

FSANZ Call For Submissions – Application A1247

D-Allulose as a Novel Food

20 November 2023

Deadline for Submissions 6pm (Canberra time) 20 December 2023

Australian
Beverages

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 more than \$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 whole industry, 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 supports a healthy and balanced diet.

Introduction

The Australian Beverages Council Limited (ABCL) appreciates the opportunity to provide comments to Food Standards Australia New Zealand (FSANZ) on its Call for Submission of Application A1247: D-Allulose as a Novel Food.

The ABCL acknowledges and supports FSANZ continuing to review applications for new ingredients for use in food and beverages.

The ABCL has documented its responses in the form of a table, for ease of summarising the main issues and our responses.

The ABCL supports the application from Samyang, as D-allulose offers the food and beverage industry an alternative ingredient for sugar replacement. D-allulose brings its own set of unique qualities to formulating new beverages, such as providing a sweetness profile similar to sugar, while reducing the kilojoules. It gives an upfront sweetness to the flavour profile in beverages, that is lacking in some of the currently available sweeteners.

In reviewing this consultation, the ABCL and its members recommend the following:

- That there be no predetermined maximum permitted use level (MPL) for D-allulose. Should FSANZ deem it necessary to establish an MPL for non-alcoholic beverages, the ABCL recommends a limit of 3.5%, as outlined in the submitted application by Samyang.
- For the energy value of D-allulose, the ABCL recommends alignment with international markets, and to address potential disparities resulting from rounding, recommends either the adoption of the Applicant's suggested value of 1.0 kJ/g, or the allowance of rounding to one decimal place.
- The ABCL strongly urges FSANZ to include all beverage categories, as classified under the Food Standards Code in ANZ, to be able to use D-allulose in formulations.
- The ABCL seeks clarification from FSANZ on whether the inclusion of D-allulose in the NIP would impact carbohydrate/sugar values and consequently influence nutrient content claims related to sugar.
- The ABCL contends that FSANZ should notify the WTO of this application so that its member states have the opportunity to respond.
- The ABCL acknowledges that there will only be trade benefits for industry if all appropriate categories are covered in the permission of use, and the regulations (regarding MPL's and energy factor) are harmonised completely with international markets.

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No.	Issue	The ABCL's Response
1	<p><u>Maximum Permitted Use Level (MPL)</u></p> <p>FSANZ is proposing to lower D-allulose use levels compared to the maximum use levels proposed in the application.</p> <p>This is to mitigate the risk of laxation.</p>	<p>The Australian Beverages Council Limited (ABCL) recommends there is no predetermined maximum permitted use level (MPL) for D-allulose. Should FSANZ deem it necessary to establish an MPL for non-alcoholic beverages, the ABCL recommends a limit of 3.5%, as outlined in the submitted application.</p> <p>The ABCL bases its position on the self-limiting nature of D-allulose usage, its resemblance to other food ingredients (e.g., fructose), and its similarity to other sweeteners (e.g., polyols). Considering these factors, the ABCL contends that the imposition of an MPL is unnecessary, as potential concerns related to laxation effects can be adequately addressed through advisory statements. Furthermore, limitations on use are informed by the potential distortion of sensory profiles.</p> <p>The ABCL asserts that the implementation of mandatory advisory statements (when D-allulose is used above a certain level), under Standard 1.2.3, as other ingredients are dealt with, would sufficiently mitigate laxation concerns, presenting a preferable alternative to reducing the requested limits proposed by the Applicant.</p> <p>Drawing attention to the practices of the United States Food and Drug Administration (US FDA), which has set a limit of 3.5% on D-allulose, the ABCL notes that such restrictions are based on technological considerations, including impacts on product flavour profiles. In addition to the US, Chile, Columbia and Mexico all have an MPL of 3.5% D-allulose in non-alcoholic beverages. The ABCL contends that Australian limits should not be more restrictive than those allowed in these countries to facilitate global harmonisation of formulations.</p> <p>Additionally, the ABCL highlights the regulatory frameworks in Korea and Japan, where no specific limits on D-allulose use exist. These countries rely on advisory statements to address potential consumer concerns related to laxation effects.</p> <p>In conclusion, the ABCL advocates for a pragmatic regulatory approach that prioritizes the establishment of advisory statements over the imposition of lower MPLs, aligning with global practices and fostering harmonisation in formulations.</p>

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2	<p><u>Energy value for D-allulose:</u></p> <p>The Applicant requested an energy value of 1.0kJ/g, whereas by calculation, FSANZ is proposing 1.88kJ/g rounded up to 2kJ/g.</p> <p>This is a 100% overage from the original requested value (i.e., 1.0 versus 2.0).</p>	<p>The ABCL acknowledges FSANZ's proposal to round energy values to the nearest whole number. However, a discernible variance has been observed in comparison to key international markets, as outlined in the consultation document:</p> <ol style="list-style-type: none"> 1. United States (0.4 cal/g = 1.672 kJ/g) 2. Korea and Japan (0 kJ/g) <p>To align more closely with these international markets and to address potential disparities resulting from rounding, the ABCL recommends either the adoption of the Applicant's suggested value of 1.0 kJ/g or the allowance of rounding to one decimal place.</p> <p>It is crucial to note that FSANZ's proposed energy factor deviates from established international standards and does not facilitate harmonisation with identified markets. The ABCL emphasizes the importance of aligning with global practices to mitigate potential trade implications and to facilitate greater export market access for Australian products.</p> <p>The ABCL urges FSANZ to harmonise its approach with other international markets, as rounding energy values to a whole number can significantly impact outcomes, particularly when dealing with initial values that are very small compared to the majority of other energy values, which are comparatively larger. In light of these considerations, the ABCL requests that FSANZ carefully evaluate and adjust its approach to energy value rounding, taking into account the proposed value of 1.0 kJ/g or allowing rounding to one decimal place to better align with international standards and facilitate harmonisation in the interest of trade consistency.</p>
3	<p><u>Nutrition Claims</u></p> <p>FSANZ propose D-allulose be excluded from the amount of sugars in the NIP (including carbohydrate amount) due to the way it metabolises in the body.</p> <p>i.e. 0g sugar/100g (& serve size)</p>	<p>D-allulose is virtually unmetabolized in the human body and for the purposes of nutrition labelling a low energy factor of 2 kJ/g is proposed.</p> <p>For these reasons, FSANZ has proposed foods containing D-allulose are permitted to make nutrition content claims about sugar, i.e. % free, low sugar(s), reduced/lite and no added sugar(s) on foods that contain D-allulose and otherwise meet existing claim conditions. E.g., a food displaying a low sugar claim must have a sugars concentration of no more than 2.5 g/100 mL for liquid food.</p> <p>ABCL agrees with this decision, however, the ABCL requests that FSANZ confirms how D-allulose will be aligned in the new definition of 'sugars', as per the recent gazettal of proposal P1062 Defining added sugars for claims. Given that the above claims will be allowed, the ABCL requests D-allulose be excluded from the</p>

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		added sugars definition. We request confirmation from FSANZ that this is a correct assumption.
4	<p><u>Formulation Development</u></p> <p>D-allulose is produced to function as a sugar replacer, i.e. low-energy substitute for conventional sugar ingredients, particularly sucrose.</p> <p>The applicant, Samyang, has proposed a usage level up to 3.5%. However, FSANZ are proposing a usage level of 1.5%.</p>	<p>The ABCL does not agree with FSANZ proposing a usage level of 1.5%.</p> <p>The ABCL wishes to express its regulatory stance regarding FSANZ's proposed adjusted use levels of 1.5% The ABCL holds the position that the suggested levels are not be suitable for facilitating the comprehensive substitution of sugar.</p> <p>The applicant, Samyang, has proposed a level of 3.5% for beverages application, and on viewing the applicant's suggested usage in various beverage prototypes, usage of D-allulose is required at up to 3.5%, depending on the beverage type.</p> <p>It is imperative to recognize that D-allulose is approximately 70% as sweet as sugar. Consequently, the industry would require a dosage exceeding 1.5% to effectively substitute sugar, considering the relative sweetness factor.</p> <p>The ABCL urges FSANZ to carefully reconsider and assess the appropriateness of the proposed adjusted use levels, taking into account the inherent sweetness disparity between D-allulose and sugar. Such consideration is crucial to enable industry to achieve meaningful sugar replacement while maintaining product palatability and consumer acceptance.</p> <p>We appreciate FSANZ's attention to this matter and look forward to collaborative efforts in establishing regulatory standards that align with industry requirements and facilitate the successful incorporation of Allulose as a sugar substitute.</p> <p>The ABCL appreciates the opportunity for industry to share their feedback on A1247. Nevertheless, as part of this process, the industry should also be granted the opportunity to express their views on regulatory limits that are imposed, especially when they deviate from the proposed use levels by the applicant. This is essential to ensure comprehensive coverage across relevant food categories. Without this consideration, the industry may encounter substantial regulatory challenges that could be mitigated through alignment with international markets.</p> <p>We re-iterate that a 3.5% usage level is the minimum required for beverages. D-allulose is not fit for purpose as a sugar replacer at 1.5% usage in non-alcoholic beverages.</p>
5	<p><u>Missing Categories</u></p> <p>As a low energy carbohydrate, D-allulose will provide industry with an alternative to sucrose</p>	<p><u>Full Expansion of Beverage Categories is Required</u></p> <p>The ABCL strongly urges FSANZ to include all beverage types, as classified under the Food Standards Code in ANZ, to be able to use D-allulose in formulations.</p>

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	<p>and other higher energy sugar ingredients.</p> <p>FSANZ has loosely based the proposed food classes/group (as named and proposed under the DRAFT regulation) on the food classes listed under Schedule 15.</p> <p>Not identifying all beverage categories could result in the inadvertent use of D-allulose and create issues with enforcement, especially when whole food categories have not been requested by the Applicant or included under the consultation paper.</p>	<p>There are obvious food categories missing from Table 1 of the consultation paper, which limit the number of food categories permitted to use D-allulose within their formulations.</p> <p>For clarity, and to avoid confusion (from unintended interpretational issues), the ABCL suggest identifying food categories under each class of food as per Schedule 15.</p> <p>Some examples of beverage categories which have not been included (based on categories listed under <u>Schedule 15-5 Table of permissions for food additives</u>) are:</p> <ul style="list-style-type: none"> 1.1.2 Liquid milk products and flavoured liquid milk; 13.3 Formulated meal replacements and formulated supplementary foods; 13.4 Formulated supplementary sports foods; 13.5 Food for special medical purposes; 14.1 Non-alcoholic beverages and brewed soft drinks; 14.1.1.2 Carbonated, mineralised and soda waters; 14.1.2 Fruit and vegetable juices and fruit and vegetable juice products; 14.1.2.1 Fruit and vegetable juices; 14.1.2.2 Fruit and vegetable juice products ; 14.1.3.3 Brewed soft drink; 14.1.4 Formulated Beverages; 14.1.5 Coffee, coffee substitutes, tea, herbal infusions and similar products; 14.3 Alcoholic beverages not included in item 14.2. <p>Noting 14.1.3 is listed under Table 1 permissions as 'Water based flavoured drinks'.</p> <p>One of the many benefits of expanding the scope of use of D-allulose to all beverage categories is the benefit to consumers. By providing more options for food and beverages to contain D-allulose, the industry will have more opportunities to create a wider variety of products, which in turn, benefits the consumer.</p>
6	<p><u>Declaration of energy and nutrients in the NIP</u></p> <p>If one or more components listed in subsection S11-2(3) (other than organic acids) is present in the food singly or in combination, in an amount no</p>	<p>The Australian Beverages Council Limited (ABCL) wishes to bring to FSANZ's attention its primary regulatory concern, which pertains to the requirement regarding the declaration of D-allulose in the Nutrition Information Panel (NIP). This issue, in particular, raises significant concerns for the ABCL.</p> <p>The current regulatory framework presents a dual perspective: while there is no obligation to disclose D-allulose in the NIP, except</p>

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	<p>less than 5g/100g, and available carbohydrate by difference is used, then the NIP must include individual declarations of these substances (including D-allulose).</p> <p>This information will enable consumers to make informed food choices.</p>	<p>through an inclusion in the ingredient statement, a contradictory provision exists. When D-allulose is utilised singly or in combination with substances outlined in Schedule 11-2(3) (excluding organic acids) and the value surpasses 5g/100g, there is a requirement for identification in the NIP.</p> <p>This duality poses challenges and may contribute to consumer confusion, undermining the objective of facilitating informed choices. The ABCL contends that consumers can make informed decisions based on the ingredient statement, as per established requirements.</p> <p>The ABCL seeks clarification from FSANZ on whether the inclusion of D-allulose in the NIP would impact carbohydrate/sugar values and consequently influence nutrient content claims related to sugar. Confirmation on this matter is essential for regulatory compliance and consumer transparency.</p> <p>Additionally, the ABCL proposes that D-allulose be labelled in the NIP akin to sugar alcohols, positioned under sodium at the bottom of the NIP. This would involve labelling D-allulose explicitly, along with its corresponding value, aligning with industry standards and minimising consumer confusion arising from assumptions about its metabolic properties.</p>
7	<p><u>WTO notification</u></p> <p>FSANZ deemed WTO notification not necessary given the use of D-allulose is voluntary and permissions vary across different countries.</p>	<p>The ABCL contends that FSANZ should notify the WTO of this application so that its member states have the opportunity to respond. Otherwise, proposed changes by FSANZ could lead to lack of harmonisation in international markets.</p> <p>Global harmonisation is especially important to beverages organisations, where global formulations exist.</p>
8	<p><u>Cost and Benefits to industry</u></p> <p>FSANZ mentions that this permission would provide industry with an extra option for a low -energy substitute for sugar in foods and drinks.</p>	<p>The ABCL agrees that permission to use D-allulose will provide industry with an additional option for a low-energy substitute for sugar in foods and drinks, however, reiterates our point that expansion of beverage categories is required.</p> <p>The benefit to industry is directly based on the permission to use D-allulose. Current permissions are solely based on the Applicant's request and FSANZ does not appear to have included any additional categories.</p> <p><u>This is of major concern to the ABCL:</u></p> <p>Identifying and ensuring all appropriate categories are included within the regulatory permissions will allow industry to leverage the full extent of this ingredient use.</p>

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		<p>All beverage categories need to be included in the permissions of use. i.e. all non-alcoholic and alcoholic beverages, dairy beverages, etc).</p>
9	<p><u>Trade Facilitation</u></p>	<p><u>Harmonised with International Markets</u></p> <p>The ABCL acknowledges that there will only be trade benefits for industry if all appropriate categories are covered in the permission of use, and the regulations (regarding MPL's/energy factor) are harmonised completely with international markets.</p>
10	<p><u>"Other than D-allulose" missing paragraph (b) update in Schedule 4 S4-2</u></p> <p>The Draft Variation only mentions of the definition of sugar relating to the reference to 'Hexose Monosaccharides' in Schedule 4, S-2 (a), 2 (b) is missing.</p>	<p><u>Schedule 4: S4-2 Definition [include updated wording 'other than D-allulose' in paragraph (b) (i)]</u></p> <p>The ABCL requests D-allulose (as a hexose monosaccharide identified under paragraph (b)) should be explicitly mentioned and excluded as part of 'hexose monosaccharide' reference and treated in the same way as the 'monosaccharides' reference under paragraph (a), <u>as well as in paragraph (b)</u> i.e. 'hexose monosaccharide (other than D-allulose)' should be in (a) and (b).</p> <p><u>Schedule 4—Nutrition, health and related claims.</u> S4-2 (Note, paragraph (a) of the definition of "sugars") Repeal the paragraph, substitute:</p> <p>(a) in Standard 1.2.7, Standard 1.2.8 and Schedule 4 (except where it appears with an asterisk as 'sugars')—means monosaccharides <u>(other than D-allulose)</u> and disaccharides; and</p> <p>The ABCL request that (b) is updated as per (a) update:</p> <p>(b) otherwise—means any of the following products, derived from any source:</p> <ul style="list-style-type: none"> (i) hexose monosaccharides <u>(other than D-allulose)</u> and disaccharides, including dextrose, fructose, sucrose and lactose; (ii) starch hydrolysate; (iii) glucose syrups, maltodextrin and similar products; (iv) products derived at a sugar refinery, including brown sugar and molasses; (v) icing sugar; (vi) invert sugar; (vii) fruit sugar syrup; <p>but does not include:</p> <ul style="list-style-type: none"> (i) malt or malt extracts; or (ii) sorbitol, mannitol, glycerol, xylitol, polydextrose, isomalt, maltitol, maltitol syrup, erythritol or lactitol. <p>Note Sugar is defined differently—see section 1.1.2—3. Note Sugars* is relevant for claims about no added sugar.</p>



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11	<p><u>Unit of Measure</u></p> <p>Schedule 25 updates:</p> <p>Overall, as per previous comments regarding food category descriptions and MPL unit of measure.</p>	<p><u>Preferred Unit of Measure is mg/Kg</u></p> <p>To avoid doubt and confusion, the ABCL posits a regulatory suggestion aimed at mitigating ambiguity and confusion within the existing framework. The recommendation is to align/reference food categories under Schedule 15. We further recommend, for ease of reference and calculation, the utilisation of units of milligrams per kilogram (mg/Kg) for measurement, in line with the established treatment of other Maximum Permitted Levels (MPLs) within the Code (in declaring concentration).</p> <p>This proposal seeks to enhance clarity, streamline reference processes, and facilitate uniformity across food categories. By aligning with Schedule 15 and employing a standardized unit of measurement, specifically mg/kg, the regulatory landscape can be rendered more comprehensible and navigable.</p> <p>The ABCL appreciates FSANZ's consideration of this recommendation, recognising its potential to foster a more cohesive and user-friendly regulatory environment. We anticipate that the adoption of these measures will contribute to increased regulatory efficiency and understanding among stakeholders.</p>
12	<p><u>Exclusivity</u></p> <p>D-allulose may only be sold under Samyang's brand name 'Nexweet' for a period of 15 months commencing on the date of gazettal of the draft variation.</p>	<p><u>Post-approval Circumstances</u></p> <p>The ABCL supports this exclusivity period, given the investment that the Applicant has made to have its ingredient included for use in Australia and New Zealand.</p>

Conclusion

The ABCL and its members appreciate the opportunity to provide comments to the Consultation and welcomes additional meetings with FSANZ to discuss these issues further, if required. For enquiries regarding the contents of this submission, please do not hesitate to contact [REDACTED]

Yours sincerely,

[REDACTED]

Response ID ANON-789J-4JGN-5

Submitted to Application A1247 D-allulose as a Novel Food
Submitted on 2023-12-20 17:19:15

[Redacted]

[Redacted]

Introduction

Name

Name:

[Redacted]

Email address

Email:

[Redacted]

Name of your business, organisation (please write N/A if this does not apply)

Organisation:

Australian Beverages Council Ltd

Please identify which of the following groups you mostly closely identify with

Groups to which you belong:

Food industry group

If other please specify:

Who is the contact person for this submission

Please include name, email address and phone number:

[Redacted]

[Redacted]

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