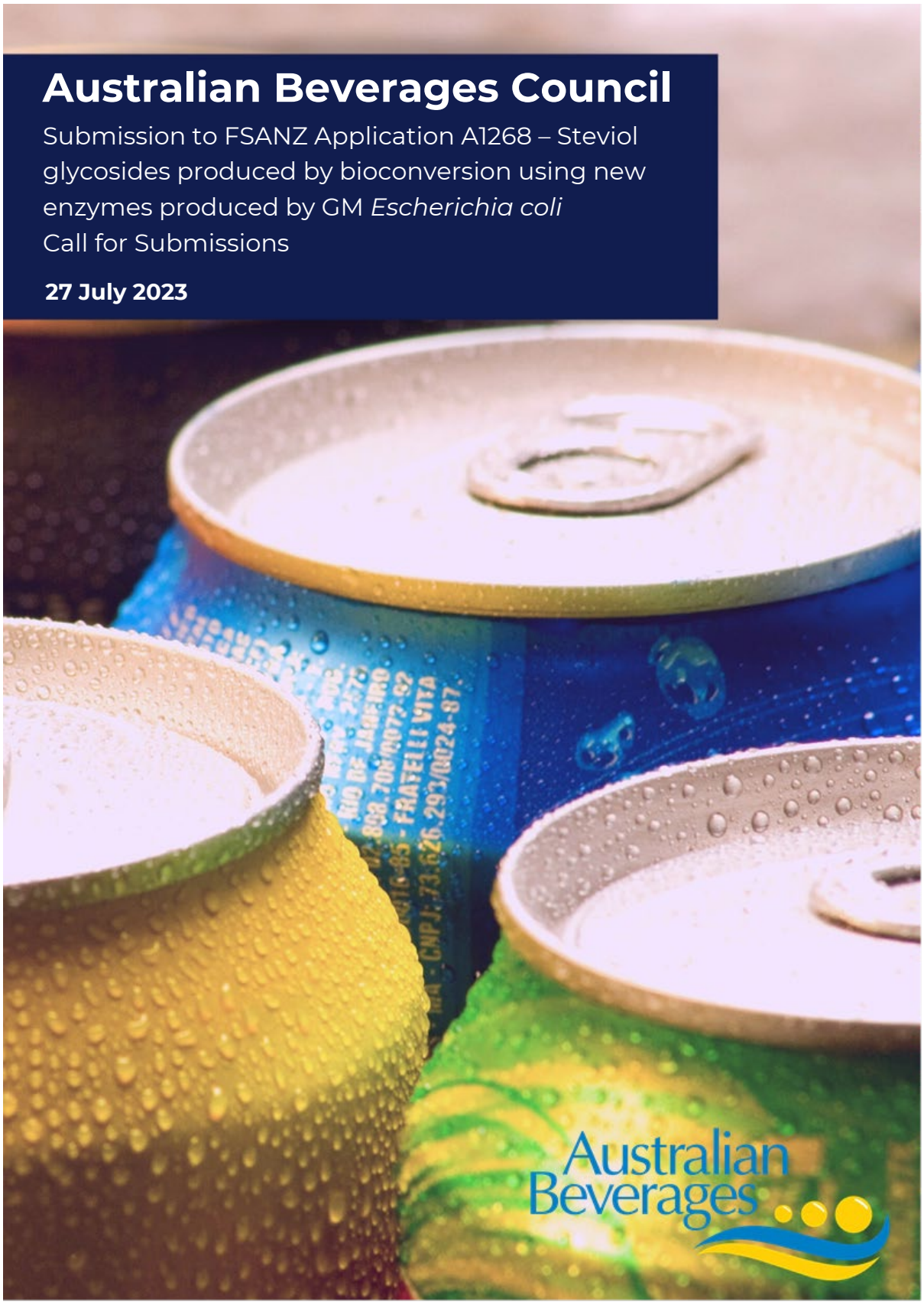
Australian Beverages Council

Submission to FSANZ Application A1268 – Steviol glycosides produced by bioconversion using new enzymes produced by GM *Escherichia coli*
Call for Submissions

27 July 2023



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About the Australian Beverages Council Limited

The Australian Beverages Council Limited (ABCL) is the leading peak body representing the non-alcoholic beverages industry, and the only dedicated sector representative of its kind in Australia.

The ABCL represents approximately 95 per cent of the non-alcoholic beverages industry's production volume and our member companies are some of Australia's largest drinks manufacturers. The ABCL also represents many micro, small and medium-sized companies across the country. Collectively, the ABCL's members contribute more than $7 billion to the Australian economy and employ over 50,000 people across the nation. The industry also pays $1.2 billion in taxation per annum along its supply chain, and for every direct employee in the beverages 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 represent the range of beverages produced by 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, ready-to-drink coffees, kombucha, flavoured milk products and flavoured plant milks.

The ABCL advocates on issues such as portion sizes, front-of-pack and nutritional labelling, responsible industry marketing and advertising, and canteen guidelines, among others. Our members are responsible and responsive, listening to consumers and innovating to stand by a commitment to provide and promote more informed choice to Australians that support a healthy and balanced diet.

1. Introduction

The ABCL appreciates the opportunity to provide comments to Food Standards Australia New Zealand (FSANZ) on its Call for Submissions for Application A1268 – Steviol glycosides produced by bioconversion using new enzymes produced by GM *Escherichia coli*.

2. ABCL position on the draft variation

The ABCL advocating on behalf of the non-alcoholic beverages industry in Australia, supports in principle the draft variation as proposed in Attachment A of FSANZ's consultation paper on A1268 – Call for Submissions, to:

- permit the use of three new GM enzymes for the bioconversion production method of two steviol glycosides, rebaudiosides M and I.

Rationale:

FSANZ has previously assessed several applications using the bioconversion (or alternatively known as the 'enzyme modified') method of manufacture, to which the ABCL has submitted comments in support of, including:

- A1157 – Enzymatic production Rebaudioside M (2018)
- A1176 – Enzymatic production of steviol glycosides (2019)
- A1183 – Enzymatic production of Rebaudioside E (2020).

The ABCL understands A1268 is seeking approval by FSANZ for the inclusion of three new GM enzymes as processing aids to produce steviol glycosides Rebaudioside M and I using the bioconversion method in accordance with the Food Standards Code (the Code). The three new GM enzymes are:

- Uridine triphosphate (UTP)-glucose-1-phosphate uridylyltransferase (EC 2.7.7.9) produced by GM *Escherichia coli* K-12, expressing the gene for UTP-glucose-1- phosphate uridylyltransferase from *Bifidobacterium bifidum*;
- Uridine diphosphate (UDP)-Glucosyltransferase produced by GM *Escherichia coli* K12, expressing the gene for UDP-glucosyltransferase from Oryza sativa (rice); and
- Sucrose synthase (EC 2.4.1.13) produced by GM *Escherichia coli* K-12, expressing the gene for sucrose synthase from Glycine max (soybean).

The ABCL supports FSANZ's risk assessment on the technological justification for the use of the three enzymes as processing aids in the bioconversion production method of steviol glycosides, and the assessment that they have a history of safe use.

Furthermore, the bioconversion production method of steviol glycosides is already permitted in international regulations such as Codex Alimentarius standards and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Framework for Steviol Glycosides (the Framework).

The ABCL supports FSANZ's assessment of Application A1268 underpinning the proposed draft variation to the Code as outlined in Attachment A of the consultation paper.

3. ABCL points for consideration

In reviewing the consultation paper, the ABCL requests FSANZ to consider the below additional points relevant to subsections in the paper and Schedule 3 of the Code.

3.1 Draft variation to Schedule 3 – Identity and Purity (as per Attachment A)

Currently under Schedule 3 – paragraph 35(2)(c), permissions for use of enzyme type and sources for the enzymatic conversion (bioconversion) production method for steviol glycosides are for prescribed rebaudiosides only as listed in subsection S3-35(1) i.e., rebaudiosides D, M and AM.

With the proposed new wording in Attachment A, it is not clear that the approval of the three new enzymes as per A1268 will only apply to rebaudiosides M and I. Users of these enzymes and/or ingredient (steviol glycoside) manufacturers may be confused with the proposed wording in the paragraph S3-35(2)(c) for approval as it implies that gene sources and enzymes are interchangeable across D, M, I and AM.

3.2 P1061 – Code Maintenance inclusion of JECFA specifications Monographs 25 and 26

The ABCL notes that via Proposal P1051 – Code Revision (2020), FSANZ adopted changes to section S3- 35, including the following:

- Deletion of paragraph S3-35(2)(a) - preparation for steviol glycosides obtained from the leaves of the *Stevia rebaudiana* Bertoni plant (INS 960a):

> (2) The preparation must be obtained from the leaves of the *Stevia rebaudiana* Bertoni plant by using one of the following processes:
>
> (a) the leaves are extracted with hot water and the extracts are purified using ion-exchange resins followed by recrystallisation from methanol or aqueous ethanol;

Figure 1. is an extract from Compilation No.14 of Schedule 3 – 35 – Specification for steviol glycosides from *Stevia rebaudiana* Bertoni in force as at 26 March 2021.

We also note the reason for this deletion was due to the updates to paragraph S3-2(1)(b) to include reference to published JECFA specifications Monographs 22 (2018) and 23 (2019). There was also a subsequent change to the title of section S3-35 as a result.

As per sub-section 1.3.1.4 in the A1268 consultation paper, FSANZ notes P1061 Code Maintenance Proposal 2023 will include JECFA Monographs 25 and 26. Under Annex 3 of the JECFA Monograph 26 the method as described in **S3-35(2)(c) enzymatic conversion method** is listed. We are seeking clarity from FSANZ on the potential subsequent changes to S3-35 as a result of the inclusion of monographs 25 and 26 via P1061.

3.3 Draft variation to Schedule 18 – Processing Aids (as per Attachment A)

The ABCL notes the draft variation as per Attachment A inconsistently uses the terms 'containing' versus 'expressing' in the listings of the three new GM enzymes in subsection S18-9(3). We also note that in the consultation paper and supporting document 1 – Risk and technical assessment, the consistent term used is 'expressing' for all three enzymes.

3.4 World Trade Organization (WTO) implication (section 2.3.2)

In section 2.3.2 of the consultation paper, FSANZ does not consider it necessary to submit a WTO notification under Australia and New Zealand's obligations to the WTO technical barriers to trade (TBT) or application of sanitary and phytosanitary (SPS) measures agreement. The reasons for this being the following:

1) The relevant international standard/guidance for processing aids is JECFA and Food Chemicals Codex general specifications, in the absence of a 'general standard' for processing aids in Codex Alimentarius (Codex);
2) JECFA specifications for steviol glycosides production methods includes the bioconversion method, with a list of already permitted enzymes which are "very comparable" to those in A1268 and perform the same function.

The ABCL recommends FSANZ consider the potential for trade implications with the approval of these three new GM enzymes in the production of steviol glycosides via bioconversion, given the differences in gene sources and enzymes between those listed in Codex Alimentarius (Codex) standards (JECFA specifications – Monograph 26 and set by FSANZ. Monitoring of changes to Codex standards and texts, including the Framework and agility to align national regulations with those amendments is imperative for trade facilitation. In this instance, while there may be harmonisation with production technologies, technical barriers to trade may arise between FSANZ and Codex without such equivalency in gene sources and enzymes listed.

3.5 Consideration for costs and benefits to industry (section 2.4.1.1)

The overarching industry need for the approval of this variation is to harmonise with international regulations for market entry requirements. Secondly, it enables greater industry access to sufficient cost-effective supply of minor glycosides and approval for use at a country level.

4. Conclusion

In summation, the ABCL supports the draft variation to the Code as proposed by FSANZ in Attachment A of the A1268 consultation paper.

We welcome all future opportunities to engage with FSANZ on this application or any other matters relevant to the production and use of steviol glycosides.

5. Further Enquiries

Should you have any queries regarding the positions detailed in this submission, please contact:

[redacted]

[redacted]