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

Date of publication: 8 January 2024

## Document Subject and Purpose

In this document, we publish the Food Standards Scotland’s (FSS) risk management recommendations on applications for one food additive, one feed additive, one food flavouring and the removal of eight permitted flavouring substances, one food contact material, two novel foods and three genetically modified organisms (for food and feed uses).

Since the end of the EU exit transition period, FSS and the Food Safety Authority (FSA) have adopted technical guidance and quality assurance processes used by the European Food Safety Authority (EFSA) to be able us to undertake Great Britain (GB) safety assessments for regulated product applications. Further information is available on our website:

[Regulated products application guidance](https://www.food.gov.uk/business-guidance/regulated-products-application-guidance)

These risk management recommendations take into account the opinion of FSS, which also considers:

* The safety assessments of FSS for each application;
* Potential impacts that would result from the authorisation of these regulated products; and
* Other legitimate factors that Scottish Ministers may want to consider before making a decision regarding authorisation.

The final FSS proposed risk management recommendations made to the Scottish Ministers will also consider stakeholders’ views received from this consultation.

A parallel consultation is being published by the FSA to inform Ministers' determination in England and Wales (with the Health Minister in Northern Ireland kept informed).

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## Our safety assessment and opinion

Our risk assessors deliver the science behind our advice. They are responsible for identifying and characterising hazards and risks to health and assessing levels of exposure.

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

The risk management recommendations will be considered by the Scottish Ministers to inform determinations on the authorisations of the regulated product applications in Scotland.

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## Risk management recommendations

FSS have made risk management recommendations on the applications for the authorisations for one food additive, one feed additive, one food flavouring and the removal of eight permitted flavouring substances, one food contact material, two novel foods and three genetically modified organisms (for food and feed uses).

The FSS risk management recommendation for each application is published within a separate annex (linked below), including the regulated product ID number and title of the application. A link to the individual opinion/safety assessments is provided in each Annex.

A safety assessment was not required for the removal of eight food flavourings from the domestic list (RP2184) but potential impacts and other legitimate factors have been considered in developing the recommendations.

Food Additive

[Annex A RP 1112, Steviol Glycosides from Fermentation (Reb M) (new specification)](#_Background)

Feed Additive

[Annex B RP694 Saccharomyces cerevisiae CNCM I-1079](#_Annex_B:_RP694)

Flavourings

[Annex C RP1466 2-Hydroxy-4-methoxybenzaldehyde](#_Annex_C:_RP1466)

[Annex D RP2184 removal of eight permitted food flavouring substances from the domestic list](#_Background_1)

Food Contact Materials

[Annex E RP1190 phosphoric acid, mixed esters with 2-hydroxyethyl methacrylate (HEMAP) (CAS No. 52628-03-2)](#_Background_2)

Novel Foods

[Annex G RP1033 Isomaltooligosaccharide (IMO) (Extension of use)](#_Background_4)

Genetically Modified Organisms

[Annex H RP1123 GMB151 (GMO for food and feed uses)](#_Background_7)

[Annex I RP1232 GHB811 Cotton (GMO for food and feed uses)](#_Background_6)

[Annex J RP1506 GMB151 (GMOs for food and feed uses)](#annexj)

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## Further information

If you require a more accessible format of this document, please send details to the email address for comments and your request will be considered.

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

## Background

FSS have undertaken a safety assessment of application RP1112 for the new specification of use of steviol glycosides (E 960b) produced by fermentation as a food additive (sweetener) from Amyris Inc. Amyris Inc have applied for the authorisation of a rebaudioside M that is made by fermenting food grade cane sugar with genetically modified (GM) *Saccharomyces cerevisiae*.

## Safety assessment summary

FSS safety assessment was published on 12 April 2024 and can be found [here](https://www.food.gov.uk/sites/default/files/media/document/RP1112-Assessment-steviol-glycosides-produced-by-fermentation.pdf). The assessment for 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. 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](https://www.legislation.gov.uk/eur/2008/1333/article/12) of [Regulation (EC)1333/2008](https://www.legislation.gov.uk/eur/2008/1333/introduction), which states that any permitted food additive made using a different production method needs to be authorised.

## Relevant Legislation

Legislation in respect of food additives applies to this application. In particular it is noted that this application must fulfil the following requirements:

* [Regulation (EC) 1331/2008](https://www.legislation.gov.uk/eur/2008/1331) sets out the process to authorise new food
* [Regulation (EC) 1333/2008](https://www.legislation.gov.uk/eur/2008/1333/contents) sets out a list of approved food additives and their conditions of use
* [Regulation (EU) 231/2012](https://www.legislation.gov.uk/eur/2012/231/introduction) sets out specifications for food additives

## Proposed 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 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 |  | | |
| 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 | Trivial name | Formula | Conversion factor |
| Rebaudioside M | C56H90O33 | 0.25 |
| Molecular weight and CAS No. | Trivial name | CAS Number | Molecular weight (g/mol) |
| Rebaudioside M | 1220616-44-3 | 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 | | | |
| Solubility | Freely soluble to slightly soluble in water. | | |
| pH | Between 4.5 and 7.0 (1 in 100 solution) | | |
| Purity | | | |
| Total ash | Not more than 1% | | |
| Loss on drying   Kaurenoic acid | Not more than 6 % (105 °C, 2h)   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 |  | | |
| Total (aerobic) plate count | Not more than 1000 CFU/g | | |
| Yeast | Not more than 100 CFU/g | | |
| 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

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 (EC) 1333/2008.

## Labelling

No new labelling required. There is no impact on old label stock as a transition period is not required.

## Other legitimate factors

In developing the risk management recommendations, FSS 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.

FSS have 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, FSS have 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.

## Northern Ireland

Whilst Northern Ireland businesses would not be able to use reb M produced by fermentation in foods there are a variety of other steviol glycosides authorised for use and so this should not lead to disadvantages to Northern Ireland businesses.

## Risk Management Recommendation

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

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Annex B: RP694 – *Saccharomyces cerevisiae* CNCMI-1079 (new use) (Feed Additive)

## Background

FSS have undertaken a safety assessment of application RP694 for the new use of *Saccharomyces cerevisiae* CNCM I-1079), under the category of ‘zootechnical’ and in the functional groups ‘gut flora stabiliser’ and ‘physiological condition stabiliser’ for its use in calves, and all other ruminants and Camelidae for rearing and fattening, at their correspondent developmental stage, was received from Lallemand Animal Nutrition UK. Since receipt of the application, the applicant has subsequently withdrawn the proposal for the feed additive to be classified in the ‘physiological condition stabiliser’ functional group.

## Safety Assessment Summary

FSS safety assessment was published on 15 December 2023 and can be found [here.](https://www.food.gov.uk/research/research-projects/safety-assessment-rp694-s-cerevisiae) The assessment for the proposed 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.

## 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 [Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) on additives for use in animal nutrition including:

* [Article 4 and 7](https://www.legislation.gov.uk/eur/2003/1831/chapter/II) Application for authorisation of a new or new use of a feed additive
* [Article 5](https://www.legislation.gov.uk/eur/2003/1831/article/5) Conditions for authorisation
* [Article 6](https://www.legislation.gov.uk/eur/2003/1831/article/6) and [Annex I](https://www.legislation.gov.uk/eur/2003/1831/annex/I) Categories of feed additives and functional groups
* [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted) Labelling and packaging requirements apply, if authorised
* [Article 17](https://www.legislation.gov.uk/eur/2003/1831/article/17) Register of feed additives – An entry will be required

[Article 21](https://www.legislation.gov.uk/eur/2003/1831/article/21) and [Annex II](https://www.legislation.gov.uk/eur/2003/1831/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](https://joint-research-centre.ec.europa.eu/publications/fad-2010-0121_en). Valid methods exist for:

(a) Identification of the bacterial strain *Saccharomyces cerevisiae* CNCM I-1079.

[Annex IV](https://www.legislation.gov.uk/eur/2003/1831/annex/IV/adopted) 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 [Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) there are additional labelling requirements required by [Annex VII of Regulation (EC) 767/2009.](https://www.legislation.gov.uk/eur/2009/767/annex/VII)

## Proposed terms of authorisation

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(2) and 5 (3) of Regulation (EC) 1831/2003,](https://www.legislation.gov.uk/eur/2003/1831/article/5) 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 × 1010 CFU/g (Non-coated/encapsulated preparations)  1.0 × 1010 CFU/g (Coated/encapsulated preparations) |
| *Characterisation of the active substance(s)* | | Viable cells of *Saccharomyces cerevisiae* CNCM I-1079 |
| *Analytical methods[[1]](#footnote-2)* | | Identification: Polymerase chain reaction (PCR) method (DD CEN/TS 15790:2008)[[2]](#footnote-3) |
| Enumeration: pour plate method using chloramphenicol glucose yeast extract agar (BS EN 15789:2021)[[3]](#footnote-4) |
| *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 × 109 |
| *Maximum content* | Not applicable |
| *Other provisions* | | The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture. |

## Specifications

*Saccharomyces cerevisiae* CNCM I-1079 shall be allocated to the additive category ‘zootechnical additives’ and to the functional group ‘gut flora stabilisers’, as specified in Annex I of Regulation (EC) 1831/2003. More detailed specification is included in TOA section above.

## 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 Camelidae, 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)](https://www.legislation.gov.uk/uksi/1992/2966/contents)

-  [The Control of Substances Hazardous to Health Regulations 2002 (legislation.gov.uk)](https://www.legislation.gov.uk/uksi/2002/2677/contents)

Main animal species and their subgroups are defined in Annex IV of Regulation (EC) 429/2008. [DN: although Camelidae are not defined here]

FSS considers there is no basis to propose specific requirements for post-market monitoring.

## Labelling

Feed additives labelling must include details pursuant to [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) of assimilated [Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents). As this feed additive falls under the ‘zootechnical’ category it is also subject to additional labelling set out in [Annex III of assimilated Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted) and [Annex VI of assimilated Regulation (EC) 767/2009](https://www.legislation.gov.uk/eur/2009/767/annex/VI).

## Post Market Monitoring

FSS 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).](https://www.legislation.gov.uk/eur/2020/1374) [Article 1 of 429/2008](https://www.legislation.gov.uk/eur/2008/429/article/1) indicates this should be classified as a minor species.
* Ruminants
* Minor species
* Zootechnical category and function

## Trade

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

## Other legitimate factors

In developing the risk management recommendations, FSS 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.

FSS 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 *Saccharomyces cerevisiae* CNCM I-1079 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, FSS 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

It is the opinion of FSS, as per [Article 4 & 7 Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/chapter/II) that *Saccharomyces cerevisiae* (CNCM I-1079), 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, 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. FSS recommends the authorisation of this feed additive on the proposed terms of authorisation.

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

## Background

FSS have undertaken a safety assessment of application RP1466 for the new authorisation of 2-hydroxy-4-methoxybenzaldehyde as a new flavouring substance to be used in food, was received from Firmenich S.A.

## Safety Assessment Summary

FSS safety assessment was published on 12 April 2024 and can be found [here](https://www.food.gov.uk/research/research-projects/safety-assessment-rp1466-2-hydroxy-4-methoxybenzaldehyde). The assessment for authorisation of 2-hydroxy-4-methoxybenzaldehyde, is safe under the proposed conditions of use and at the anticipated levels of intake. Therefore, there are no concerns over safety of over the proposed use.

## Relevant legislation

The process to authorise new flavouring substances in line with [Article 9](https://www.legislation.gov.uk/eur/2008/1334/article/9) of [Regulation (EC) 1334/2008](https://www.legislation.gov.uk/eur/2008/1334/introduction) is set out in the common authorisation procedure for food additives, food enzymes and food flavourings – [Regulation (EC) 1331/2008](https://www.legislation.gov.uk/eur/2008/1331).

In particular:

* [Article 3](https://www.legislation.gov.uk/eur/2008/1331/article/3) - Main stages of the common procedure
* [Article 7](https://www.legislation.gov.uk/eur/2008/1331/article/7) - Updating the domestic list

[Regulation (EC) 1334/2008](https://www.legislation.gov.uk/eur/2008/1334/introduction) on flavourings and certain food ingredients with flavouring properties for use in and on foods:

* [Article 11(3)](https://www.legislation.gov.uk/eur/2008/1334/article/11) – Inclusion of flavourings and source materials in the domestic list

## Proposed terms of authorisation

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

## Supplementary information

The general requirements for authorising new flavourings are that they are safe and their use would not mislead consumers. This new flavouring meets these requirements.

## 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 (EU) 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 (EC) No. 1334/2008.

## Other legitimate factors

In developing the risk management recommendations, FSS 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.

FSS 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, FSS have assessed the potential impacts that would result from the authorisation of this food flavouring (new authorisation) 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 2-hydroxy-4-methoxybenzaldehyde 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

Businesses in Northern Ireland can already use this flavouring substance in food.

## Risk Management Recommendation

It is the opinion of FSS, as per [Article 5 Regulation (EC) 1331/2008](https://www.legislation.gov.uk/eur/2008/1331/article/5), that 2-hydroxy-4-methoxybenzaldehyde, is safe and is not liable to have an adverse effect on the target population, environmental safety and human health under the proposed conditions of use. FSS recommend authorising this food flavouring on the proposed terms of authorisation.

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Annex D: RP2184 – removal of eight permitted food flavouring substances from the domestic list

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

## Background

FSS have undertaken a safety assessment of application RP2184 for the removal of eight food flavouring substances that are proposed to be removed from the domestic list. The 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)

## Safety Assessment Summary

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

## Relevant legislation

FSS has not identified any relevant provisions of law that would impact authorisation of the removals.

## Description of flavouring substances being considered for removal

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

The eight 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 should have 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.

## Supplementary information

The UK Flavour association (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 requirement/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 effective date of the Ministerial decision, 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 imported into GB before the coming into force date.

## Other legitimate factors

In developing the risk management recommendations, FSS 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 eight flavouring substances which are not widely used in foods or drink sold on the market in Scotland, FSS consider there are no relevant other legitimate factors that need to be taken into consideration.

## Impacts

As part of the risk analysis process, FSS has assessed the potential impacts that would result from the removal of eight food flavouring substances 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).

## 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 eight 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.

## Risk Management Recommendation

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

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

## Background

FSS have undertaken a safety assessment of application RP1190 for the new authorisation of phosphoric acid, mixed esters with 2-hydroxyethyl methacrylate (HEMAP) (CAS No. 52628-03-2)intended to be used in plastic food contact materials.

## Safety Assessment Summary

FSS safety assessment was published on (insert date) and can be found here . The assessment for the new authorisation of HEMAP is safe under the proposed conditions of use set out within the application. Therefore, there were no concerns over safety of the proposed process.

## Relevant legislation

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

[Regulation (EC) 1935/2004](https://www.legislation.gov.uk/eur/2004/1935/contents) in particular, but not limited to:

* [Article 8](https://www.legislation.gov.uk/eur/2004/1935/article/8) General requirements for the authorisation of substances
* [Article 9](https://www.legislation.gov.uk/eur/2004/1935/article/9) Application for the authorisation of a new substance (main steps of the common procedure)
* [Article 10](https://www.legislation.gov.uk/eur/2004/1935/article/10) Opinion of the Food Safety Authority
* [Article 11](https://www.legislation.gov.uk/eur/2004/1935/article/11) Authorisation
* [Article 15](https://www.legislation.gov.uk/eur/2004/1935/article/15) Labelling

## Proposed terms of authorisation

The proposed terms of authorisation are set out below

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FCM substance No | Ref. No | CAS No | Substance name | Use as additive or polymer production aid  (yes/no) | Use as monomer or other starting substance or macromolecule obtained from microbial fermentation  (yes/no) | FRF applicable  (yes/no) | SML  [mg/kg] | SML(T)  [mg/kg]  (Group restriction No) | Restrictions and specifications |
| TBC1 |  | 52628-03-2 | Phosphoric acid, mixed esters with 2-hydroxyethyl methacrylate2 | no | yes | no | 0.05 |  | 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 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.

## Definitions

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

In developing the risk management recommendations, FSS 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. FSS 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, FSS 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 by businesses in Northern Ireland. Our proposed authorisation brings GB into alignment with Northern Ireland.

## Risk Management Recommendation

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

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Annex F: RP RP956 – Magnesium L-threonate (new authorisation) (novel food)

## Background

FSS have undertaken a safety assessment of application RP956 for the new authorisation of magnesium L-threonate. The application also requests that magnesium L-threonate monohydrate is permitted as a form of magnesium to be used in the manufacture of food supplements and added to the table which is set out in [Schedule 2](https://www.legislation.gov.uk/uksi/2019/651/schedule/2) of [The Nutrition (Amendment etc.) (EU Exit) Regulations 2019.](https://www.legislation.gov.uk/uksi/2019/651/contents)

## Safety assessment summary

The FSS/FSA safety assessment was published on 28 March 2024 and can be found [here](https://www.food.gov.uk/research/research-projects/safety-assessment-magnesium-l-threonate-as-a-novel-food-for-use-in-food-supplements). The assessment 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.

## Relevant Legislation

For new novel foods to be authorised to be placed on the market in GB, an application shall be submitted in accordance with [Regulation (EU) No. 2015/2283](https://www.legislation.gov.uk/eur/2015/2283/contents).

The following articles for submission are to be used:

* [Article 4](https://www.legislation.gov.uk/eur/2015/2283/article/4) for novel food consultation process
* [Article 10](https://www.legislation.gov.uk/eur/2015/2283/article/10) for novel foods administrative and scientific requirements
* [Article 14](https://www.legislation.gov.uk/eur/2015/2283/article/14) for traditional foods from third countries
* [Regulation (EU) 2015/2283 food as per Article 11](https://www.legislation.gov.uk/eur/2015/2283/contents)  setting out requirements and process for the approval of novel foods
* [Regulation (EC) 178/2002](https://www.legislation.gov.uk/eur/2002/178) (General Food Law - labelling and advertising provisions). To note that the precautionary principle under [Article 7](https://www.legislation.gov.uk/eur/2002/178/article/7) of Regulation (EC) 178/2002 is specifically referred to under Regulation (EU) 2015/2283.
* [Regulation (EU) 2017/2470](https://www.legislation.gov.uk/eur/2017/2470) establishing the (Union) list of novel foods
* [Regulation (EU 2017/2469](https://www.legislation.gov.uk/eur/2017/2469/contents) laying down administrative and scientific requirements for applications.
* [Schedule 2 of The Nutrition (Amendment, etc.) (EU Exit) Regulations 2019)](https://www.legislation.gov.uk/uksi/2019/651/contents)
* [The Food Supplements (Scotland) Regulations 2003](https://www.legislation.gov.uk/ssi/2003/278)

## Proposed terms of authorisation

Table 1

|  |  |  |  |
| --- | --- | --- | --- |
| Authorised Novel Food | Conditions under which the Novel Food may be used | | Additional specific labelling requirements |
| Magnesium L-threonate monohydrate | *Specified food category* | *Maximum Levels* | 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. |
| Food supplements as defined in the Food Supplements (Scotland) Regulations 2003 for persons aged 18 years or above, excluding pregnant and lactating women [and equivalents in England and Wales] | 3 g/per day |

## 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: C8H16MgO11  Chemical name: 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 H20)): 5.8 - 7.0  Arsenic: ≤1 ppm  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 (Scotland) 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.

## 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 standards supplements requirements).
* Will be labelled as ‘magnesium L-threonate'.

## Definitions

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

## Other legitimate factors

In developing the risk management recommendations, FSS 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. FSS 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, FSS have 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 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. Magnesium-L-threonate has been authorised by the EU. There is no significant divergence to the FSS’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 FSS’ proposed terms of authorisation.

## Risk Management Recommendation

It is the opinion of FSS, as per [Article 11 Regulation (EU) 2015/2283](https://www.legislation.gov.uk/eur/2015/2283/article/11), that magnesium L-threonate monohydrate, as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use. FSS recommends authorising this novel food on the proposed terms of authorisation.

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Annex G: RP1033 – Isomaltooligosaccharide (IMO) extension of use) (novel food)

## Background

FSS have undertaken a safety assessment of application RP1033 for the extension of use of Isomaltooligosaccharide (IMO) (also known as oligo-isomaltose). IMO is currently authorised as a novel food under [Commission Implementing Regulation (EU) 2017/2470](https://www.legislation.gov.uk/eur/2017/2470/introduction), 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.

## Safety assessment summary

FSS safety assessment was published on 28 March 2024 and can be found [here](https://www.food.gov.uk/research/research-projects/safety-assessment-change-of-conditions-of-use-for-the-novel-food-isomalto-oligosaccharides). The assessment for the extension of use of IMO 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. The anticipated intake levels and the proposed uses in food and food supplements was not considered to be nutritionally disadvantageous.

## Relevant Legislation

For extensions of use to authorised novel foods to be placed on the market in Great Britain, an application shall be submitted in accordance with  [Regulation (EU) 2015/2283](https://www.legislation.gov.uk/eur/2015/2283/contents). The following articles for submission are to be used:

* [Article 4](https://www.legislation.gov.uk/eur/2015/2283/article/4) for novel food consultation process
* [Article 10](https://www.legislation.gov.uk/eur/2015/2283/article/10) for novel foods administrative and scientific requirements
* [Article 14](https://www.legislation.gov.uk/eur/2015/2283/article/14) for traditional foods from third countries
* [Regulation (EU) 2017/2470](https://www.legislation.gov.uk/eur/2017/2470) establishing the (Union) list of novel foods
* [Regulation (EU) 2017/2469](https://www.legislation.gov.uk/eur/2017/2469/contents) laying down administrative and scientific requirements for applications
* [Regulation (EU) 2015/2283](https://www.legislation.gov.uk/eur/2015/2283/contents) setting out requirements and process for the authorisation of novel foods
* [Article 7](https://www.legislation.gov.uk/eur/2015/2283/article/7) of Regulation (EU) 2015/2283 on the general conditions for inclusions of novel foods in the list
* [Article 10](https://www.legislation.gov.uk/eur/2015/2283/article/10) of Regulation (EU) 2015/2283 on the procedure for authorising the placing on the market of a novel food and updating the list
* [Regulation (EU) 1169/2011](https://www.legislation.gov.uk/eur/2011/1169) on the provision of food information to consumers

## Proposed terms of authorisation

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

|  |  |  |  |
| --- | --- | --- | --- |
| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements |
| Isomaltooligosaccharide | *Specified food category* | *Maximum levels* |  |
|  | 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 |  |
|  | 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**  **(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 (EU) 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.

## 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) 1169/2011. When made from wheat, IMO must be labelled in accordance with the labelling requirements set out in [Article 21 of Regulation (EU) 1169/2011.](https://www.legislation.gov.uk/eur/2011/1169/article/21)

## Other legitimate factors

In developing the risk management recommendations, FSS 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.

FSS have 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 these products should generally result in greater market competition, supporting growth and innovation in the sector.

## Impacts

As part of the risk analysis process, FSS have 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 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. 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 (NIRMS).

## Risk Management Recommendation

It is the opinion of FSS, as per [Article 11 Regulation (EU) 2015/2283,](https://www.legislation.gov.uk/eur/2015/2283/article/11) that the extension of use of IMO 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. FSS recommend authorising this novel food on the proposed terms of authorisation are set out below.

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Annex H: RP1123 – GMB151 (new authorisation) (genetically modified organisms GMOs) for food and feed uses)

## Background

FSS have undertaken a safety assessment of application RP1123 for the new authorisation of genetically modified GMB151 soybean for import, processing and food and feed uses. 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 Scotland, an application shall be submitted in accordance with [Regulation (EC) 1829/2003](https://www.legislation.gov.uk/eur/2003/1829/contents).  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

FSS safety assessment was published on 5 April 2024 and can be found [here](https://www.food.gov.uk/sites/default/files/media/document/RP1123-GMB151_soybean_FINAL.pdf). The assessment for authorisation of GMB151. 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, FSS concluded that GMB151 soybean is as safe as its conventional counterpart with respect to its potential effects on human and animal health.

## Relevant Legislation

For new GMOs for food and feed uses to be placed on the market in Scotland, an application shall be submitted in accordance with [Regulation (EC) 1829/2003](https://www.legislation.gov.uk/eur/2003/1829/contents).  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.

* [Regulation (EC) 1829/2003](https://www.legislation.gov.uk/eur/2003/1829/contents) [Article 5](https://www.legislation.gov.uk/eur/2003/1829/article/5) (food) and [Article 17](https://www.legislation.gov.uk/eur/2003/1829/article/17) (feed): Application for authorisation
* [Regulation (EC) 1829/2003](https://www.legislation.gov.uk/eur/2003/1829/contents) [Article 6](https://www.legislation.gov.uk/eur/2003/1829/article/6) of (food) and [Article 18](https://www.legislation.gov.uk/eur/2003/1829/article/18) (feed): Opinion of the Food Safety Authority
* [Regulation (EC) 1829/2003](https://www.legislation.gov.uk/eur/2003/1829/contents) [Article 13(1)](https://www.legislation.gov.uk/eur/2003/1829/article/13) of (food) and [Article 25(2)](https://www.legislation.gov.uk/eur/2003/1829/article/25) (feed): Labelling
* [Regulation (EC) 1830/2003](https://www.legislation.gov.uk/eur/2003/1830/contents) [Article 4(6)](https://www.legislation.gov.uk/eur/2003/1830/article/4) of (products consisting of or containing GMOs): Labelling

## Proposed 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 Regulation (EC) 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 Regulation (EC) 1829/2003 the Designation 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 Regulation (EC) 1829/2003, and in Article 4(6) of Regulation (EC) 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 Regulation (EC) 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 Regulation (EC) 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

In Scotland the competent authority responsible for performing an environmental risk assessment for the purposes of Article 6 of assimilated [Regulation (EC) 1829/2003](https://www.legislation.gov.uk/eur/2003/1829/contents), is the Scottish Ministers. 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 GB. 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 Scottish Government considered the advice of ACRE and confirmed that they are content with its findings.

The ACRE advice have been considered in the preparation of FSS’ opinion The FSA has consulted the competent authority in Wales for their opinion, which we will be taken into consideration before making our final recommendation to the Scottish Ministers.

In Scotland the competent authority responsible for performing an environmental risk assessment for the purposes of Article 6 of [Regulation (EC) 1829/2003](https://www.legislation.gov.uk/eur/2003/1829/contents), is the Scottish Ministers. 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 GB. 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 Scottish Government considered the advice of ACRE and confirmed that they are content with its findings.

The ACRE advice have been considered in the preparation of FSS’ opinion which will be taken into consideration before making a final recommendation to the Scottish Ministers.

ACRE’s advice is available on the Government of the United Kingdom website at;

[ACRE advice: applications to market GM soybeans and maize - GOV.UK](https://www.gov.uk/government/publications/acre-advice-applications-to-market-gm-soybeans-and-maize)

## Labelling

In accordance with [Regulation (EC) 1830/2003](https://www.legislation.gov.uk/eur/2003/1830/contents), 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.

## Other legitimate factors

In developing the risk management recommendations, FSS 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. FSS has not identified any applicable other legitimate factors to date, 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, FSS have 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 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) 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 FSS’s recommendation to authorise aligns with the product authorisation in Northern Ireland

## Risk Management Recommendation

It is the opinion of FSS, as per [Article 6 Regulation (EC) 1829/2003](https://www.legislation.gov.uk/eur/2003/1829/article/6), that GMB151, 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. FSS recommend authorising this genetically modified organism on the proposed terms of authorisation.

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Annex I RP1232 – GHB811 Cotton (new authorisation) (genetically modified organisms (GMOs) for food and feed uses)

## Background

FSS have undertaken a safety assessment of application RP1232 for the new authorisation of genetically modified GHB811 cotton for import, processing and food and feed uses. The application does not cover cultivation and therefore no GHB811 cotton will be grown in the UK.

## Safety assessment summary

FSS safety assessment was published on 5 April 2024 and can be found [here.](https://www.food.gov.uk/sites/default/files/media/document/RP1232-GHB811_cotton_FINAL.pdf) The assessment for authorisation of GHB811. 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, FSS concluded that GHB811 cotton is as safe as its conventional counterpart with respect to its potential effects on human and animal health.

## Relevant Legislation

For new GMOs for food and feed uses to be placed on the market in Scotland, an application shall be submitted in accordance with Regulation (EC) 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.

* [Regulation (EC) 1829/2003](https://www.legislation.gov.uk/eur/2003/1829/contents) [Article 5](https://www.legislation.gov.uk/eur/2003/1829/article/5) (food) and [Article 17](https://www.legislation.gov.uk/eur/2003/1829/article/17) (feed): Application for authorisation
* [Regulation (EC) 1829/2003](https://www.legislation.gov.uk/eur/2003/1829/contents) [Article 6](https://www.legislation.gov.uk/eur/2003/1829/article/6) of (food) and [Article 18](https://www.legislation.gov.uk/eur/2003/1829/article/18) (feed): Opinion of the Food Safety Authority
* [Regulation (EC) 1829/2003](https://www.legislation.gov.uk/eur/2003/1829/contents) [Article 13(1)](https://www.legislation.gov.uk/eur/2003/1829/article/13) of (food) and [Article 25(2)](https://www.legislation.gov.uk/eur/2003/1829/article/25) (feed): Labelling
* [Regulation (EC) 1830/2003](https://www.legislation.gov.uk/eur/2003/1830/contents) [Article 4(6)](https://www.legislation.gov.uk/eur/2003/1830/article/4) of (products consisting of or containing GMOs): Labelling

## Proposed terms of authorisation

The following is for authorisation as a 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 Regulation (EC) 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 Regulation (EC) 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 Regulation (EC) 1829/2003, and in Article 4(6) of Regulation (EC) 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 Regulation (EC) 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 Regulation (EC) 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 26 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

In Scotland the competent authority responsible for performing an environmental risk assessment for the purposes of Article 6 of [Regulation (EC) 1829/2003](https://www.legislation.gov.uk/eur/2003/1829/contents), is the Scottish Ministers. 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 GB. ACRE has considered the environmental risk assessment (ERA) of [GHB811 ]. The scope of the application does not include cultivation and only covers the import, processing, and food and feed use of [GHB811]. ACRE concluded that [GHB811] would not raise safety concerns in the event of accidental release of viable seeds or propagating material into the environment. The Scottish Government considered the advice of ACRE and confirmed that they are content with its findings.

The ACRE advice have been considered in the preparation of FSS’ opinion which will be taken into consideration before making a final recommendation to the Scottish Ministers.

ACRE’s advice is available on the Government of the United Kingdom website at:

[ACRE advice: applications to market GM cotton and rice - GOV.UK](https://www.gov.uk/government/publications/acre-advice-application-to-market-gm-cotton--2)

## Labelling

In accordance with [Regulation (EC) 1830/2003](https://www.legislation.gov.uk/eur/2003/1830/contents), 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.

## Other legitimate factors

In developing the risk management recommendations, FSS 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. FSS has not identified any applicable other legitimate factors to date, 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 GMB811 should generally result in greater market competition, supporting growth and innovation in the sector.

## Impacts

As part of the risk analysis process, FSS have 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 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) 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. FSS’s recommendation to authorise aligns with the product authorisation in Northern Ireland.

## Risk Management Recommendation

It is the opinion of FSS, as per [Article 6 Regulation (EC) 1829/2003](https://www.legislation.gov.uk/eur/2003/1829/article/6), that GHB811 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. FSS recommends authorising this genetically modified organism on the proposed terms of authorisation.

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Annex J: RP1506 – GMB151 (new authorisation) (genetically modified organisms (GMOs for food and feed uses)

## Background

FSS have undertaken a safety assessment of application RP1506 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). The application does not cover cultivation and therefore no maize DP4114 x MON 810 x MIR604 x NK603 will be grown in the UK.

## Safety assessment summary

FSS safety assessment was published on 5 April 2024 and can be found [here.](https://www.food.gov.uk/sites/default/files/media/document/RP1506-DP4114xMON810xMIR604xNK603_Maize_FINAL%20%28002%29.pdf) The assessment for authorisation of maize DP4114 x MON 810 x MIR604 x NK603. 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, maize DP4114 x MON 810 x MIR604 x NK603 does not cause any nutritional concerns. Overall, FSS concluded that 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.

## Relevant Legislation

For new GMOs for food and feed uses to be placed on the market in Scotland, an application shall be submitted in accordance with [Regulation (EC) 1829/2003](https://www.legislation.gov.uk/eur/2003/1829/contents).  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.

* [Regulation (EC) 1829/2003](https://www.legislation.gov.uk/eur/2003/1829/contents) [Article 5](https://www.legislation.gov.uk/eur/2003/1829/article/5) (food) and [Article 17](https://www.legislation.gov.uk/eur/2003/1829/article/17) (feed): Application for authorisation
* [Regulation (EC) 1829/2003](https://www.legislation.gov.uk/eur/2003/1829/contents) [Article 6](https://www.legislation.gov.uk/eur/2003/1829/article/6) of (food) and [Article 18](https://www.legislation.gov.uk/eur/2003/1829/article/18) (feed): Opinion of the Food Safety Authority
* [Regulation (EC) 1829/2003](https://www.legislation.gov.uk/eur/2003/1829/contents) [Article 13(1)](https://www.legislation.gov.uk/eur/2003/1829/article/13) of (food) and [Article 25(2)](https://www.legislation.gov.uk/eur/2003/1829/article/25) (feed): Labelling
* [Regulation (EC) 1830/2003](https://www.legislation.gov.uk/eur/2003/1830/contents) [Article 4(6)](https://www.legislation.gov.uk/eur/2003/1830/article/4) of (products consisting of or containing GMOs): Labelling

## Proposed terms of authorisation

The proposed terms of authorisation are set out below.

The following is for authorisation as a 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

For the purposes of Articles 7(3) and 19(3) of Regulation (EC) 1829/2003, the following unique identifiers are specified for genetically modified DP4114 × MON 810 × MIR604 × NK603 maize and sub-combinations as follows—

DP-ØØ4114-3 x MON-ØØ81Ø-6 x SYN-IR6Ø4-5 x MON-ØØ6Ø3-6; for genetically modified maize DP4114 × MON 810 × MIR604 × NK603

SYN-IR6Ø4-5 x MON-ØØ6Ø3-6 x DP-ØØ4114-3; for genetically modified maize MIR604 × NK603 × DP4114

MON-ØØ81Ø-6 x MON-ØØ6Ø3-6 x DP-ØØ4114-3; for genetically modified maize MON 810 × NK603 × DP4114

MON-ØØ81Ø-6 x SYN-IR6Ø4-5 x DP-ØØ4114-3; for genetically modified maize MON 810 × MIR604 × DP4114

MON-ØØ81Ø-6 x SYN-IR6Ø4-5 x MON-ØØ6Ø3-6; for genetically modified maize MON 810 × MIR604 × NK603

MON-ØØ6Ø3-6 x DP-ØØ4114-3; for genetically modified maize NK603 × DP4114

SYN-IR6Ø4-5 x DP-ØØ4114-3; for genetically modified maize MIR604 × DP4114

SYN-IR6Ø4-5 x MON-ØØ6Ø3-6; for genetically modified maize MIR604 × NK603

MON-ØØ81Ø-6 x DP-ØØ4114-3; for genetically modified maize MON 810 × DP4114

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 Regulation (EC) 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)](https://www.legislation.gov.uk/eur/2003/1829/article/13) and [25(2)](https://www.legislation.gov.uk/eur/2003/1829/article/25) of [Regulation (EC) 1829/2003,](https://www.legislation.gov.uk/eur/2003/1829/contents) and in Article [4(6)](https://www.legislation.gov.uk/eur/2003/1830/article/4) of [Regulation (EC) 1830/2003](https://www.legislation.gov.uk/eur/2003/1830/contents), 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)](https://www.legislation.gov.uk/eur/2003/1829/article/7) and [19(3)](https://www.legislation.gov.uk/eur/2003/1829/article/19) of [Regulation (EC) 1829/2003](https://www.legislation.gov.uk/eur/2003/1829/contents), the method specified in sub-paragraph (2) is 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)](https://www.legislation.gov.uk/eur/2003/1829/article/7) and [19(3)](https://www.legislation.gov.uk/eur/2003/1829/article/19) of [Regulation (EC) 1829/2003](https://www.legislation.gov.uk/eur/2003/1829/contents), the reference material “AOCS 0607-A2” (for SYN-IR6Ø4-5) is accessible via the [American Oil Chemists Society](https://www.aocs.org/technical-products/certified-reference-materials-crms/), “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://joint-research-centre.ec.europa.eu/index_en)

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 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

In Scotland the competent authority responsible for performing an environmental risk assessment for the purposes of Article 6 of [Regulation (EC) 1829/2003,](https://www.legislation.gov.uk/eur/2003/1829/contents) is the Scottish Ministers. 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 GB. 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 maize DP4114 x MON 810 x MIR604 x NK603 would not raise safety concerns in the event of accidental release of viable seeds or propagating material into the environment. The Scottish Government considered the advice of ACRE and confirmed that they are content with its findings.

The ACRE advice have been considered in the preparation of FSS’ opinion which will be taken into consideration before making a final recommendation to the Scottish Ministers.

ACRE’s advice is available on the Government of the United Kingdom website at;

[ACRE advice: applications to market GM soybeans and maize - GOV.UK](https://www.gov.uk/government/publications/acre-advice-applications-to-market-gm-soybeans-and-maize)

## Labelling

In accordance with [Regulation (EC) 1830/2003](https://www.legislation.gov.uk/eur/2003/1830/contents), 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 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.

## Other legitimate factors

In developing the risk management recommendations, FSS 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. FSS has not identified any applicable other legitimate factors to date, 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, FSS have 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 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) 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 approved for use in Northern Ireland, FSS’s recommendation to authorise aligns with the product authorisation in Northern Ireland.

## Risk Management Recommendation

It is the opinion of FSS, as per [Article 6 Regulation (EC) 1829/2003](https://www.legislation.gov.uk/eur/2003/1829/article/6), that maize DP4114 x MON 810 x MIR604 x NK603 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. FSS recommend authorising this genetically modified organism on the proposed terms of authorisation are set out below.

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1. Details of the analytical methods is set out in the document referenced “Ares(2015)76595 - 09/01/2015” and last updated on 6 June 2016, available at the following address of the Reference Laboratory[: https://joint-research-centre.ec.europa.eu/reports-and-technical-documentation/fad-2010-0121\_en.](https://joint-research-centre.ec.europa.eu/reports-and-technical-documentation/fad-2010-0121_en) [↑](#footnote-ref-2)
2. DD CEN/TS:15790:2008 “Animal Feeding Stuffs – PCR typing of probiotic strains of Sacccharomyces cerevisiae (yeast)”. Published by the British Standards Institution on 31st January 2009 (ISBN 978 0 580 61806 2). Available from the British Standards Institution [https://knowledge.bsigroup.com](https://knowledge.bsigroup.com/) [↑](#footnote-ref-3)
3. BS EN 15789:2021 *“Animal feeding stuffs. Methods of sampling and analysis. Detection and enumeration of Saccharomyces cerevisiae used as feed additive”.* Published by the British Standards Institution on 30th November 2021 (ISBN 978 0 580 99832 4) and available at: [https://knowledge.bsigroup.com](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R0733). [↑](#footnote-ref-4)