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Consultation on the amendment to the specification of one food additive (RP1194 - Rebaudioside M)

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.
* Consumers and wider stakeholders.

## Consultation subject and purpose

We recently consulted on a regulated product application for the modification/extension of use 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](https://consult.foodstandards.gov.scot/regulatory-policy/misc-consultation/).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 E960 steviol glycosides would need to change to E960a steviol glycosides from stevia, although the actual technical specification will remain unchanged.

We ask stakeholders to consider any relevant provisions of retained European Union (EU) law and other legitimate factors (other evidence further supporting clear, rational and justifiable risk analysis, such as technical feasibility and environmental factors). This is stakeholders’ opportunity for input on the advice given to Ministers to inform decision making.

A parallel consultation is being published by the FSA.

## 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 Scotland, England 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](https://www.legislation.gov.uk/eur/2008/1331/contents) 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 the subject of a recent consultation. We are now seeking stakeholders’ feedback in relation to the proposed technical specification for E 960c so that, should this food additive be authorised, the retained EU Regulation 231/ 2012 setting out technical specifications for food additives can be amended.

If the new steviol glycoside entry (E960c) is authorised and therefore is added to the additive specifications in retained Regulation 231/2012, there will also be a consequential change where the existing additive specification for steviol glycosides (E960) derived from the stevia leaf will be renamed E960a ‘Steviol glycosides from stevia’. This is to clearly differentiate between the two substances.

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

The proposed specification is included in [Annex B](#_Annex_B:_RP1194). Details of the proposed authorisation of E 960c can be found in the consultation on [authorisation](https://consult.foodstandards.gov.scot/regulatory-policy/misc-consultation/).

## Engagement and consultation process

Details of all validated applications for regulated products are published on the [Register of Regulated Product Applications](https://www.food.gov.uk/risk-analysis/register-of-regulated-product-applications), which is hosted 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 relevant to this consultation?

The consultation pack provides the background information and details you will need to know in order to respond.

**How to respond**

## Comments should be provided within 2 weeks of the date of this publication and any comments received are subject to the same privacy statement as consultations, details of which can be found in our [consultations privacy notice.](https://www.foodstandards.gov.scot/privacy/privacy-notices/consultations-privacy-notice)

If you wish to comment on the applications in this consultation, all responses should be submitted through the Citizen Space entry, where the questions can be answered and other feedback given.

## Next steps

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

## Publication of response summary

Within three months of a consultation ending, we aim to publish a summary of responses received and provide a link to it from this page. You can find information on how we handle data provided in response to consultations in our [consultations privacy notice.](https://www.foodstandards.gov.scot/privacy/privacy-notices/consultations-privacy-notice)

## Further information

This consultation has been prepared in accordance with [Scottish Government Consultation Guidance](https://www.gov.scot/publications/consultations-in-the-scottish-government-guidance/) If an Impact Assessment has been produced, this is included in the consultation documents.

## 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
* Baby Milk Action
* Campden BRI
* Cereal Ingredient Manufacturers’ Association
* Council for Responsible Nutrition UK
* Dairy UK
* Federation of Bakers
* Federation of Small Businesses (Scotland)
* Food & Drink Federation (Scotland)
* FDF Sector Group: Biscuit, Cake, Chocolate and Confectionery
* FDF Sector Group: Food additives
* Food Additives Industry Association (FAIA)
* Health Food Manufacturers’ Association
* Leatherhead Food International
* Scientific Advisory Committee on Nutrition
* Scotland Food and Drink
* Scottish Retail Consortium
* Snack, Nut and Crisp Manufacturers’ Association
* UK Flavour Association
* UK Flour Millers
* Which?

This is not an exhaustive list.

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

### Background

A routine application for the amendment of the specifications for the manufacture of the food additive steviol glycosides (E 960), contained in the Annex to retained Regulation (EU) 231/2012, 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 the subject of a recent consultation. 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 Scotland, England and Wales would not result in divergence within the UK.

Details of the proposed authorisation of rebaudioside M can be found below.

### 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 glycosides, the heading is replaced by the following:

 ‘**E 960a STEVIOL GLYCOSIDES FROM STEVIA’**

1. The following new entry is inserted after the entry for E960:

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

|  |  |
| --- | --- |
| **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 B, rebaudioside D, rebaudioside I, and stevioside.  Rebaudioside M is obtained via enzymatic bioconversion of puriﬁed 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. phafﬁi* UGT-a and *K. phafﬁi* UGT-b or their DNA shall 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   | C56 H90 O33   | 0.25   |
| Molecular weight and CAS number | Trivial name | CAS number | Molecular weight (g/mol) |
|  |  |  |
| Rebaudioside M   | 1220616-44-3   | 1291.29   |
| 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   |
| pH | Between 4.5 and 7.0 (1 in 100 solution)   |
| **Purity** |
| Total ash   | Not more than 1 %   |
| Loss on drying   | Not more than 6 % (105 °C, 2h)   |
| Residual solvent   | Not more than 5 000  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 μm [using a mesh #200 sieve with a particle size limit of 74 μm] ’   |