22nd July 2021

Food Standards New Zealand New Zealand
PO Box 10559
The Terrace
Wellington 6143

Submission for A1222 - Steviol glycosides from Yarrowia lipolytica

Dear Sir or Madam,

The New Zealand Beverage Council (NZBC) represents the manufacturers of New Zealand's juice, carbonated drink and bottled water brands, and their suppliers. The Association has established a Voluntary Code of Practice that is aimed at ensuring accurate and truthful labelling on products. In particular, the Code signifies compliance with the relevant Food Regulations and Fair-Trading requirements. This system is at the forefront of industry self-regulatory developments in New Zealand and over 95 per cent of the sold in New Zealand is supplied by NZBC members who are signatories to the Code.

The New Zealand Beverages Council, acting on behalf of the non-alcoholic refreshment beverages industry in New Zealand, would like to indicate its strong support for natural glycolipids as a new preservative in non-alcoholic beverages.

Background

The NZBC makes the following submission relating to the assessment of an application by Food Standards New Zealand New Zealand (FSANZ) which seeks to permit the use of a steviol glycoside mixture of rebaudioside M with lesser amounts of rebaudioside D (and possibly minor amounts of other steviol glycosides), produced by fermentation of simple sugars using a genetically modified Yarrowia lipolytica (Y. lipolytica) production strain (VRM0014). The steviol glycoside mixture, produced for use as a food additive in the form of a steviol glycosides preparation, is denoted rebaudioside MD by the applicant.

The purpose of FSANZ's assessment was to:

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- determine whether the proposed purpose is clearly stated and that the applicant's rebaudioside MD achieves its technological function in the quantity and form proposed to be used as a food additive; and
- evaluate any potential public health and safety issues that may arise from the use of the applicant's rebaudioside MD, produced by fermentation of simple sugars using the genetically modified Y. lipolytica, expressing steviol glycoside biosynthesis pathway genes.

The New Zealand Beverage Council's Position and Issues for Consideration

The NZBC, advocating on behalf of the non-alcoholic beverages industry in New Zealand, supports the draft variation to amend Schedule 3 – 39 to permit the use of Yarrowia lipolytica strain VRM0014 containing novel genes for the production of steviol glycosides via fermentation. It is important to note the following points in relation to the current application.

Current Use of Steviol Glycosides

The specific glycosides of rebaudiosides M and D (Reb MD) have been shown to be safe. FSANZ has previously assessed the safety of rebaudioside M (A1207) produced via fermentation from Saccharomyces cerevesiaie (S. cerevisiae) strain Y63348, and MD (A1170) produced via fermentation from S. cerevisiae strain CD15407 and confirmed these steviol glycosides to be safe to use as intense sweeteners* in a variety of beverages at maximum permitted levels (Schedule 15). The Code imposes identity and purity specifications with which all steviol glycosides must comply in Schedule 3-39. As identified in the consultation paper, the steviol glycoside preparation that was the subject of A1170 – Rebaudioside MD as a steviol glycoside from S. cerevisiae (2019), is considered chemically equivalent to that described in A1222.

The NZBC supports the inclusion of Reb MD produced via the FSANZ approved fermentation method from the genetically modified Y. lipolytica strain VRM0014, as a steviol glycoside with an INS number of 960 within the category of currently permitted foods as well as foods that will be approved in the future. It is important and relevant to this Application to emphasise the NZBC's proposed variations to permit steviol glycosides in fruit drinks (A1149 – Addition of steviol glycosides in fruit drinks) was gazetted in 2019.

*The non-alcoholic beverages industry uses the term 'non-sugar sweeteners', but for the purpose of this submission we will use 'intense sweeteners' as FSANZ has in the consultation paper.

Currently, Reb MD produced via fermentation from the genetically modified Y. lipolytica strain VRM0014 detailed in A1222 has GRAS (Generally Recognised as Safe) status in the USA for a variety of food and beverage uses. JECFA[1] recognises the specific production method detailed in A1222 as equivalent in terms of safety, if the steviol glycoside preparation complies with the specification and

[1] Compendium of Food Additive Specifications. Joint FAO/WHO Expert Committee on Food Additives, 84th meeting 2017. FAO JECFA Monographs 20

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purity requirements that exists for other production methods. The approval of this steviol glycoside preparation would allow New Zealand to become internationally competitive while encouraging an important agenda of product innovation within the non-alcoholic beverages industry.

Call to Decrease Sugar in Sugar-Sweetened Beverages (SSBs)

In recent years, both New Zealand and Australia have actively been working towards addressing the issue of rapidly increasing obesity rates and associated chronic disease. Sugar in the diet has been highlighted as a major contributor to obesity and chronic disease, and it is therefore incumbent on the regulator to consider safe and suitable alternatives to reduce energy intake derived from sugars.

Governments on both sides of the Tasman are proposing initiatives related to food, nutrition and health for the food industry to implement to improve the diet and health of New Zealanders and Australians. Safe developments in sweeteners, such as A1222, should be considered an important part of assisting manufacturers to provide broader choice of low and no-calorie options so that consumers have more choices that meet their nutritional needs, ultimately helping them adopt and maintain an overall healthy and balanced diet.

Past and current Government initiatives that relate to sugar in the food supply include:

a. Labelling Logic: The Review of Food Labelling Law and Policy (2011) (The Blewett Review) provided recommendations to improve food labelling law and policy. Recommendation 12 was to review the ingredient labelling of added sugars;
b. Five-year review of the Health Star Rating system. Recent changes to the algorithm (adopted in November 2020) has lowered the HSR for many sugar-containing beverages and is pushing industry to reformulate to provide more lower and no-sugar options;
c. Labelling of sugars on packaged foods and drinks consultation which is ongoing and under consideration by the Food Ministers' Meeting; and

Many academics, non-government organisations, consumer advocacy groups and public health professionals are seeking a marked reduction in the sugar content of food and beverages, with sugar-sweetened beverages (SSBs) of particular note.

There is increasing pressure on the non-alcoholic beverage industry to innovate through:

1. Reformulation;
2. Product and portfolio renovation;
3. Introducing new products into the market; and
4. Making applications to FSANZ to permit important innovation to occur.

One of the core challenges for non-alcoholic beverage manufacturers is to innovate as described without compromising on taste.

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The NZBC and its Members recognise the contribution of SSBs to sugar intake in New Zealand.

The NZBC has responded to this with the NZBC Healthy Kids Industry Pledge details of which can be found on the below link
https://www.nzbeveragecouncil.org.nz/positions/our-healthy-kids-pledge/
To assist beverage manufacturers to achieve the pledge's goal, the NZBC encourages and is actively seeking further innovation within the category. The approval to use Reb MD as per the method detailed in A1222 will support manufacturers to meet these goals.

NZBC Members require flexibility and opportunity to innovate and develop new products using a broader range of intense sweeteners, like steviol glycosides. Only through this, will manufacturers be able to provide consumers with greater choice of premium low- and no- sugar beverages.

Allowing the non-alcoholic beverages industry to use innovative sweeteners as a replacement for sugar and to reduce sugar content in beverages, is vitally important as the industry has responded to consumer calls to reduce sugar in the food supply. This is also important to enable beverage manufacturers to work with public health policy authorities to achieve current initiatives and the industry's ambitious sugar reduction pledge.

Technological Justification of Reb MD
The currently approved methods for the preparation of steviol glycosides produces different degrees of various glycosides. Rebaudiosides M and D are minor glycosides and present at much lower levels than other glycosides in the leaves of Stevia rebaudiana Bertoni. The Application highlights that the intense sweetener produced through this method is primarily Reb M with lesser amounts of Reb D.

Reb MD has been shown to have more favourable sensory characteristics compared to other major glycosides. This would allow non-alcoholic beverage manufacturers access to more favourable taste profiles which provide sweetness without compromising on taste or significantly increasing the amount of energy in the product. This in turn would lead to greater consumer acceptance of products containing intense sweeteners.

Support Reb MD Specification
The Reb MD produced by fermentation using a Y. lipolytica production strain that has been engineered to produce steviol glycosides, meets the purity parameters of specifications currently listed in Schedule 3 -39 of the Code i.e., steviol glycosides must meet an assay value of not less than 95% total steviol glycoside content, and is consistent with the purity specifications in the FAO JECFA Monograph 20 for 'steviol glycosides from Stevia rebaudioside Bertoni'2.

[2] Compendium of Food Additive Specifications. Joint FAO/WHO Expert Committee on Food Additives, 84th meeting 2017. FAO JECFA Monographs 20

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Therefore, the NZBC supports the addition of the strain Y. lipolytica containing novel genes to Schedule 3-39 for the production of steviol glycosides with the same specification as currently approved for steviol glycosides obtained from fermentation.

Support Labelling

The NZBC supports the existing labelling requirements in the Code for steviol glycosides will apply to this Reb MD mixture and requires a declaration as a food additive in the statement of ingredients on the label of the food or beverage, either using the food additive name 'steviol glycosides' or the International Numbering System (INS) code number 960. The NZBC also supports FSANZ's decision that "the most appropriate INS number for labelling purposes for all steviol glycosides is 960". This will allow the same labelling requirements as currently stands according to Standard 1.2.4 and for INS 960 to be used as stated in Schedule 8 without having to disclose the specifics regarding the processing method.

The NZBC appreciates the proposed changes to the Code is to the specification of the steviol glycosides as a food additive, and that the existing labelling requirements would apply. Consequently, the production method used under this application does not currently have a new INS number assigned and therefore would appropriately be INS 960.

The NZBC acknowledges FSANZ's consideration to change the INS number for steviol glycosides to discern steviol glycosides produced by different methods e.g., from plant (960a), fermentation (960b) and enzymatic (yet to be assigned) once the work by the Codex Committee on Food Additives has been completed. The NZBC welcomes targeted stakeholder consultation when FSANZ commences this work.

The NZBC notes FSANZ's assessment that this Reb MD preparation is a food produced using gene technology. Section 1.5.2-4 of the Code states that labelling with 'genetically modified' is not required if the ingredient of food "has been highly refined where the effect of the refining process is to remove novel DNA or novel protein". Although, the strain Y. lipolytica is genetically modified to produce steviol glycosides, the NZBC supports FSANZ's assessment that it is highly unlikely that novel protein or DNA will be present in the Reb MD preparation and therefore in a food for sale. Therefore the NZBC supports Reb MD as per Application A1222 would not be required to be labelled as 'genetically modified' as any novel DNA present would be subject to purification and, therefore, removed. In the case of Reb MD containing novel DNA or protein, then the requirement to label 'genetically modified' would apply in accordance with Section 1.5.2-4.

Support ADI for Steviol Glycosides

Reb MD produced by genetically modified Y. lipolytica has been found to follow the same metabolic fate as other steviol glycosides previously assessed by FSANZ and therefore it is appropriate to support the current ADI of 0 to 4 mg/kg body weight for steviol glycosides.

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The NZBC supports FSANZ's updated safety assessments for steviol glycosides for various Applications and the recommendation of the continued use of the current ADI.

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Conclusion

The NZBC, acting on behalf of the non-alcoholic beverages industry in New Zealand, **strongly supports** the proposed approach by FSANZ to Application A1222 Steviol glycosides from *Yarrowia lipolytica*, specifically:

1. Amending Schedule 3-39 to permit the *Yarrowia lipolytica* strain VRM0004 containing novel genes for the production of steviol glycosides.
2. Allowing the same specification, usage and ADI as currently permitted for other steviol glycosides.
3. Allowing the same labelling requirements as other steviol glycosides in the use of INS 960.
4. Not requiring Reb MD produced by this method to be labelled 'genetically modified' if no novel DNA or protein is present in the final food.

glycosides from *Yarrowia lipolytica*.

For further information:

To discuss this submission or any aspect contained therein, please contact:

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