AUSTRALIAN BEVERAGES COUNCIL

Submission to Application A1222 – Steviol glycosides from *Yarrowia lipolytica* Consultation Paper

22 July 2021

About the Australian Beverages Council Limited

The Australian Beverages Council Limited (ABCL) has been the leading peak body representing the non-alcoholic beverage industry for more than 70 years, and the only dedicated industry representative of its kind in Australia.

The ABCL represents approximately 90 per cent of the non-alcoholic beverage industry's production volume and our Member companies are some of Australia's largest drinks manufacturers. The ABCL also represents many small and medium-sized companies across the country. Collectively, the ABCL's Members contribute more than $7 billion to the Australian economy and they employ over 50,000 people across the nation. The industry also pays $1.2 billion in taxes per annum and for every one direct employee who works in the beverage manufacturing industry, there are 4.9 jobs required elsewhere in the economy to produce and retail beverages.

The ABCL strives to advance the industry as a whole, as well as successfully representing the range of beverages produced by our Members. These include carbonated soft drinks, energy drinks, sports and electrolyte drinks, frozen drinks, bottled and packaged waters, fruit juice and fruit drinks, cordials, iced teas, kombuchas, ready-to-drink coffees, flavoured milk products and flavoured plant milks.

The unified voice of the ABCL offers Members a presence beyond individual representation to promote fairness in the standards, regulations, and policies concerning non-alcoholic beverages. The ABCL plays a role in educating consumers on making informed choices which encourage balance, moderation and common sense.

The ABCL advocates on issues such as portion sizes, nutritional labelling, responsible industry marketing and advertising, and canteen guidelines, among others. Our Members listen to consumers and adapt their products accordingly by making positive changes and standing by a commitment to promote greater choice, appropriate portions and by developing an ever increasing range of low and no kilojoule products.

The ABCL is an important conduit between the non-alcoholic beverage industry and governments, supporting the Australian Government, State and Territory Governments and Local Councils.

The ABCL introduced a dedicated juice division, Juice Australia [JA] (formerly Fruit Juice Australia), in 2009 and a dedicated water division, the Australasian Bottled Water Institute [ABWI], in 2011. Through these divisions, and various committees, our organisation and Members continue to adapt and flourish.

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Background

The ABCL makes the following submission relating to the assessment of an application by Food Standards Australia 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 glycoside preparation, is denoted rebaudioside MD by the applicant.

The purpose of FSANZ's assessment was to:

- 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 Australian Beverages Council's Position and Issues for Consideration

The ABCL, advocating on behalf of the non-alcoholic beverages industry in Australia, 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 cerevisiae (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 ABCL 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 ABCL'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 per the FSANZ consultation paper.

The ABCL has also supported similar Applications for the permission of steviol glycosides produced through fermentation (A1170) and enzymatic conversion methods (A1172, A1176 and A1183).

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 purity requirements that exists for other production methods. The approval of this steviol glycoside preparation would allow Australia 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 Australia and New Zealand 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 Australians and New Zealanders. Safe developments in sweeteners, such as A1222, should be considered an important part of assisting manufacturers to provide broader choice of low- and no-sugar 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
d. The Healthy Food Partnership looks at ways to improve nutrition status of Australians. The Reformulation Working Group recently released specific targets for beverages to reduce sugar.

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.

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

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.

The ABCL and its Members recognise the contribution of SSBs to sugar intake in Australia.

The ABCL has responded to this with the ABCL Sugar Reduction Pledge in which the non-alcoholic beverages industry has committed to a 20 per cent reduction in sugar across the industry's portfolio by 2025. This industry-led initiative released its first progress report in 2019 showing a 7 per cent reduction in sugar content across non-alcoholic beverages for the period 2015 – 2018, and a total 12 per cent reduction from 2015 to 2020, surpassing the Pledge's first target of 10 per cent by 2020. To assist beverage manufacturers to achieve the pledge's goal, the ABCL 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.

Need for Innovation in Low and No Sugar Non-Alcoholic Beverages

The ABCL commissioned a 22-year longitudinal analysis of water-based beverage sales trends in Australia[2]. This study found a significant 30 per cent decrease in per capita sugar contribution from non-alcoholic water-based beverages over the 22-year period from 1997 to 2018, equivalent to a reduction in 127 grams of sugar per person, per year. In 1997, Australians consumed 83 litres of sugar-sweetened beverages per person compared to 61 litres per person per year in 2018. In contrast, 88 litres of no-and low-sugar choices, such as plain and sparkling water and no-sugar soft drinks, were consumed per capita in 2018.

This research demonstrates an important shift in consumer behaviour which is reflective of both the Australian Dietary Guidelines' recommendations to limit consumption of SSBs and the industry's efforts to encourage healthier choices by providing a broader choice of low and no-sugar varieties for consumers. The industry will continue to innovate within this category, and it is expected consumer behaviour will continue to shift towards choosing low- and no-sugar options.

ABCL 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

[2] Shrapnel, W.S & Butcher, B.E. Sales of Sugar-sweetened Beverages in Australia: A Trend Analysis from 1997 to 2018. *Nutrients* (2020).

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'[3].

Therefore, the ABCL 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 ABCL 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 ABCL 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 ABCL 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.

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

The ABCL 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 ABCL welcomes targeted stakeholder consultation when FSANZ commences this work.

The ABCL 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 ABCL 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. The ABCL supports Reb MD as per Application A1222 not be required to be labelled as 'genetically modified' if no novel DNA or protein is present. 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.

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

Conclusion

The ABCL, acting on behalf of the non-alcoholic beverages industry in Australia, **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 novel protein is present in the final food.

The ABCL would like to thank FSANZ for the opportunity to make a submission on Application A1222 Steviol glycosides from *Yarrowia lipolytica*.

For further information:

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

[redacted]