Consultation on Market Authorisation of 10 Regulated Food and Feed Products December 2024: Summary of Stakeholder Responses

The consultation was launched on 18 December 2024 and closed on 19 February 2025. This is a summary of the consultation responses, the main themes identified and the Food Standard Agency's (FSA) responses to these.

Applications

The applications on which the consultation sought views are listed below.

Stakeholders' views, comments and feedback were sought in relation to regulated product applications for one food additive, one feed additive, one food flavouring and the removal of 8 permitted flavouring substances, one food contact materials (FCM), 3 genetically modified organisms (GMO) (for food and feed uses) and 2 novel foods.

RP1112?- Steviol Glycosides (E 960b) produced by fermentation (new specification of a permitted food additive)

- RP694?- Saccharomyces cerevisiae CNCM I-1079 (new authorisation) (feed additive)
- RP1466?- 2-Hydroxy-4-methoxybenzaldehyde (new authorisation) (flavouring)
- RP2184?- revocation of 8 permitted food flavouring substances from the domestic list?
- RP1190?- phosphoric acid, mixed esters with 2-hydroxyethyl methacrylate (HEMAP) (CAS No. 52628-03-2) (new authorisation) (FCM)
- RP1123?– GMB151 (new authorisation) (GMOs for food and feed uses)
- RP1232?- GHB811 Cotton (new authorisation) (GMOs for food and feed uses)
- RP1506?- Genetically modified maize DP4114 x MON 810 x MIR604 x NK603 and sub-combinations (new authorisation) (GMOs for food and feed uses)
- RP1033?- Isomaltooligosaccharide (IMO) (extension of use) (novel food)
- RP956?– Magnesium L-threonate (new authorisation) (novel food)

To ensure representation across a broad spectrum of opinion, stakeholders with a range of interests in the regulated products received additional targeted communications about the public consultation. Stakeholders were encouraged to consider any relevant provisions of assimilated law and other legitimate factors (for example, consumer interests, technical feasibility and environmental factors).

The consultation reach was comprehensive, with automatic notifications sent to 43,774 UK-wide subscribers of FSA alerts at the time of launch, including FSA subscribers registered specifically to receive updates in relation to national content – 36,170 subscribers to England, 20,431 subscribers to Northern Ireland and 21,292 subscribers to Wales.

The FSA has a reach of 130,035 LinkedIn followers (as of 18 December 2024) and on LinkedIn the consultation had 7,500 impressions (the number of times a post appears in a user's feed) and 194 engagements. The FSA consultation page received 3,129 pageviews and 2,628 visitors from 18 December 2024 to 19 February 2025.

Food Standards Scotland (FSS) launched a consultation in parallel which can be found here.

The FSA is grateful to those who responded. The responses are grouped by theme and set out below.

Characteristics of Respondents

The FSA received a total of 12 consultation responses: 9 representing industry, 2 enforcement bodies, and one non-governmental organisation. Across the 12 respondents, 5 reported their location as England, 4 reported their location as Wales and 3 reported their location as UK wide.

4 responses were received by FSS in the parallel consultation.

Summary of Responses

The number of responses was low in comparison with actual numbers of stakeholders reached. The comments, together with the FSA's responses to these, are set out in below.?

Summary of Substantive Comments

The responses to the consultation have been analysed and the main themes identified. The FSA's responses to the comments made are included below.

1. Support for Authorisations

1. (a) Regulated Product/s: Novel food RP956

Summary of stakeholders' comments:

One respondent supports the proposed authorisation of magnesium L-threonate for use in food supplements, highlighting that they have no safety concerns for intended consumers. They note that including it in Schedule 2 of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 would ensure regulatory clarity and facilitate market entry.

Another respondent also noted that the inclusion of magnesium L-threonate in UK legislation as a permitted form of magnesium, would help maintain alignment with EU regulations and prevent regulatory divergence.

FSA response:

We note your comments and thank you for your response.

1. (b) Regulated Product/s: GMOs RP1123 RP1232 RP1506

Summary of stakeholders' comments:

2 respondents gave comments in favour of recommending to ministers the authorisation of these GMO products on the proposed terms of authorisation set out by the FSA. Neither had concerns on the safety of these GMOs. One noted that these GMOs have already been approved in other markets without significant safety concerns. They expressed a desire for these GMOs to be approved in the UK as well, in order to align with key markets and prevent trade disruptions. Both respondents support a common framework approach across England, Northern Ireland, Wales and Scotland to avoid trade disruption. One respondent emphasised the scientific integrity of the risk assessment and how the common framework approach guarantees a high standard of food safety and consumer protection throughout the UK.

FSA response:

We note your comments and thank you for your response.

1. (c) Regulated Product/s: Feed additive RP694

Summary of stakeholders' comments:

One respondent gave a positive response to the proposed new use of this feed additive. They have no concerns on the safety, and they agree with the recommendation to ministers to authorise on the proposed terms outlined by the FSA. The respondent emphasises the importance of farmers having access to a wide range of feed additives. They acknowledge the provisional common framework for Food and Feed Safety and Hygiene agreed upon by ministers in England, Northern Ireland, Wales, and Scotland. They stress the need for this framework to ensure harmonised approvals across England, Northern Ireland, Wales, and Scotland to prevent disruption.

FSA response:

Main theme of response: We note your comments and thank you for your response.

1. (d) Regulated Product/s: Flavouring revocation RP2184

Summary of stakeholders' comments:

4 respondents support transitional measures for foods containing certain flavourings. One respondent agrees with our view that there should be no significant impact on UK businesses from revoking them from the list and believes these measures will help with foods imported from non-EU countries, allowing time for communication and checks. Another respondent has no objection to withdrawing unused flavourings and agrees that remaining food should be sold off to avoid waste. A third respondent highlights that flavourings are low-volume ingredients with high minimum order quantities and long shelf life, so sufficient notice should be given to the industry, although none are in widespread use. The fourth respondent notes that the EU has similar transitional measures in place through Commission Regulation (EU) 2024/234, allowing foods lawfully placed on the market before 25 January 2024, to remain on sale until their minimum durability or use-by date. They advocate for similar measures in Great Britain to maintain a level playing field, including for products in transit from third countries before the revocation from the list.

FSA response:

We note your comments and thank you for your response. As set out in the Risk Management Recommendation document (Annex 4) transitional measures will be proposed to allow foods

containing the flavourings (and the flavourings themselves), that could legally be placed on the market before the date of the legislation, to remain on sale until their use by date or best before date. This will include food containing these flavourings (and the flavourings themselves), that were exported to Great Britain before the date of revocation.

1. (e) Regulated Product/s: Food additive RP1112

Summary of stakeholders' comments:

One respondent specifically noted that they do not hold any concerns regarding the proposed specification for Steviol Glycosides (E 960b) "Rebaudioside M", produced by fermentation with Saccharomyces cerevisiae.

FSA response:

We note your comments and thank you for your response.

2. Main theme of response: Concerns/Queries

2. (a) Regulated Product/s: GMO RP1123, RP1506 and RP1232

Summary of stakeholders' comments:

One respondent raised concerns regarding the risk assessments for the 3 GMO products stating that they do not adequately consider the risks of herbicide tolerance, including pesticide residue impacts on human health. They noted that these GM crops are likely to be heavily sprayed with herbicides, increasing risks to health and the environment. The respondent claims that the persistence of herbicide residues in food and feed poses potential dangers to consumers, and herbicide-resistant traits may cause environmental issues if accidentally released.

FSA response:

Thank you for your response. The 3 GM applications referred to are for import only. This means the crops will not be cultivated or treated with pesticides or herbicides in the UK. Each GMO application as part of the food and feed safety assessment, undergoes an environmental risk assessment by the Advisory Committee on Release to the Environment, where the risk to the environment or human health is assessed in comparison to their non-GM counterpart. Pesticides present on imported food/ feed must comply with the maximum residue levels and import tolerance levels as set by the Health and Safety Executive. These are set as a result of a risk assessment and are set below the levels which would pose a consumer safety concern.

2. (b) Regulated Product/s: Novel food RP1033

Summary of stakeholders' comments:

One respondent noted that the EU authorisation specifies that data protection applies only to newly authorised extension of use categories, which will be separate from existing generic authorisations as per Regulation (EU) 2025/97. However, the respondent claims that the UK proposal lacks clarity on how this distinction will be maintained. The respondent requests that the food categories with data protection be clearly distinguished from those under the previous generic authorisation.

FSA response:

Thank you for your response. The proposed terms of authorisation will clearly specify that data protection applies exclusively to the newly authorised extensions of use.

3. Main theme of response: Divergence

3. (a) Regulated Product/s: Novel food RP956

Summary of stakeholders' comments:

One respondent expressed concerns about the UK's proposal to set a maximum level of 3 g for magnesium L-threonate in food supplements. They note that this results in a lower amount of base magnesium compared to the EU's maximum level of 250 mg, potentially disadvantaging GB businesses marketing their products in the EU. The respondent highlights that the UK Expert Group on Vitamins and Minerals found 400 mg/day of supplemental magnesium to be safe, while EFSA set the tolerable upper intake level at 250mg/day for certain magnesium salts. They claim that setting the maximum level based on the source material rather than the base magnesium is arbitrary and below safe levels. The respondent requests that the maximum level be revised to 250mg of magnesium per day for clarity and consistency.

FSA response:

Thank you for your response. The FSA has taken this into consideration when evaluating our recommendation with respect to RP956.

Revising the maximum level to 250 mg magnesium/day does not present a significant change from the consulted level of 3 g per day of the source material as this remains within the parameters described as safe in the safety assessment. Therefore, the FSA will be recommending the authorisation of magnesium L-threonate at 250 mg magnesium/day.

3. (b) Regulated Product/s: Novel food RP1033

Summary of stakeholders' comments:

One respondent raised that for food supplements, the EU sets a maximum limit of 10g/day whilst the FSA proposes a set limit of less than 100% on a weight basis. The respondent requested a maximum limit based on daily intake, such as 10g/day, rather than a percentage on a weight basis.

FSA response:

Thank you for your response. The EU authorisation allows for the use of IMO as the active ingredient in food supplements, but only up to 10g. This limit is based on the recommended daily intake. In Great Britain, the applicant is proposing IMO as an ingredient for sweetening purposes only in food supplements, not as the main active ingredient. This is why we use a percentage on weight basis.

3. (c) General Divergence

Summary of stakeholders' comments:

One respondent gave a general response to reduce divergence from the EU as much as possible.

A second respondent noted their primary concern is the growing regulatory divergence from the EU, as the authorisation of a new additive or differing conditions of use for a novel food in the UK would further expand the list of regulatory differences impacting the food industry post-Brexit.

FSA response:

We note your comment and thank you for your response.

3. (d) Regulated Product/s: Feed Additive RP 694 & GMO RP1123, RP1506 and RP1232

Summary of stakeholders' comments:

One respondent acknowledged that there are no issues regarding trade via internal markets due to the UK nations proposing aligned authorisations, however, if divergence were to occur, it would cause issues for processors and those farming across borders.

FSA response:

We note your comment and thank you for your response.

4. Main theme of response: General comments

4. (a) Regulated Product/s: Revocation of 8 food flavourings RP 2184

Summary of stakeholders' comments:

One respondent commented on the proposed revocation of 8 food flavourings, stating they think it could be clearer that the reason for removal relates to their very limited use and not around any issues around their safety.

FSA response:

Thank you for your comment. As highlighted in the Risk Management Recommendation document (Annex 4 insert hyperlink), the application is to remove 8 'flavouring substances under evaluation' as they are not widely used and so the flavourings industry has decided not to provide additional data for the FSA to complete the evaluation.

4. (b) Regulated Product/s: Feed Additive RP 694 & GMO RP1123, RP1506 and RP1232

Summary of stakeholders' comments:

One respondent noted that while they do not foresee there being any considerable impacts associated with the proposed authorisations of one feed and 3 GMOs, they believe that wider repercussions should be considered through robust consultation specifically with feed suppliers and processors.

FSA response:

We note your comment and thank you for your response.

4. (c) Progress Updates

Summary of stakeholders' comments:

On providing further feedback one respondent expressed that it is important to be aware of authorisation progress to maintain competitive advantage.

FSA response:

We note your comment and thank you for your feedback.

4. (d) General

Summary of stakeholders' comments:

5 respondents provided general responses that did not raise any concerns on the proposed authorisations.

FSA response:

Main theme of response: Thank you for your response.

Next steps

The authorisation process requires ministers in England, Wales and Scotland to make decisions on the authorisation of the following:

- a new specification of an existing permitted food additive
- a new authorisation for one feed additive
- a new authorisation for one food flavouring?
- the revocation of 8 food flavourings (one application covering 8 food flavourings)
- a new authorisation for one FCM
- 3 new authorisations for 3?GMOs for food and feed uses
- a new authorisation of one novel food
- an extension of use of an existing novel food

In Northern Ireland, the Health Minister will be informed of the recommendation to authorise.

The FSA/FSS safety assessments on these applications concluded that the products are safe to be authorised based on their proposed terms of authorisation.

A consultation response outlined a concern regarding the divergence with the EU on maximum permitted levels of magnesium L-threonate (RP 956) in food supplements. We have reviewed the levels permitted in the EU and note that aligning with these levels represents a minor increase in level and remains within the parameters of safe as described by the safety assessment. As there are no safety concerns with the levels permitted in the EU, the final FSA advice on the terms of authorisation for magnesium L-threonate will be amended to align with the EU.

There have been no further identified reasons to change the advice to ministers on the remaining applications during the consultation process.?On that basis, the final FSA recommendation to ministers will be to authorise these applications on the proposed terms of authorisation outlined in the FSA Risk Management recommendations, including the 8 flavouring substance revocation.?

Please be advised that the proposed terms of authorisation remain subject to modification until the official authorisation date.

Should ministers determine that the requirements for authorisation have been met, they will consider authorising the products, including the revocation of 8 flavouring substances, as per the proposed terms of authorisation.