



20 December 2023

Project Manager

Food Standards Australia New Zealand

PO Box 5423

KINGSTON ACT 2604

AUSTRALIA

RE: Submission – A1247 – D-allulose as a novel food [269-23]

Following are the comments that Buderim Foods wishes to present on the Application.

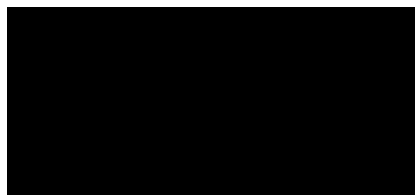
Thank you for the opportunity to provide input to the Call for Submissions for A1247.

If you require any further information, please do not hesitate to contact me.

Sincerely

[Redacted signature]

[Redacted contact information]





Call for submissions – A1247 – D-allulose as a novel food

Submission by: Buderim Foods Pty Ltd

20 December 2023





Buderim Foods Pty Ltd

Buderim Foods Pty Ltd is a Queensland family-owned business that specialises in ginger products.

We are well known for our confectionery range of syruped and crystalised ginger. Research and development space within our business has a major focus on developing products that are healthier for our consumers.

Position

Buderim Foods has reviewed FSANZ's assessment and **supports** approval of D-allulose a novel food.

Overall Comments

Buderim foods has reviewed the Call for submissions document including the supporting Technical and Risk assessment material provided.

Buderim Foods notes the following:

- the application is to amend the Australia New Zealand Food Standards Code (the Code) to permit the sale of D-allulose as a novel food in Australia and New Zealand.
- D-allulose is intended to be added to foods as a low-energy substitute for conventional sugar ingredients, particularly sucrose.
- the Applicant's request for amendment of the Code's requirements for nutrition content claims about sugar(s) for foods containing added D-allulose.
- the requirement for approval of the main production enzyme as a processing aid.

Buderim Foods supports approval of D-allulose as a novel food as it presents an opportunity for Australian and New Zealand food manufacturers to foster innovation leading to products better able to protect and promote improved health outcomes for consumers.

The use of an effective and safe alternative to sugar is of enormous benefit to Australian public health. FSANZ should consider more strongly the importance of public health (fighting obesity) that such a dietary novel food can bring.





Specific Comments

Risk Assessment

Buderim Foods notes FSANZ concluded:

- there is no toxicological risk to public health and safety from consumption of D-allulose in food, or from the use of D-psicose 3-epimerase in the production of D-allulose.
- there is no public health or safety concerns identified in the microbiological safety assessment of D-allulose and healthy adults.
- there is no public health and safety risks identified to be associated with the use of *M. foliorum* in the production of D-psicose 3-epimerase.
- there is no toxicological risk to public health and safety from the intake of D-allulose from food based on the proposed maximum use levels from the application.
- based on the dietary intake assessment, in some instances, there was a risk of a laxative effect at the proposed levels for some food classes. This potential occurred where the intake of D-allulose would be above the threshold for laxation of 0.4 g/kg/bw (28g for a 70 kg adult).

Buderim Foods supports the conclusions EXCEPT the conclusion of the dietary intake assessment.

Dietary intake assessment

Buderim Foods notes the food consumption data used for the dietary intake assessments were:

- 2011-12 Australian National Nutrition and Physical Activity Survey (2011-12 NNPAS), one 24-hour food recall survey of 12,153 Australians aged 2 years and above, with a second 24-hour recall undertaken for 64% of respondents (ABS, 2015).
- 2002 New Zealand National Children's Nutrition Survey (2002 NZ CNS), one 24-hour food recall covering 3,275 New Zealand school children aged 5-14 years, with 25% of respondents also completing a second 24-hour recall (Ministry of Health 2005).
- 2008-09 New Zealand Adult Nutrition Survey (2008 NZ ANS): a 24-hour recall of 4,721 New Zealanders aged 15 years and above, with a second 24-hour recall undertaken for 25% of respondents. (Ministry of Health 2011a; Ministry of Health 2011b).

Buderim Foods notes that FSANZ proposes lower maximum use levels for those foods/food classes than the maximum use levels originally proposed by the applicant (as given in Table 1 of the CFS).

Buderim Foods notes the significant regulatory burden faced by industry when the maximum permitted levels vary from those in other jurisdictions.





For example, in the USA, the Generally Recognized as Safe (GRAS) use limit for beverages for allulose (including juice drinks) is 3.5–5% whereas the maximum level proposed by FSANZ is 1.5%.

The United States Food and Drug Administration (FDA) considers that D-allulose intake of less than 0.5-0.6 g/kg bw/day as safe which closely aligns with FSANZ's assessment of 0.4 g/kg bw/day. However, as A Buderim Foods understands, the difference in the maximum levels may be attributed to the dietary intake assessment methodology.

Risk Management

Proposed Conditions of use

Buderim Foods notes the adjustments to food class names and maximum permitted levels of D-allulose from those requested in the application. With respect to Table 1 in the CFS – it would have been helpful if the category number had been included and not just the description.

Buderim Foods further notes the significantly reduced maximum permitted use levels for some product categories:

- 5.2 Sugar Confectionery
- 11.2 Sugars and Sugar syrups
- 20.2.0.4 Sauces and toppings (including mayonnaises and salad dressings)
- 4.3.4 Fruit and vegetable spreads including jams, chutneys and related products
- 4.3.4.1 Low joule chutneys, low joule jams and low joule spreads

Buderim Foods requests:

- FSANZ considers further interrogation and explanation of the dietary modelling to justify any discrepancy from international permitted levels.
- FSANZ consider harmonisation of domestic levels with those internationally as much as possible.
- FASANZ consider that D-Allulose follow at least harmonization of usage levels and associated labelling to that of other common Sugar Alcohols namely sorbitol.
- FASANZ consider removing Table 1 from the CFS, and follow labelling convention consistent with the current Food Standard Code Schedule 15 for sugar alcohols.
- FASANZ consider removing restriction for use of D-allulose in the sugar confectionery category. This has been supported by GRAS 893 application in the USA (Link below), which states that the use of allulose should be self-regulating in foods. Scientific review of the evidence on the metabolism, caloric value, glycemic response and cariogenic potential of allulose (link below) further supports the removal of restrictions for use of D-allulose based on the fermentability of D-allulose ingested.

Link - GRAS 893 application - <https://www.fda.gov/media/151854/download>

Link - Scientific review of the evidence on the metabolism, caloric value, glycemic response and





cariogenic potential of allulose - <https://downloads.regulations.gov/FDA-2019-D-0725-0012/content.pdf>

Energy Value for D-allulose

Buderim Foods supports the proposed energy value for D-allulose of 2kJ/g.

Buderim Foods supports the exclusion of D-allulose from the amount of carbohydrate and sugars in the NIP.

Under existing Code provisions, if one or more components listed in subsection S11—2(3) (other than organic acids) is present in a food, singly or in combination, in an amount of no less than 5 g/100 g and if carbohydrate content is determined using the *available carbohydrate by difference* calculation then the amount of the component must be listed in the NIP. The amount of D-allulose would therefore need to be listed in the NIP if present in a food at a concentration of 5 g/100 g or more. This information will enable consumers to make informed food choices.

Nutrition content and health claims

Buderim Foods supports the permission for foods containing D-allulose to make nutrition content claims about sugars (as listed above) provided other claim conditions for sugars are met.

Specification

Buderim Foods supports the proposal not to set an individual specification for D-allulose, relying on Food Chemicals Codex and the Merck Index.

Exclusivity

Buderim Foods notes the proposal to grant exclusive use permission on the basis that they have invested significantly in the technology development and safety studies.

Given that D-allulose is already permitted for use in other jurisdictions as set out in the CFS, this is likely to result in barriers to trade for products already on the market outside of Australia and New Zealand. Companies in ANZ who wish to take up the opportunity to incorporate D-allulose in their existing or new products will have only one supply option which will potentially reduce the number of new products available if companies are nervous about continuity of supply from a single company.

Regulatory approval for D-psicose 3-epimerase enzyme

Buderim Foods supports regulatory approval for D-psicose 3-epimerase enzyme.

FSANZ Act assessment requirements

Consideration of costs and benefits

Industry





FSANZ note that Industry would have an extra option for a low-energy substitute for sugar as an ingredient in foods and drinks if this application is approved.

FSANZ has not considered the cost impact on industry resulting from the exclusive permission granted to the applicant – this may limit the opportunity for companies who are unable to secure supply from the applicant due to price or continuity of supply.

This will also limit products manufactured overseas to be marketed in ANZ if the D-allulose ingredient is not supplied by the applicant.

Draft variation to the ANZ Food Standards Code

Buderim Foods request that the proposed amendment to Section S25-2 (table) include a reference to description heading number in Schedule 15, for example:

- (i) bakery products (including bread) (S15 – 7) (limit: 5% (w/w));

This will make it MUCH easier to relate this list to Schedule 15 which contains other permissions.



Submitted to Application A1247 D-allulose as a Novel Food
Submitted on 2023-12-20 16:49:19

[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:
Buderim Foods Pty Ltd

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

Groups to which you belong:
Food business

If other please specify:

Who is the contact person for this submission

Please include name, email address and phone number:

[Redacted]
[Redacted]
[Redacted]

[Redacted]

[Redacted]

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Submission

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If you would prefer to upload your submission please upload your file here

Please provide a PDF copy:
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