Consultation on applications for miscellaneous regulated products: two novel foods, one flavouring and one food additive: summary of responses

Summary of stakeholder responses and communication of FSA decision.

This consultation was issued on 17 October 2022 and closed on 11 December 2022.

Food Standards Scotland (FSS) launched a consultation in parallel. This report is a summary of the consultation responses and the FSA's responses to these.

Stakeholders' views were sought in relation to the authorisation of two novel foods, which were submitted for authorisation to be placed on the GB market in accordance with Retained EU Regulation 2015/2283, and one flavouring and one food additive authorisation which were submitted for authorisation to be placed on the GB market, in accordance with Retained EU Regulation 1331/2008.

The novel foods, food additive and flavouring applications in this consultation are currently authorised for use in Northern Ireland, in line with legislation that applies there.

Authorisation of one new novel food:

- RP1158 - Vitamin D2 mushroom powder

Extension of the authorised use for one authorised novel food:

- RP1292 - UV-treated Baker's Yeast (Saccharomyces cerevisiae)

Authorisation of one new flavouring:

- RP1382 - 3-(1-((3,5-dimethylisoxazol-4-yl)methyl)-1H-pyrazol-4-yl)-1-(3-hydroxybenzyl)imidazolidine-2,4-dione

Modification to the existing authorisation for a food additive (sweetener) to include a new method for the production of rebaudioside M

- RP1194 – Rebaudioside M

Following this public consultation on Miscellaneous Regulated Products, the Food Standards Agency (FSA) and Food Standards Scotland (FSS) identified a difference between the online and PDF versions of the consultation, which had been missed and omissions in the consultation in respect of two of the [four] products ahead of Statutory Instrument drafting (should Ministers move to authorise).

In the interests of transparent policymaking, we made stakeholders aware by launching an additional, short, targeted, consultation on 23 January 2023, to run for two weeks, to ensure that all the proposed legislative changes have been subject to fair and proper consultation.

Stakeholders were asked to consider any relevant provisions of retained EU law and 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 31,073 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 – 25,375 subscribers to England, 14,078 subscribers to Northern Ireland and 14,876 subscribers to Wales.

The FSA is grateful to those who responded. The comments, together with the FSA's responses to these, are set out below.

Key stakeholders whose businesses/organisations are likely to be affected by or to have an interest in these novel foods, flavouring and food additive, 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 consultation was also shared with the FSA's 60,034 Twitter and 98,141 LinkedIn followers. The FSA consultation page received approximately 608 views.

Characteristics of respondents

A total of four positive consultation responses to the first consultation were received: all from industry. Respondents gave their location as UK-wide or England. Two positive responses were received to the second mini consultation.

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

Summary of responses

All responses received were in support of the authorisations and proposals for the 18-month transitional arrangements for one of the products, a food additive. The transitional arrangement is to allow for existing stocks to be exhausted where the criterion of a new authorisation differs from the existing food additive authorisation. This is to avoid supply-chain and economic impacts to businesses. No responses have been received in opposition to the measures proposed.

The full text to the responses received to the consultations is given below, together with our responses to these comments.

Comments received and FSA responses to these

Question 1: Do you have any concerns on the safety of the novel foods, flavouring or food additive which have not been considered below with respect to the intended consumers?

Comments from CRN UK

CRN UK does not have any concerns regarding the safety of the novel foods, flavouring or food additive which have not already been considered during the UK risk analysis process.

FSA's Response

Comments noted.

Comments from The British Soft Drinks Association (BSDA)

BSDA did not identify any safety concerns.

FSA's Response

Comments noted.

Question 2: Do you have any comments or concerns on the impacts in consideration of authorising or not authorising the individual novel foods, flavouring or food additive, and if in favour of authorisation, the terms on which these are authorised?

Comments from CRN UK

CRN UK is in favour of authorising the individual novel foods, flavouring and food additive, as no safety concerns have been highlighted during the risk analysis process, and because such authorisation will help to minimise legislative divergence between Great Britain (GB) and Northern Ireland (NI). In the interests of removing barriers to trade between GB and NI, and also barriers to trade between GB and the European Union (EU), CRN UK is pleased to note that the same specifications and conditions of use as those in the EU legislation are being proposed for the various substances, where applicable.

FSA's Response

Comments noted.

Comments from The British Soft Drinks Association (BSDA)

Not authorising this additive would have a detrimental impact for our members as significant trade is made between GB and EU/NI. To have different recipes/labels in different parts of the UK and for the EU is a considerable burden to business. To not have this additive authorised will also impact innovation potential for GB FBOs.

FSA's Response

Comments noted.

Comments from The Health Food Manufacturers' Association (HFMA)

The Health Food Manufacturers' Association, which represents 147 manufacturers and suppliers of specialist health products in the UK, is in favour of the authorisations and the terms on which these are authorised. Since the proposed legislation mirrors the legislation which applies in the EU and Northern Ireland (under the current terms of the Northern Ireland Protocol), this does not create unwanted divergence and enables greater market access for products which contain these

ingredients. In particular, the authorisation of Rebaudioside M (RP1194) has led to the change in name of E960 to E960a which is a widely used ingredient in food supplements. Therefore, this additive authorisation closes the current divergence in terms of labelling of this ingredient to enable the same finished product to be placed on the market in GB, EU and NI.

FSA's Response

Comments noted.

Comments from UK Flavour Association

The UK Flavour Association supports the authorisation of the flavouring substance.

FSA's Response

Comments noted.

Question 3. With respect to the food additive application RP1194 and the label change from E960 to E960a, do you consider a transition period would be appropriate and, if so, how long should this be?

Comments from CRN UK

Given that label changes will be required to a very wide variety of foods, including food supplements, and given the extensive time and cost factors involved in such label changes, a transition period to enable these changes is absolutely essential. Such a transition period needs to be at least 18 months, for the reasons outlined in the Annex.

FSA's Response

Comments noted.

Comments from The British Soft Drinks Association (BSDA)

Yes, there should be a transition period and we would agree with the proposal in Annex D 'that the food additive 'steviol glycosides' (E 960) and foods containing it, which are labelled or placed on the market up to 18 months after the entry into force of the implementing legislation and which comply with the requirements of the current legislation, may be marketed until the stocks are exhausted.'

FSA's Response

Comments noted.

Comments from The Health Food Manufacturers' Association (HFMA)

We highlighted the proposed 18-month transition for the label change to our members and did not receive any feedback therefore we assume that 18-months is appropriate. 18 months for the label change followed by permitted sell through is what we have supported in the past for previous labelling issues. However, it should be noted that a period of at least 18 months will be required, and we are strongly against a reduction to the length of the transition period. Anything less than 18-months would be problematic for companies to meet and could subsequently led to

unnecessary write-offs of pre-printed labels.

FSA's Response

Comments noted.

Question 4. Are there any other factors that should be considered by Ministers that have not been highlighted?

CRN UK is not aware of any factors that have not already been highlighted, either above or in the consultation, that should be considered by Ministers.

FSA's Response

Comments noted.

Additional Consultation

I. Food additive rebaudioside M.

Question 1. Do you have any feedback concerning the specification of E 960c, enzymatically produced steviol glycosides?

Comments from CRN UK

CRN UK is pleased to note the intention to include the specification of E 960c, enzymatically produced steviol glycosides, within the Annex of retained Regulation 231/2012. Inclusion of this specification will again help minimise divergence, and subsequent barriers to trade, between Great Britain (GB) and Northern Ireland (NI), and between GB and the European Union (EU).

FSA's Response

Comments noted.

Comments from The British Soft Drinks Association (BSDA)

We are fully in support for the specification to be aligned with the EU specification. To have different recipes/labels in different parts of the UK and for the EU is a considerable burden to business.

FSA's Response

Comments noted.

Question 2. Do you have any other feedback?

Comments from The British Soft Drinks Association (BSDA)

Not authorising this additive would have a detrimental impact for our members as significant trade is made between GB and EU/NI. To not have this additive authorised will also impact innovation potential for GB FBOs. There should be a transition period and we would agree with the proposal in Annex D of the original consultation 'that the food additive 'steviol glycosides' (E 960) and

foods containing it, which are labelled or placed on the market up to 18 months after the entry into force of the implementing legislation and which comply with the requirements of the current legislation, may be marketed until the stocks are exhausted.

FSA's Response

Comments noted.

II. Vitamin D2 mushroom powder.

Question 1. Do you have any concerns on the safety of the novel food which have not been considered within the consultation pack with respect to the intended consumers?

Comments from CRN UK

CRN UK does not have any concerns regarding the safety of the novel food which have not already been considered within the consultation pack with respect to the intended consumers.

FSA's Response

Comments noted.

Question 2. Do you have any comments or concerns on the impacts in consideration of authorising or not authorising the individual novel food, and if in favour of authorisation, the terms on which these are authorised (as outlined in the FSA/FSS opinions within the consultation pack)?

Comments from CRN UK

CRN UK is in favour of authorising the individual novel food, as no safety concerns have been highlighted during the risk analysis process, and because such authorisation will help to minimise legislative divergence between GB and Northern Ireland NI. In the interests of removing barriers to trade between GB and NI, and also barriers to trade between GB and the EU, CRN UK is pleased to note that the same conditions of use as those in the EU legislation are being proposed for the novel food.

FSA's Response

Comments noted.

Question 3. Are there any other factors that should be considered by Ministers that have not been highlighted?

Comments from CRN UK

CRN UK is not aware of any factors that have not already been highlighted, either above or in the consultation, that should be considered by Ministers.

FSA's Response

Comments noted.

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 applications. Ministers in Northern Ireland will be informed of the final recommendations.

The FSA/FSS risk assessment opinions on these applications concluded that the products are safe to be authorised based on the proposed terms of authorisation. No reasons to change the advice that these novel foods, flavouring and food additive should be recommended for authorisation have been identified during the consultation process. On that basis, the final advice to respective Ministers will be to authorise these novel foods, flavouring and food additive on the proposed terms of authorisation outlined in the FSA/FSS opinions.

Should Ministers move 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 opinion.

Regulations in Northern Ireland will not be amended as the novel foods, food additive and flavouring are already authorised for use in Northern Ireland, in line with legislation that applies there.

List of respondents

1. CRN UK
2. The British Soft Drinks Association (BSDA)
3. The Health Food Manufacturers' Association (HFMA)
4. UK Flavour Association