Consultation on the specification for food additive rebaudioside M (RP1194)

We are seeking stakeholders' feedback in relation to the proposed technical specification for E 960c because should this food additive be authorised by Ministers, Retained EU Regulation 231/2012 will need to be amended to include the technical specification for E 960c.

Launch date: 23 January 2023

Respond by: 06 February 2023

This consultation will be of most interest to:

- Food industry trade associations.
- Food business operators in the UK wishing to use the food additive.
- Enforcement Authorities, including Local Authorities, Port Health Authorities and District Councils.
- Consumers and wider stakeholders.

A list of interested parties is included in Annex A.

Consultation subject and purpose

We recently consulted on a regulated product application for the amendment of the specification for the manufacture of the food additive steviol glycosides (E 960) to include rebaudioside M (E 960c, enzymatically produced steviol glycosides), for use as an existing permitted low-calorie, high intensity sweetener.

However, we have identified that there had been an omission within the original consultation and therefore we are now seeking stakeholders' feedback in relation to the proposed technical specification for E 960c. It should also be noted that, as a consequence, the name and E number of the existing additive E 960 steviol glycosides would need to change to E 960a steviol glycosides from stevia, although the actual technical specification will remain unchanged.

We ask stakeholders to consider any relevant provisions of retained EU law and other legitimate factors (other evidence further supporting clear, rational and justifiable risk analysis, such as technical feasibility and environmental factors). This consultation provides the opportunity for stakeholders' views to be taken into account, to inform Ministers.

A parallel consultation is being published by FSS.

Details of consultation

Introduction

In order to be placed on the market, applications for the authorisation of regulated products must be submitted for authorisation in Great Britain (GB), where the decision on authorisation is made by the respective Ministers in England, Scotland and Wales. This is a function that was

previously carried out at a European Union (EU) level. In Northern Ireland, EU legislation on food additives continues to apply under the current terms of the Protocol on Ireland/Northern Ireland (NIP). This means that such products require authorisation under the EU's authorisation procedures before being placed on the market in Northern Ireland.

Subject of this consultation

In accordance with Retained EU Regulation 1331/2008 which establishes a common authorisation procedure for food additives, food enzymes and flavourings, the food additive rebaudioside M (E 960c, enzymatically produced steviol glycosides) was submitted for authorisation.

The authorisation of this food additive was recently consulted on. We are now seeking stakeholders' feedback in relation to the proposed technical specification for E 960c because should this food additive be authorised by Ministers, Retained EU Regulation 231/ 2012 will need to be amended to include the technical specification for E 960c.

If the new steviol glycoside entry (E 960c) is to be added to the additive specifications in regulation 231/2012, there will also be a consequential change where the existing additive specification for steviol glycosides (E 960) derived from the stevia leaf will be renamed E 960a 'Steviol glycosides from stevia'.

The specification included within this consultation is in line with legislation that applies in Northern Ireland, under the NIP. Therefore, authorising in England, Scotland and Wales would not result in divergence within the UK.

The proposed specification is included in Annex B. Details of the proposed authorisation of E 960c can be found in the consultation on authorisation.

Engagement and consultation process

Details of all validated applications for regulated products are published on the Register of Regulated Product Applications on the Food Standards Agency website.

Stakeholders are invited to consider the questions posed below in relation to any relevant provisions of retained EU law and other legitimate factors.

Following the consultation process a summary of responses will be published and made available to stakeholders and Ministers.

Questions asked in this consultation:

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

How to respond

Comments should be provided within 2 weeks of the date of this publication and any comments received are subject to our consultations privacy notice.

Comments should be emailed to: RPconsultations@food.gov.uk with the subject line 'Regulated products consultation – RP1194'.

Please state in your response whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents) and in which nation you are based.

Next steps

Any feedback to this revision will be considered, along with the consultation responses, when finalising advice to UK Ministers.

Publication of response summary

We aim to publish a summary of responses to this consultation within 12 weeks of the consultation closing.
For information on how the FSA handles your personal data, please refer to the Consultation privacy notice.
Responses will be shared with FSS.

Further information

If you require a more accessible format of this document, please send details to the named contact for responses to this consultation and your request will be considered.

This consultation has been prepared in accordance with HM Government consultation principles.

Thank you on behalf of the Food Standards Agency for participating in this public consultation.

Yours,
Hayley Bland
Regulated Products Policy Advisor,
Regulated Service

Annex A: List of stakeholders

Key stakeholder trade associations which are represented across all four nations of the UK which have a strong interest in food additives will be contacted directly for feedback on this consultation:

- Breakfast Cereals UK
- British Dietetic Association
- British Nutrition Foundation
- British Fruit Juice Association
- British Retail Consortium
- British Soft Drinks Association
- British Specialist Nutrition Association
- Business Wales
- Baby Milk Action
- Campden BRI
- Cereal Ingredient Manufacturers' Association
- Council for Responsible Nutrition UK
- Dairy UK
- Federation of Bakers
- Federation of Small Businesses (Wales)
- Federation of Small Businesses (Northern Ireland)

- Food & Drink Federation (England)
- FDF Sector Group: Biscuit, Cake, Chocolate and Confectionery
- FDF Sector Group: Food additives
- Food & Drink Federation (Wales)
- Food Additives Industry Association (FAIA)
- Health Food Manufacturers' Association
- Leatherhead Food International
- Northern Ireland Food and Drink Association
- Northern Ireland Retail Consortium
- Provision Trade Federation
- Scientific Advisory Committee on Nutrition
- Snack, Nut and Crisp Manufacturers' Association
- UK Flavour Association
- UK Flour Millers
- Welsh Retail Consortium
- Which?

This is not an exhaustive list.

Annex B: RP1194 – Rebaudioside M (modification to specification)

Background

An application for the amendment of the specifications for the manufacture of the food additive steviol glycosides (E 960) to include a new method for the production of rebaudioside M, for use as an existing permitted low-calorie, high intensity sweetener was submitted as set out in Retained EU Regulation 1331/2008.

The authorisation of this food additive was recently consulted on. We are now seeking stakeholders' feedback in relation to amendments to the technical specification for E 960 (steviol glycosides) so that, should rebaudioside M be authorised, the relevant legislation setting out a technical specification can be laid.

The specification included within this consultation is in line with legislation that applies in Northern Ireland, under the NIP. Therefore, authorising in England, Scotland and Wales would not result in divergence within the UK.

Details of the proposed authorisation of rebaudioside M can be found in the consultation on authorisation.

Proposed specification

It is proposed that the Annex to Retained EU Regulation 231/2012 is amended as follows:

1. In the entry for E 960 steviol glycoside, the heading is replaced by the following:
   'E 960a STEVIOL GLYCOSIDES FROM STEVIA'
2. The following new entry is inserted after the entry for E 960:

'E 960c(i) REBAUDIOSIDE M PRODUCED VIA THE ENZYME MODIFICATION OF STEVIOL GLYCOSIDES FROM STEVIA

Category	Details
Definition	Rebaudioside M is a steviol glycoside composed predominantly of rebaudioside M with minor amounts of other steviol glycosides such as rebaudioside A, rebaudioside B, rebaudioside D, rebaudioside I, and stevioside. Rebaudioside M is obtained via enzymatic bioconversion of puri?ed steviol glycoside leaf extracts (95% steviol glycosides) of the *Stevia rebaudiana* Bertoni plant using UDP-glucosyltransferase and sucrose synthase enzymes produced by the genetically modified yeasts *K. phaffi* (formerly known as *Pichia pastoris*) UGT-a and *K. phaffi* UGT-b that facilitate the transfer of glucose from sucrose and UDP-glucose to steviol glycosides via glycosidic bonds. After removal of the enzymes by solid-liquid separation and heat treatment, the purification involves concentration of the rebaudioside M by resin adsorption, followed by recrystallisation of rebaudioside M resulting in a final product containing not less than 95 % of rebaudioside M. Viable cells of the yeasts *K. phaf?i* UGT-a and *K. phaf?i* UGT-b or their DNA shall not be detected in the food additive.
Chemical name	Rebaudioside M: 13-[(2-O-?-D-glucopyranosyl-3-O-?-D-glucopyranosyl-?-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-?-D-glucopyranosyl-3-O-?-D-glucopyranosyl-?-D-glucopyranosyl ester
Molecular formula	C56 H90 O33, conversion factor 0.25
Trivial name	Rebaudioside M
Molecular weight	Molecular weight (g/mol): 1291.29
CAS number	1220616-44-3
Assay	Not less than 95% 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

Identification: pH	Between 4.5 and 7.0 (1 in 100 solution)

Purity

Substance type	Definition
Total ash	Not more than 1 %
Loss on drying	Not more than 6 % (105 °C, 2h)
Residual solvent	Not more than 5000 mg/kg ethanol
Arsenic	Not more than 0.015 mg/kg
Lead	Not more than 0.2 mg/kg
Cadmium	Not more than 0.015 mg/kg
Mercury	Not more than 0.07 mg/kg
Residual protein	Not more than 5 mg/kg
Particle size	Not less than 74 ?m [using a mesh #200 sieve with a particle size limit of 74 ?m]