risk management recommendations, the FSA has had regard to the other legitimate factors (including consumer interests, political, environmental, societal and technical feasibility) that ministers will consider as part of their decision on whether to authorise.

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

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

Impacts
As part of the risk analysis process, the FSA has assessed the potential impacts that would result from the authorisation of this food flavouring substance, 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.

European Union (EU)

This flavouring substance, 2-hydroxy-4-methoxybenzaldehyde, has already been authorised by the EU 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.

Risk Management Recommendation

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.

Annex 4
FSA Risk Management Recommendation
RP2184 - removal of eight permitted food flavouring substances from the domestic list

An application to update the list of flavouring substances to remove eight flavouring substances on the terms below has been submitted. It is for ministers in England, Wales and Scotland to decide whether to authorise the removal.

Introduction

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)

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.

Relevant Legislation

The FSA has not identified any relevant provisions of assimilated law that would impact authorisation of the removals.

Terms of Authorisation

In March 2024, the UK Flavour Association (UKFA) submitted an application for the removal of 8 flavouring substances from the domestic list.

The 8 flavouring substances 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)

The UKFA stated that they do not anticipate the removal having any impact on businesses as they are not widely used by the global flavourings industry. The removal of the entries was requested as industry have decided not to provide the additional information which would be required to complete the evaluation of these flavouring substances.

Transitional Requirements/ Provisions

Transitional measures are proposed to allow foods containing the flavourings (and the flavourings themselves), that could legally be placed on the market before the coming into force date of the legislation, to remain on sale until their use by date or best before date. This will include food containing these flavourings (and the flavourings themselves), that were exported to Great Britain before the coming into force date.

Further Explanation/ Rationale

N/A

Post Market Monitoring

N/A

Definitions

N/A

Other Legitimate Factors

In developing the risk management recommendations, the FSA has had regard to the other legitimate factors (including consumer interests, political, environmental, societal and technical feasibility) that ministers will consider as part of their decision on authorisation. As the proposal is to remove 8 flavouring substances which are not widely used in foods or drink sold on the market in Great Britain, the FSA consider there are no relevant other legitimate factors that need to be taken into consideration.

Impacts

As part of the risk analysis process, the FSA has assessed the potential impacts that would result from the removal of the flavourings should ministers decide to authorise the application. 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).

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-European Union 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.

Risk Management Recommendation

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.

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

An application for authorisation in Great Britain of this food contact material (FCM) on the terms below has been submitted. It is for ministers in England, Wales and Scotland to decide whether to authorise the FCM.

Introduction

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, 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.

Safety Assessment Summary

HEMAP is intended to be used as a component within plastic food contact materials, specifically kitchen countertops and sinks. The FSA and FSS safety assessment concluded there was no concern to human safety based on its proposed conditions of use set out within the application. A restriction in the form of a specific migration limit (SML) of 0.05 mg/kg was recommended based on the proposed conditions of use. This is the maximum permitted quantity of this substance that can transfer from the plastic into a food without causing a risk to health.

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

Please note: a new safety assessment is in the process of being issued. The reason for reissuance is to reflect the agreed name change by the applicant to phosphoric acid, mixed esters with 2-hydroxyethyl methacrylate. The change of name will not affect the content or outcome of the safety assessment.

Relevant legislation

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

Assimilated Regulation (EC) No 1935/2004 in particular, but not limited to:

- Article 8. General requirements for the authorisation of substances
- Article 9. Application for the authorisation of a new substance (main steps of the common procedure)
- Article 10. Opinion of the Food Safety Authority
- Article 11. Authorisation
- Article 15. Labelling

Terms of Authorisation

The proposed terms of authorisation are set out below.

Category	Information
FCM substance No	TBC[1]
Ref. No	
CAS No	52628-03-2
Substance name	Phosphoric acid, mixed esters with 2-hydroxyethyl methacrylate2
Use as additive or polymer production aid (yes/no)	no
Use as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes/no)	yes
FRF applicable (yes/no)	no
SML [mg/kg]	0.05
SML(T) [mg/kg] (Group restriction No)	

Category	Information
Restrictions and specifications	Only to be used at up to 0.35 % (w/w) to manufacture polymethylmethacrylate. The SML is expressed as the sum of the mono-, di- and triesters of phosphoric acid and the mono-, di-, tri- and tetraesters of diphosphoric acid.

Specification

- Where appropriate, specifications or restrictions of use concerning the petitioned substance are set out within the terms of the authorisation.
- As per the safety assessment, it is appropriate to apply a specific migration limit (SML) of 0.05 mg/kg for this non-defined mixture. Furthermore, the non-defined mixture should only be used at levels up to 0.35% (w/w) in the manufacture of kitchen worktops and sinks (polymethylmethacrylate).

Proposed Uses

- HEMAP is intended to be used in the manufacture of acrylic kitchen worktops and sinks.
- The non-defined mixture of HEMAP should only be used at levels up to 0.35% (w/w) in the manufacture of kitchen worktops and sinks (polymethylmethacrylate (PMMA)). PMMA is a synthetic polymer used to engineer transparent and rigid thermoplastic.

Supplementary information

- We are proposing to assign this substance with the FCM (ID) number of 1082. This will reflect the number allocated to the EU authorisation of the same substance, and we believe this will mitigate any trade impacts.

- Following the naming format of similar substances to HEMAP and noting that EU decided to use an alternative name that appeared to reflect our observations, we approached the applicant to ask whether they would agree to a name change. The applicant agreed to change the name to phosphoric acid, mixed esters with 2-hydroxyethyl methacrylate. This will ensure the name aligns with the existing EU authorisation and it is also expected to minimise trade barriers.

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.

Transitional Requirements/Provisions

N/A

Further Explanation/ Rationale

N/A

Post Market Monitoring

N/A

Definitions

To the extent that terms are included but not defined within this document, please see the definitions set out in assimilated Regulation (EC) No 1935/2004 and https://www.legislation.gov.uk/eur/2011/10/contents

Other Legitimate Factors

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

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

Impacts

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

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.

Risk Management Recommendation

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.

Annex 6
FSA Risk Management Recommendation
RP1123 – GMB151 (new authorisation) (Genetically Modified Organisms (GMOs) for food and feed uses)

An application for the authorisation in Great Britain of this genetically modified organism (GMO) on the terms below has been submitted. It is for ministers in England, Wales and Scotland to decide whether to authorise the GMO.

Introduction

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 (GB market), 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.

Safety Assessment Summary

The food/feed safety of the newly expressed proteins was assessed, and no safety concerns were raised in terms of their toxicological potential, allergenic potential, and nutritional quality. Based on the comparative analysis and the nutritional assessment, GMB151 soybean does not cause any nutritional concerns. Overall, the FSA and FSS concluded that GMB151 soybean is as safe as its conventional counterpart with respect to its potential effects on human and animal health.

Safety assessment: RP1123 Assessment of the safety of genetically modified GMB151 soybean for food and feed uses under assimilated Regulation (EC) No. 1829/2003

Any Relevant Provisions of Assimilated Law

- Article 5 assimilated Regulation (EC) No. 1829/2003 (food) and Article 17 (feed): Application for authorisation
- Article 6 of assimilated Regulation (EC) No. 1829/2003 (food) and Article 18 (feed): Opinion of the Food Safety Authority
- Article 13(1) of assimilated Regulation (EC) No. 1829/2003 (food) and Article 25(2) (feed): Labelling
- Article 4(6) of Assimilated Regulation (EC) No. 1830/2003 (products consisting of or containing GMOs): Labelling

Terms of Authorisation

The proposed terms of authorisation are set out below.

The following is for authorisation as a new GMO product:

- RP1123 - BCS-GM151-6 Soybean

Genetically modified organism and unique identifier

1. For the purposes of Articles 7(3) and 19(3) of assimilated Regulation (EC) No.1829/2003, the unique identifier BCS-GM151-6 is specified for genetically modified GMB151 soybean.

Designation and specification of the products -

2. For the purposes of Articles 4(2) and 16(2) of assimilated Regulation (EC) No. 1829/2003 the dDesignation and specification of the products are :—

(a)foods and food ingredients containing, consisting of or produced from genetically modified soybean BCS-GM151-6;

(b)feed containing, consisting of, or produced from genetically modified soybean BCS-GM151-6; and

(c)products containing or consisting of genetically modified soybean BCS-GM151-6 for uses other than those provided for in sub-paragraphs (a) and (b), with the exception of cultivation.

Labelling

3. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of assimilated Regulation (EC) No.1829/2003, and in Article 4(6) of assimilated Regulation (EC) No. 1830/2003, the ‘name of the organism’ is ‘soybean’.

The words ‘not for cultivation’ shall appear on the label of, and in documents accompanying, the products containing or consisting of genetically modified soybean BCS-GM151-6 specified with their unique identifiers, with the exception of food and food ingredients.

Method for detection

4. (1) For the purposes of Articles 7(3) and 19(3) of assimilated Regulation (EC) No. 1829/2003, the method specified in sub-paragraph (2) is to be used for the detection of genetically modified soybean event BCS-GM151-6.

(2) The method is set out in the document entitled “Event-specific Method for the Quantification of soybean GMB151 by Real-time PCR”, reference “EURL-VL-01/18VP” and published 23 July 2020.

(3) The method of DNA extraction for use in the detection method specified in sub-paragraph (2) is set out in the document entitled “Soybean Seeds Sampling and DNA Extraction Report on the Validation of a DNA Extraction Method from Soybean Seeds”, reference “CRLVL13/05XP” and dated 14 May 2007.

(4) For the purposes of Articles 7(3) and 19(3) of assimilated Regulation (EC) No. 1829/2003, the reference material “ERM®-BF443” is accessible via the Joint Research Centre (JRC) of the European Commission

Monitoring plan for environmental effects

5.The authorisation holder must ensure that the monitoring plan for environmental effects, which accompanied the application for authorisation of genetically modified soybean BCS-GM151-6, reference number “RP1123” submitted to the Food Safety Authority on 25 May 2021, is implemented.

The authorisation holder must submit to the Food Safety Authority annual reports on the implementation of, and the results of the activities set out in, the monitoring plan in accordance with the format set out in Annex 2 of Decision 2009/770.

Authorisation holder

6. (1) The name and address of the authorisation holder is BASF Agricultural Solutions Seed US LLC, 100 Park Avenue, 07932, Florham Park, New Jersey, US

(2) The authorisation holder is represented in Great Britain by BASF PLC, 2 Stockport Exchange, Railway Road, Stockport, Cheshire, SK1 3GG

Supplementary Information

Environmental Risk Assessment

The Advisory Committee on Releases to the Environment (ACRE) is the advisory body on deliberate release to the environment for the respective competent authorities in Great Britain; in Wales these are the Welsh ministers. ACRE has considered the Environmental Risk Assessment (ERA) of

GMB151 soybean. The scope of the application does not include cultivation and only covers the import, processing, and food and feed use of GMB151 soybean. ACRE concluded that GMB151 soybean would not raise safety concerns in the event of accidental release of viable seeds or propagating material into the environment.

The FSA has consulted the competent authority in Wales for their opinion, which we will take into consideration before making our final recommendation to ministers.

ACRE's advice is available on the GOV.UK

https://www.gov.uk/government/publications/acre-advice-applications-to-market-gm-soybeans-and-maize

Labelling

- In accordance with assimilated Regulation (EC) No. 1830/2003, concerning the traceability and labelling of GMOs 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.

Transitional Requirements/ Provisions

N/A

Further Explanation/ Rationale

N/A

Post Market Monitoring

N/A

Definitions

N/A

Other Legitimate Factors

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

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

Impacts

As part of the risk analysis process, the FSA has assessed the potential impacts that would result from the authorisation of this GMO for food and feed uses, 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.

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.

Risk Management Recommendation

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

Annex 7
FSA Risk Management Recommendation
RP1232 - GHB811 Cotton (new authorisation) (Genetically Modified Organisms (GMOs) for food and feed uses)

An application for the authorisation in Great Britain of this genetically modified organism (GMO) on the terms below has been submitted. It is for ministers in England, Wales and Scotland to decide whether to authorise the GMO.

Introduction

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 Great Britain market, 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.

Safety Assessment Summary

The food/feed safety of the newly expressed proteins was assessed, and no safety concerns were raised in terms of their toxicological potential, allergenic potential, and nutritional quality. Based on the comparative analysis and the nutritional assessment, GHB811 cotton does not cause any nutritional concerns. Overall, the FSA and FSS concluded that GHB811 cotton is as safe as its conventional counterpart with respect to its potential effects on human and animal health.

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

Any Relevant Provisions of Assimilated Law

- Article 5 assimilated Regulation (EC) No. 1829/2003 (food) and Article 17 (feed): Application for authorisation
- Article 6 assimilated Regulation (EC) No. 1829/2003 (food) and Article 18 (feed): Opinion of the Food Safety Authority
- Article 13(1) assimilated Regulation (EC) No. 1829/2003 (food) and Article 25(2) (feed): Labelling
- Article 4(6) Assimilated Regulation (EC) No. 1830/2003 (products consisting of or containing GMOs): Labelling

Terms of Authorisation

The proposed terms of authorisation are set out below

The following is for authorisation as new GMO product:

- RP1232 - BCS-GH811-4 Cotton

Genetically modified organism and unique identifier

1. For the purposes of Articles 7(3) and 19(3) of assimilated Regulation (EC) No. 1829/2003, the unique identifier BCS-GH811-4 is specified for genetically modified GHB811 cotton.

Designation and specification of the products -

2. For the purposes of Articles 4(2) and 16(2) of assimilated Regulation (EC) No. 1829/2003 the Designation and specification of the products are:

(a)foods and food ingredients containing, consisting of or produced from genetically modified cotton BCS-GH811-4;

(b)feed containing, consisting of, or produced from genetically modified cotton BCS-GH811-4; and

(c)products containing or consisting of genetically modified cotton BCS- GH811-4 for uses other than those provided for in sub-paragraphs (a) and (b), with the exception of cultivation.

Labelling

3. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of assimilated Regulation (EC) No. 1829/2003, and in Article 4(6) of assimilated Regulation (EC) No. 1830/2003, the 'name of the organism' is 'cotton'.

The words 'not for cultivation' shall appear on the label of, and in documents accompanying, the products containing or consisting of genetically modified cotton BCS- GH811-4 specified with their unique identifiers, with the exception of food and food ingredients.

Method for detection

4.(1) For the purposes of Articles 7(3) and 19(3) of assimilated Regulation (EC) No. 1829/2003, the method specified in sub-paragraph (2) is to be used for the detection of genetically modified cotton BCS-GH811-4.

(2) The method is set out in the document entitled "Event-specific Method for the Quantification of Cotton GHB811 by Real-time PCR", reference "EURL-VL-04/18VP" and published 13 July 2020 (amended by EURL-VL-04/18VR Corrigendum).

(3) The method of DNA extraction for use in the detection method specified in sub-paragraph (2) is set out in the document entitled "Cotton Seeds Sampling and DNA Extraction Report on the Validation of DNA Extraction Method from Cotton Seeds", reference "CRLVL13/04XP" and dated 14 March 2007.

(4) For the purposes of Articles 7(3) and 19(3) of assimilated Regulation (EC) No. 1829/2003, the reference material “ERM®-BF442” is accessible via the Joint Research Centre (JRC) of the European Commission.

Monitoring plan for environmental effects

5. The authorisation holder must ensure that the monitoring plan for environmental effects, which accompanied the application for authorisation of genetically modified cotton BCS-GH811-4, reference number “RP1232” submitted to the Food Safety Authority on 27 August 2021, is implemented.

The authorisation holder must submit to the Food Safety Authority annual reports on the implementation of, and the results of the activities set out in, the monitoring plan in accordance with the format set out in Annex 2 of Decision 2009/770.

Authorisation holder

6. (1) The name and address of the authorisation holder is BASF Agricultural Solutions Seed US LLC, 100 Park Avenue, 07932, Florham Park, New Jersey, US

(2) The authorisation holder is represented in Great Britain by BASF PLC, 2 Stockport Exchange, Railway Road, Stockport, Cheshire, SK1 3GG

Supplementary Information

Environmental Risk Assessment

The Advisory Committee on Releases to the Environment (ACRE) is the advisory body on deliberate release to the environment for the respective competent authorities in Great Britain; in Wales these are the Welsh ministers. ACRE has considered the environmental risk assessment (ERA) of GHB811 cotton. The scope of the application does not include cultivation and only covers the import, processing, and food and feed use of GMB151 soybean. ACRE concluded that GHB811 cotton would not raise safety concerns in the event of accidental release of viable seeds or propagating material into the environment.

The FSA has consulted the competent authority in Wales for their opinion, which we will take into consideration before making our final recommendation to ministers.

ACRE’s advice is available on GOV.UK

https://www.gov.uk/government/publications/acre-advice-application-to-market-gm-cotton--2

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.

Transitional Requirements/ Provisions

N/A

Further Explanation/ Rationale

N/A

Post Market Monitoring

N/A

Definitions

N/A

Other Legitimate Factors

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

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

Impacts

As part of the risk analysis process, the FSA has assessed the potential impacts that would result from the authorisation of this GMO for food and feed uses, 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.

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 in there. The FSA's recommendation to authorise aligns with the product authorisation in Northern Ireland.

Risk Management Recommendation

The FSA risk management recommendation is that Cotton GHB811, as described in this application, is safe and is not liable to have an adverse effect on the target population, environmental safety and or human health at the intended concentrations of use.

Annex 8
FSA Risk Management Recommendation
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)

An application for the authorisation in Great Britain of this genetically modified organism (GMO) on the terms below has been submitted. It is for ministers in England, Wales and Scotland to decide whether to authorise the GMO.

Introduction

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.

Safety Assessment Summary

The food/feed safety of the newly expressed proteins was assessed, and no safety concerns were raised in terms of their toxicological potential, allergenic potential, and nutritional quality. Based on the comparative analysis and the nutritional assessment, genetically modified maize DP4114 x MON 810 x MIR604 x NK603 does not cause any nutritional concerns. Overall, the FSA and FSS concluded that genetically modified maize DP4114 x MON 810 x MIR604 x NK603 is as safe as its conventional counterpart with respect to its potential effects on human and animal health.

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

Any Relevant Provisions of Assimilated Law

- Article 5: assimilated Regulation (EC) No.1829/2003 (food) and Article 17 (feed): Application for authorisation
- Article 6: assimilated Regulation (EC) No.1829/2003 (food) and Article 18 (feed): Opinion of the Food Safety Authority
- Article 13(1): assimilated Regulation (EC) No.1829/2003 (food) and Article 25(2) (feed): Labelling

- Article 4(6): Assimilated Regulation (EC) No. 1830/2003 (products consisting of or containing GMOs): Labelling

Terms of Authorisation

The proposed terms of authorisation are set out below.

The following is for authorisation as new GMO product:

- RP1506 - DP-ØØ4114-3 x MON-ØØ81Ø-6 x SYN-IR6Ø4-5 x MON-ØØ6Ø3-6 maize and sub-combinations.

Genetically modified organism and unique identifier

2. For the purposes of Articles 7(3) and 19(3) of assimilated Regulation (EC) No.1829/2003, the following unique identifiers are specified for genetically modified DP4114 × MON 810 × MIR604 × NK603 maize and sub-combinations as follows—

a) DP-ØØ4114-3 x MON-ØØ81Ø-6 x SYN-IR6Ø4-5 x MON-ØØ6Ø3-6; for genetically modified maize DP4114 × MON 810 × MIR604 × NK603
b) SYN-IR6Ø4-5 x MON-ØØ6Ø3-6 x DP-ØØ4114-3; for genetically modified maize MIR604 × NK603 × DP4114
c) MON-ØØ81Ø-6 x MON-ØØ6Ø3-6 x DP-ØØ4114-3; for genetically modified maize MON 810 × NK603 × DP4114
d) MON-ØØ81Ø-6 x SYN-IR6Ø4-5 x DP-ØØ4114-3; for genetically modified maize MON 810 × MIR604 × DP4114
e) MON-ØØ81Ø-6 x SYN-IR6Ø4-5 x MON-ØØ6Ø3-6; for genetically modified maize MON 810 × MIR604 × NK603
f) MON-ØØ6Ø3-6 x DP-ØØ4114-3; for genetically modified maize NK603 × DP4114
g) SYN-IR6Ø4-5 x DP-ØØ4114-3; for genetically modified maize MIR604 × DP4114
h) SYN-IR6Ø4-5 x MON-ØØ6Ø3-6; for genetically modified maize MIR604 × NK603
i) MON-ØØ81Ø-6 x DP-ØØ4114-3; for genetically modified maize MON 810 × DP4114
j) MON-ØØ81Ø-6 x SYN-IR6Ø4-5; for genetically modified maize MON 810 x MIR604.

Designation and specification of the products -

2. For the purposes of Articles 4(2) and 16(2) of assimilated Regulation (EC) No.1829/2003 the designation and specification of the products are —

(a)foods and food ingredients containing, consisting of or produced from genetically modified maize as referred to in paragraph 1;

(b)feed containing, consisting of, or produced from genetically modified maize as referred to in paragraph 1;

(c)products containing or consisting of genetically modified maize as referred to in paragraph 1 for uses other than those provided for in sub-paragraphs (a) and (b), with the exception of cultivation.

Labelling

3. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of assimilated Regulation (EC) No. 1829/2003, and in Article 4(6) of assimilated Regulation (EC) No. 1830/2003, the 'name of the organism' is 'maize'.

The words 'not for cultivation' shall appear on the label of, and in documents accompanying, the products containing or consisting of genetically modified maize as referred to in paragraph 1 specified with their unique identifiers, with the exception of food and food ingredients.

Method for detection

4.(1) For the purposes of Articles 7(3) and 19(3) of assimilated Regulation (EC) No. 1829/2003, the methods specified in sub-paragraph (2) are to be used for the detection of genetically modified maize referred to in paragraph 1.

(2) The methods are set out in:

(a)for DP4114, the document entitled "Event-specific Method for the Quantification of maize DP-ØØ1144-3 using Real-time PCR", reference "EURL-VL-02/14VP" and dated 10 April 2018;

(b)for MON 810, the document entitled "CRL assessment on the validation of an event specific method for the relative quantitation of maize line MON 810 DNA using real-time PCR as carried out by Federal Institute for Risk Assessment (BfR)", reference "CRL-VL-25/04VR" and dated 10 March 2006.

(c)for MIR604, the document entitled "Event-specific Method for the Quantification of maize Line MIR604 Using Real-time PCR - Protocol", reference "CRLVL04/05VP Corrected version 1 30/03/2010" and dated 03 April 2007;

(d)for NK603, the document entitled "Event-specific method for the quantitation of maize line NK603 using real-time PCR - Protocol", reference "CRLVL27/04VP" and published 10 January 2005.

(3) The method of DNA extraction for use in the detection method specified in sub-paragraph (2) is set out in the document entitled "Report on the In-house Validation of a DNA Extraction Method from Ground maize Seeds and Validated DNA Extraction Method", reference "EURL-VL-02/14XP" and dated 10 April 2018.

(4) For the purposes of Articles 7(3) and 19(3) of assimilated Regulation (EC) No. 1829/2003, the reference material "AOCS 0607-A2" (for SYN-IR6Ø4-5) is accessible via the American Oil Chemists Society at https://www.aocs.org/crm, "ERM®-BF439" (for DP-ØØ4114-3), "ERM®-BF413" (for MON-ØØ81Ø-6) and "ERM®-BF415" (for MON-ØØ6Ø3-6) are accessible via the Joint Research Centre (JRC) of the European Commission https://crm.jrc.ec.europa.eu/.

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Monitoring plan for environmental effects

5. The authorisation holder must ensure that the monitoring plan for environmental effects, which accompanied the application for authorisation of genetically modified maize referred to in paragraph 1, reference number "RP1506" submitted to the Food Safety Authority on 31 March 2022, is implemented.

The authorisation holder must submit to the Food Safety Authority annual reports on the implementation of, and the results of the activities set out in the monitoring plan in accordance with the format set out in Annex 2 of Decision 2009/770.

Authorisation holder

6.(1) The name and address of the authorisation holder is Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, IN 46268-1054, U.S.A.

(2) The authorisation holder is represented in Great Britain by Corteva Agriscience UK Limited, European Development Centre, 3B Park Square, Milton Park, Abingdon, Oxon, OX14 4RN, United Kingdom

Supplementary Information

Environmental Risk Assessment

The Advisory Committee on Releases to the Environment (ACRE) is the advisory body on deliberate release to the environment for the respective competent authorities in Great Britain ; in Wales these are the Welsh ministers. ACRE has considered the Environmental Risk Assessment (ERA) of maize DP4114 x MON 810 x MIR604 x NK603. The scope of the application does not include cultivation and only covers the import, processing, and food and feed use of maize DP4114 x MON 810 x MIR604 x NK603. ACRE concluded that GHB811 cotton would not raise safety concerns in the event of accidental release of viable seeds or propagating material into the environment.

The FSA has consulted the competent authority in Wales for their opinion, which we will take into consideration before making our final recommendation to ministers.

ACRE's advice is available on GOV.UK

https://www.gov.uk/government/publications/acre-advice-applications-to-market-gm-soybeans-and-maize

Labelling

- In accordance with assimilated Regulation (EC) No. 1830/2003, concerning the traceability and labelling of genetically modified organisms (GMOs) 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.

Transitional Requirements/ Provisions

N/A

Further Explanation/ Rationale

N/A

Post Market Monitoring

N/A

Definitions

N/A

Other Legitimate Factors

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

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

Impacts

As part of the risk analysis process, the FSA has assessed the potential impacts that would result from the authorisation of this GMO for food and feed uses, 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.

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 in there. The FSA's recommendation to authorise aligns with the product authorisation in Northern Ireland.

Risk Management Recommendation

The FSA risk management recommendation is 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.

Annex 9
FSA Risk Management Recommendation
RP1033 - Isomaltooligosaccharide (IMO) (Extension of use) (Novel Food)

An application for authorisation in Great Britain of this novel food on the terms below has been submitted. It is for ministers in England, Wales and Scotland to decide whether to authorise the novel food.

Introduction

An application for the extension of use of Isomaltooligosaccharide (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 twelve different food categories. The application proposes the extension of IMO use as an ingredient in fifteen further food categories and for use in supplements.

For new novel foods and extensions of use to authorised novel foods to be placed on the market in Great Britain, an application shall be submitted in accordance with assimilated European Union(EU) Regulation 2015/2283. The following articles for submission are to be used:

- Article 4 for novel food consultation process
- Article 10 for novel foods administrative and scientific requirements
- Article 14 for traditional foods from third countries

Safety Assessment Summary

Following the submission of application RP1033, the FSA and FSS have undertaken a safety assessment on the proposed extension of use of IMO as a novel food.

The FSA have undertaken the assessment of the extension of use of IMO and concluded that the composition of the novel food is safe under the proposed conditions of use and does not pose a safety risk to human health. The anticipated intake levels and the proposed uses in food and food supplements was not considered to be nutritionally disadvantageous.

Safety assessment: RP1033 Change of conditions of use for the novel food, isomalto-oligosaccharides

Relevant legislation

- Assimilated Regulation (EU) 2017/2470 establishing the (Union) list of novel foods
- Assimilated Regulation (EU) 2017/2469 laying down administrative and scientific requirements for applications
- Assimilated Regulation (EU) 2015/2283 setting out requirements and process for the authorisation of novel foods
- Article 7 of Assimilated Regulation (EU) 2015/2283 on the general conditions for inclusions of novel foods in the list
- Article 10 of Assimilated Regulation (EU) 2015/2283 on the procedure for authorising the placing on the market of a novel food and updating the list
- Assimilated Regulation (EU) 1169/2011 on the provision of food information to consumers

Terms of Authorisation

The proposed terms of authorisation are set out below, with the new proposed conditions of use in bold.

- **Authorised novel food: Isomaltooligosaccharide**
- **Conditions under which the novel food may be used:**

Specified food category	Maximum levels	Additional specific labelling requirements
Energy-Reduced Soft Drinks	6.5 % w/v	1.The designation of the novel food on the labelling of the food containing it shall be 'Isomaltooligosaccharide'. 2.Foods containing the novel ingredient must be labelled as 'a source of glucose'. **3. Food supplements containing Isomaltooligosaccharide shall bear a statement that the food supplement is not to be consumed by children under 10 years of age**
Energy Drinks	5.0 % w/v	
Foods intended to meet the expenditure of intense muscular efforts, especially for sportsmen (including isotonic drinks)	6.5 % w/w	
Fruit Juices	5 % w/v	
Processed Vegetables and Vegetable Juices	5 % w/v	

Specified food category	Maximum levels	Additional specific labelling requirements
Other Soft Drinks	5 % w/v	
Cookies, Biscuits	20 % w/w	
Cereal Bars	25 % w/w	
Hard Candies	97 % w/w	
Soft Candies/Chocolate Bars	25 % w/w	
Meal replacement for weight control (as bars or milk based)	20 % w/w	
Ice Cream and Dairy Desserts	**8% w/w**	
Instant Coffee and Instant Tea	**10% w/w**	
Table-top sweeteners	**<100% w/w**	
Cakes **Shortcrust (pies and tarts)**	**20% w/w** **20% w/w**	
Pastries	**15% w/w**	
Breakfast cereals	**10% w/w**	
Condiments, Relishes, Gravies and Savoury Sauces	**10% w/w**	
Gelatine Desserts **Fruit Pie Fillings**	**15% w/w** **15% w/w**	
Fruit spreads	**50% w/w**	
Yoghurts	**2.5% w/w**	
Milk-based Drinks	**5% w/v**	
Potato, cereal, flour or starch-based snacks	**5% w/w**	
Dessert Sauces and Toppings	**50% w/v**	
Food Supplements as defined in the Food Supplements (England) Regulations 2003, the Food Supplements (Wales) Regulations 2003 and the Food Supplements (Scotland) Regulations 2003 excluding food supplements for] children under 10 years of age	**<100% w/w**	

Data protection has been applied for by the applicant for this extension of use.

Specification

Table 2 (specifications) of Regulation 2017/2470, “Isomaltooligosaccharide” does not need amending as it continues to comply with existing specifications.

Proposed uses

The novel food is an IMO which is intended to be used as a food ingredient, including as an ingredient in food supplements. The intended extension of uses of IMO seeks to use the novel food within the food categories: Ice Cream and Dairy desserts, Instant coffee and Instant Tea, Table-top sweeteners, Cakes, Shortcrust (pies and tarts), Pastries Breakfast cereals, Condiments, Relishes, Gravies and Savoury Sauces, Gelatine desserts, Fruit Pie Fillings, Jams and Jellies, Yoghurts, Milk-based Drinks, Potato, Cereal, Flour or Starch-based Snacks , Dessert Sauces and Toppings and as an ingredient in food supplements.

The products excluding food supplements are to be consumed by the general population in the categories proposed for extension of use. The IMO is proposed to be used for sweetening purposes in food supplements and the food supplements are not to be consumed by children under 10 years of age.

Supplementary Information

N/A

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, IMO must be labelled in accordance with the labelling requirements set out in Article 21 of assimilated Regulation (EU) No. 1169/2011.

Transitional Requirements/ Provisions

N/A

Further Explanation/ Rationale

N/A

Post Market Monitoring

N/A.

Definitions
N/A

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

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

Impacts
As part of the risk analysis process, the 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.

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 GB can be moved into Northern Ireland through the Northern Ireland Retail Movement Scheme.

Risk Management Recommendation

The FSA risk management recommendation is that the 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.

Annex 10
FSA Risk Management Recommendation
RP956 – Magnesium L-threonate (new authorisation) (Novel Foods)

An application for authorisation in Great Britain of this novel food on the terms below has been submitted. It is for ministers in England, Wales and Scotland to decide whether to authorise the novel food.

Introduction

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.) (EU Exit) Regulations 2019'.

For new novel foods and extensions of use to authorised novel foods to be placed on the market in Great Britain, an application shall be submitted in accordance with assimilated EU Regulation 2015/2283. The following articles for submission are to be used:

- Article 4 for novel food consultation process
- Article 10 for novel foods administrative and scientific requirements
- Article 14 for traditional foods from third countries

Safety Assessment Summary

The FSA and FSS have undertaken the assessment of magnesium L-threonate monohydrate and concluded that the novel food is safe under the proposed conditions of use and does not pose a safety risk to human health. The anticipated intake levels and the proposed use were not considered to be nutritionally disadvantageous.

Safety assessment: RP956 Magnesium L-threonate as a novel food for use in food supplements

Relevant legislation

- Assimilated Regulation (EU) 2015/2283 (Novel Foods)
- Food Supplements (England) Regulations 2003
- Food Supplements (Wales) Regulations 2003

- Schedule 2 of The Nutrition (Amendment, etc.) (EU Exit) Regulations 2019)

Terms of Authorisation

The proposed terms of authorisation are set out below

Table 1: Authorised Novel Food: Magnesium L-threonate monohydrate / Conditions under which the Novel Food may be used

Specified food category	***Maximum Levels***	**Additional specific labelling requirements**
Food supplements as defined in the Food Supplements (England) Regulations 2003 for persons aged 18 years or above, excluding pregnant and lactating women [and equivalents in Scotland and Wales]	3 g/per day	1. The designation of the novel food on the labelling of food containing it is magnesium L-threonate. 2. The labelling of food supplements containing magnesium L-threonate monohydrate shall bear a statement that those food supplements should not be consumed by children under 18 years, pregnant and lactating women.

Specification

Table 2:

Authorised Novel Food	**Specifications**
Magnesium L-threonate monohydrate	• Description/Definition - Magnesium L-threonate monohydrate is a water-soluble white powder which is manufactured via a chemical synthetic process. • Chemical formula: $C_8H_{16}MgO_{11}$ • Chemicalname: Magnesium (2R,3S)-2,3,4-trihydroxybutanoate monohydrate. • CAS No.: 500304-76-7 • Molecular weight: 312.51 Da • Solubility: Soluble in water at 1% concentration at 25°C and that is clear in solution at 1% concentration • Magnesium: 7.2 to 8.3% (mg/g) • L-Threonate: 82 to 91% • Oxalic acid/oxalate: not more than 0.5% (as oxalic acid) • Loss on drying (105 °C/4 hours): ≤5.0% • Colour (solid): White • pH (USP (1% in H_20)): 5.8 - 7.0 • Arsenic: ≤1 ppm

Authorised Novel Food	Specifications
	• Lead: ≤0.5 ppm • Cadmium: ≤0.2 ppm • Mercury: ≤0.1 ppm

Data protection has been applied for by the applicant.

Proposed Uses

- Proposed to be used as or in food supplements as defined in the Food Supplements (England) Regulations 2003) and equivalent national measures.
- Magnesium L-threonate monohydrate is intended to be consumed by adults only in the general population. It is not recommended for certain vulnerable groups, including pregnant and lactating women, and children under 18.

Supplementary Information

N/A

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'

Transitional Requirements/ Provisions

N/A

Further Explanation/ Rationale

N/A

Post Market Monitoring

N/A

Definitions

Child is defined as someone under 18, as per the summary dossiers where the applicant has stated that children under 18 are not the target population for this product.

Other Legitimate Factors

In developing the risk management recommendations, the FSA has had regard to the other legitimate factors (including consumer interests, political, environmental, societal and technical feasibility) that ministers will consider as part of their decision on authorisation. The FSA has not identified any applicable other legitimate factors to date, once it is added to Schedule 2 of The Nutrition (Amendment etc.) (EU Exit) Regulations 2019, that would prevent authorisation or affect the conditions of authorisation of this novel food. As noted above, stakeholders and the broader

public are equally invited to consider and provide their views on any relevant other legitimate factors as part of the consultation process.

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

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.

Risk Management Recommendation

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.