

Summary of stakeholder responses: Consultation on applications for authorisation of miscellaneous regulated products (Spring 2024)?

Consultation on applications for authorisation of miscellaneous regulated products: four novel foods, three food additives, removal of twenty-two food flavouring authorisations, and a proposal to set a limit for ethylene oxide in food additives.

Introduction

[This consultation was issued on 02 February 2024 and closed on 29 March 2024.](#)?

[Food Standards Scotland \(FSS\) launched a consultation in parallel.](#) This report is a summary of the consultation responses, the main themes identified and the FSA's responses to these.?

Stakeholders' views were sought in relation to the four novel food products and three food additives being authorised; twenty-two food flavouring substances being removed from authorisation; and a limit on ethylene oxide in food additives.

The applications on which the consultation sought views were:

Authorisation of four novel foods:

- RP19 Partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*) - previously referred to as Barley Rice Protein (new authorisation)
- RP200 Cetylated Fatty Acids (new authorisation)
- RP549 lacto-N-fucopentaose I (LNFP-I) and 2'-fucosyllactose (2'-FL) mixture (new authorisation)
- RP1202 3-fucosyllactose (3-FL) (produced by a derivative strain of *Escherichia coli* K-12 DH1) (new authorisation)

Authorisation of three food additives:

- RP217 Polyglycerol Polyricinoleate (PGPR) (E 476) (extension of use)
- RP1084 (E 960C) Rebaudioside M, AM and D produced via enzymatic conversion of highly purified steviol glycosides from stevia leaf extracts (new production method of an existing food additive)
- RP1140 (E 960B) Steviol glycosides produced by *Yarrowia lipolytica* (new production method of an existing food additive)

Proposal to remove twenty-two food flavouring substances from the authorised list:

RP1737 (one application covering twenty-two food flavouring substances) as requested by the flavourings industry.

Ethylene oxide:

The consultation presented the proposal to set the same limit as the EU of 0.1 mg/kg in all food additives as a proportionate approach to balance food safety with providing clarity and consistency to industry and enforcers when this substance is identified in food.

Stakeholders were encouraged to consider any relevant provisions of assimilated law¹ and other legitimate factors (for example, consumer interests, technical feasibility and environmental factors) that the FSA and FSS identified as relevant to these applications.??

The consultation reach was comprehensive, with automatic notifications sent to 37,272 UK-wide subscribers of FSA alerts at the time of launch. Automatic notifications were also issued to FSA subscribers registered to receive updates in relation to national content – 30,672 subscribers to England, 17,249 subscribers to Northern Ireland and 18,154 subscribers to Wales.

Key stakeholders whose businesses/organisations are likely to be affected by or to have an interest in these novel foods, food flavourings and food additives, were contacted directly for their feedback. To ensure representation across a broad spectrum of opinion, stakeholders with a range of interests in the regulated products were included.

The FSA has a reach of 61,400 on X (formerly known as Twitter) and 120,000 LinkedIn followers. The FSA consultation page received approximately 2,418 views from 02/02/2024 - 29/03/2024.

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

Characteristics of respondents

A total of fifteen consultation responses were received: four representing industry, six Trade Associations, one Non-Government Organisation/Professional Body, one Non –Government Organisation (with close links to Government), one Independent Public Health Nutrition Charity, one Local Authority/consumer protection organisation and one Private Individual. There were zero consultation responses received by FSS. Across the 15 respondents, all gave their location as UK-wide.

A list of those who responded can be found at the end of this page.?

Summary of responses

The number of responses was low in comparison with actual numbers of stakeholders reached.

There are no other relevant provisions of assimilated law or legitimate factors identified by the respondents.

The comments, together with the FSA's responses to these, are set out 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

Main theme of response: Support for authorisations 1(a)

Summary of Stakeholders' Comments: Ethylene oxide limit

Five respondents gave comments in favour of the proposal to set the limit of 0.1mg/kg for ethylene oxide for all food additives, commenting that this is a positive update and a proportionate approach to balance food safety whilst providing clarity and consistency to food businesses and enforcers when this substance is identified in food. The opportunity to achieve alignment across GB and the EU was welcomed. It was noted that this will facilitate trade and provide certainty, whilst preventing barriers to international trade and removing disadvantages for the GB market.

FSA's Response: We note your comments and thank you for your response.

Main theme of response: Support for authorisations 1(b)

Summary of Stakeholders' Comments: Food additive authorisations

Three respondents gave comments in favour of the authorisation of the three food additives. One respondent was in favour of the proposed specifications for E960c(ii), which are aligned with those adopted by JECFA and the EU. In addition, they noted that they are in favour of authorising the food additives as no safety concerns have been highlighted during the risk assessment process and because the authorisation will help to minimise divergence between Great Britain and the EU.

FSA's Response: We note your comments and thank you for your response.

Main theme of response: Support for authorisations 1(c)

Summary of Stakeholders' Comments: Flavouring removals. Three respondents commented that they were in favour of the removal of twenty-two flavourings from the domestic list, and in agreement that there will not be any impacts as they are not widely used across the global market. It was noted that as the flavourings have already been removed from the EU list, this action will help reduce divergence. Two respondents noted that a transition period would be helpful to allow businesses from third countries to ensure they are compliant when exporting to GB.

FSA's Response: Thank you for your response. As set out in the Risk Management Recommendation document Annex H, transitional measures will be set so that food containing these flavourings which are placed on the market before the coming into force date of the legislation will be allowed to stay on sale until their use-by date or date of minimum durability. The same applies to food containing these flavourings which are imported for the GB market as long as they were dispatched before the coming into force date of the legislation.

Main theme of response: Support for authorisations 1(d)

Summary of Stakeholders' Comments: Novel Food Authorisations. 5 respondents noted they had no concerns about the authorisation of the Novel Foods. It was noted that a robust safety process was in place.
FSA's Response: We note your comments and thank you for your response.

2.Ethylene oxide limit concerns

Main theme of response: Ethylene oxide limit concerns 2(a)

Summary of Stakeholders' Comments: One respondent raised concerns with testing ethylene oxide and 2-chloroethanol in certain products, highlighting that there could be potential false positives by setting a blanket value for all products.

FSA's Response: We note your comments and thank you for your response. We are aware there are methods available for the detection of ethylene oxide and/or 2-chloroethanol in foods, but if official control laboratories consider more work is needed then we will consider this further i.e. if there are high incidents of false positives.

Main theme of response: Ethylene oxide limit concerns 2(b)

Summary of Stakeholders' Comments: The respondent also noted concerns about the possibility of unavoidable formation of ethylene oxide and 2-chloroethanol during the manufacturing process and that it may not be possible to manufacture certain products within this limit.

FSA's Response: The proposal to set a limit of 0.1 mg/kg is a result of the recognition of the spontaneous production of ethylene oxide and 2-chloroethanol created as part of manufacturing processes. This is a proportionate approach to balance food safety with providing clarity and consistency to industry and enforcers when this substance is identified in food.

3. Ethylene oxide general comments

Main theme of response: Ethylene oxide general comments 3(a)

Summary of Stakeholders' Comments: One respondent noted that there may be an assumption that the risk for ethylene oxide and 2-chloroethanol is the same from a toxicological perspective, but the reality is that conclusive studies on this topic haven't yet occurred. It would be beneficial for a comprehensive toxicological study to be performed on 2-chloroethanol to assess the real risk association to the molecule.

FSA's Response: There is a lack of toxicity data on 2-chloroethanol and so using the precautionary principle we consider it to be of a similar toxicity to ethylene oxide.

Main theme of response: Ethylene oxide general comments 3(b)

Summary of Stakeholders' Comments: One respondent noted that the reduction of the limit for ethylene oxide and its breakdown product 2-chloroethanol across all food additives, replacing the current limit of 0.2 mg/kg to a new limit of 0.1 mg/kg for 8 specified food additives and suggested that methods are made available to enable official control laboratories to make suitable measurements.

FSA's Response: The current guidance for ethylene oxide asserts that companies should have measures in place to test for the presence of ethylene oxide. We are aware there are methods available for the detection of ethylene oxide and/or 2-chloroethanol in foods, but if official control laboratories consider more work is needed then we will consider this further.

4. Novel food concerns

Main theme of response: Novel food concerns 4(a(i))

Summary of Stakeholders' Comments: RP1202 3-fucosyllactose (3-FL) (produced by a derivative strain of Escherichia coli K-12 DH1). Two respondents noted concerns that in the safety assessments the potential for warning that 3-FL causes bloating was mentioned, they do not believe it is appropriate for products containing 3-FL to be labelled with any warning within the proposed maximum use levels.

FSA's Response: Thank you for your response. Such labelling was not considered necessary in the Risk Management Recommendations and therefore was not included in the proposed Terms of Authorisation and labelling which were the subject of this consultation.

Main theme of response: Novel food concerns 4(a(ii))

Summary of Stakeholders' Comments: One respondent asked if it is essential to label as '3-fucosyllactose (3-FL)' or could this be revised to '3-fucosyllactose'? The latter designation is used for this novel food in the EU.

FSA's Response: We note your comments and thank you for your response. The labelling designation will be 3-fucosyllactose. A similar change will be made to the labelling designation for RP549.

Main theme of response: Novel food concerns 4(b)

Summary of Stakeholders' Comments: RP549 Lacto-N-fucopentaose I (LNFP-I) and 2'-fucosyllactose (2' FL) mixture: Two respondents expressed caution around additional labelling, highlighting that it is not clear how guidance concerning not using these novel food ingredients alongside other dietary supplements can be clearly and effectively communicated to consumers.

FSA's Response: We note the comments and thank you for your response.

Main theme of response: Novel food concerns 4(c)

Summary of Stakeholders' Comments: One respondent raised concerns about permitting the addition of novel foods, including human milk identical oligosaccharides (HMiOs, RP549 and RP1202), to infant formula. The respondent expressed their opinion that the addition of optional ingredients to infant formula does not benefit infants and is instead used as a promotional tool, which allows manufacturers to command higher prices for the products, citing marketing they considered to be misleading. They requested that health and nutrition claims are not made in association with these ingredients, unless approved by a relevant body.

FSA's Response: We note your comments and thank you for your response. The FSA notes the respondent's concerns around the marketing and labelling of the HMiOs and infant formula more widely. Health Claims Legislation is the responsibility of the Department of Health and Social Care in England, FSA in Northern Ireland) the Welsh Government in Wales and Food Standards Scotland in Scotland. Food law enforcement in the UK is the responsibility of local authorities and the Advertising Standards Agency (ASA) is responsible for regulating advertising across all of the media in the UK. Nutrition and health claims are not permitted on infant formula (in accordance with assimilated Regulation (EU) 2016/127.) Infant formula legislation also restricts the inappropriate marketing and promotion of infant formula so as not to discourage breastfeeding. We advise that concerns over misleading or non-compliant marketing (including unauthorised health claims) should be raised with the organisation's local authority or the ASA.

Main theme of response: Novel food concerns 4(d)

Summary of Stakeholders' Comments: Comments were made around the process used to determine the safety of HMiOs when used in foods for infants. The respondent questioned the validity of the data provided by the applicants, since the data was obtained from clinical trials conducted by the manufacturer.

FSA's Response: The potential concern of microbial safety of the product for the very young was a core aspect of the assessment. Endotoxins can be produced by E. coli. As the novel food is produced by a microbial fermentation process using this microorganism, specification limits for the protein content (? 0.01% w/w) and levels of endotoxins (? 10 EU/mg) are defined. The shelf-life for up to 12 months included the assessment of Enterobacteriaceae, which was below the specification limit (absent in 10g). The assessment specifically considers the safety of the product in the context of its proposed use. The need for additional reassurance for infants as a vulnerable group was taken into account in the assessment.

Main theme of response: Novel food concerns 4(e)

Summary of Stakeholders' Comments: The same respondent expressed their concerns that non-mandatory ingredients have the potential to increase the microbiological load of infant formula, which is often not reconstituted with water above 70oC (as recommended by the NHS).

FSA's Response: The potential concern of microbial safety of the product for the very young was a core aspect of the assessment. Endotoxins can be produced by E. coli. As the novel food is produced by a microbial fermentation process using this microorganism, specification limits for the protein content (? 0.01% w/w) and levels of endotoxins (? 10 EU/mg) are defined. The shelf-life for up to 12 months included the assessment of Enterobacteriaceae, which was below the specification limit (absent in 10g). The assessment specifically considers the safety of the product in the context of its proposed use. The need for additional reassurance for infants as a vulnerable group was taken into account in the assessment.

Main theme of response: Novel food concerns 4(f(i))

Summary of Stakeholders' Comments: RP200 Cetylated fatty acids. One respondent requested that the labelling designation be revised from 'cetylated fatty acids preparations' to 'cetylated fatty acids preparation'. This is how the novel food is labelled in the EU and it will help reduce confusion to have the same designation within GB.

FSA's Response: We note your comments and thank you for your response. The labelling designation will be revised to state 'cetylated fatty acids preparation'.

Main theme of response: Novel food concerns 4(f(ii))

Summary of Stakeholders' Comments: One respondent noted the labelling differences in the original EU submission and the FSA/FSS Risk Management recommendation commenting that it would be helpful to understand if there is a change in the risk assessment, resulting in this apparently more cautious wording compared to the original application. (EU stated that using the ingredient in a product would not be nutritionally disadvantageous but that any supplements would not be intended for use by infants and young children, the FSA/FSS Risk Management

recommendation requires a statement 'those food supplements should not be consumed by persons under 18 years of age'.)

FSA's Response: We note your comments and thank you for your response. We would like to highlight, the labelling provision referred to, is also included in the EU authorisation for this novel food.

5. Food additive concerns

Main theme of response: Food additive concerns

Summary of Stakeholders' Comments: RP1084 Rebaudioside M, AM and D and RP1140 Steviol glycosides produced by *Yarrowia lipolytica*. One respondent noted that there is no proposed change to the Acceptable Daily Intake (ADI) as a result of this risk assessment and authorisation and suggested that it would be helpful to clarify this within the statements associated with this authorisation.

FSA's Response: We note your comments and thank you for your response. This has been specified in the Explanatory Memorandum.

6. Concerns for consumer health

Main theme of response: Concerns for consumer health

Summary of Stakeholders' Comments: One respondent supplied comments around general food safety and the use of food additives and flavourings in foods. They also noted concerns around allergens and how the public can be supported with food allergies. Comments outlined the need for healthy foods with lower fat, sugar and salt and consideration for food education.

FSA's Response: Several comments were received on a range of broad themes outside of the scope of this consultation. Thank you for your response.

7. Divergence

Main theme of response: Divergence

Summary of Stakeholders' Comments: RP19 Partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*). One respondent noted that there are considerable differences between the conditions of use and the specifications in the proposed authorisation for GB compared to the equivalent authorisation in the EU. The respondent does not disagree with the proposed conditions of use, however noted that these differences might give rise to some confusion for companies trying to market in both GB and the EU.

FSA's Response: We note your comments and thank you for your response. For authorisations, the conditions of use may differ in the EU. This could be because the safety assessment completed by EFSA came to a different conclusion to the FSA/FSS assessment. Whilst it is not always possible to establish the reasons for this given that we are two independent regulators, it could be that the applicant had provided more evidence within their UK application that was not available to EFSA at the time of their assessment or vice-versa. For this authorisation the applicant requested different categories to that in the EU.

8. General responses

Main theme of response: General responses

Summary of Stakeholders' Comments: Two respondents outlined concerns with the timescales and processes of Novel food approvals and the impacts these delays negatively cause the UK food sector.

FSA's Response: We thank respondents for their comments, note concerns around timely authorisations and acknowledge that the time it takes to authorise applications is longer than we would like. The FSA inherited the current authorisation process from the EU, and it is clear significant change is needed to modernise the system, so we can bring benefits to consumers through a wider choice of safe food, as new, innovative products come to market more quickly. On 3rd April we launched a joint consultation with FSS which closes on the 5th June 2024.

[This consultation details two proposed changes to the process](#) (which aim to streamline and make it more efficient), and was launched following engagement with stakeholders and endorsement for the proposals from the FSA and FSS Boards.

Next Steps

The next step of the authorisation process is for relevant Ministers in England, Wales and Scotland to make decisions on the authorisation of the four novel foods, three food additives, removal of twenty-two food flavouring authorisations, and the proposal to set a limit for ethylene oxide in food additives. 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 the proposed terms of authorisation.

For RP200 cetylated fatty acids we have made a minor amend to the labelling designation from 'cetylated fatty acids preparations' to 'cetylated fatty acids preparation' This will be reflected in the recommended proposed terms of authorisation made to the Ministers.

For RP1202 we have made a minor amend to the labelling designation from '3-fucosyllactose (3-FL)' to '3-fucosyllactose' This will be reflected in the recommended proposed terms of authorisation made to the Ministers. A similar change will be made to the labelling designation for RP549.

There have been no other identified reasons to change the advice on these applications during the consultation process. On that basis, the final FSA/FSS advice to Ministers will be to authorise these applications on the proposed terms of authorisation outlined in the FSA/FSS Risk Management Recommendations. Should Ministers agree to authorise, Statutory Instruments will be prepared in England and Wales (and a Scottish Statutory Instrument in Scotland) in line with the terms of authorisation previously outlined in the FSA/FSS Risk Management Recommendations.

List of respondents

- Celtic Chemicals Ltd
- Private Individual x 1
- Katech by Ingredion
- Ingredion UK Ltd
- East of England Trading Standards Regional Group
- Office of the Government Chemist
- Nestlé UK Ltd
- UK Flavour Association
- Seasoning and Spice Association (SSA)
- Food and Drink Federation

- British Retail Consortium (BRC)
- Institute of Food Science and Technology
- First Steps Nutrition Trust
- CRN UK (Council for Responsible Nutrition)
- British Special Nutrition Association BSNA