



AUSTRALIAN
**FOOD &
GROCERY**
COUNCIL



AFGC SUBMISSION

Application A1247

D-allulose as a novel food

15 December 2023

PREFACE

The Australian Food and Grocery Council (AFGC) is the leading national organisation representing Australia's food, beverage and grocery manufacturing sector.

With an annual turnover in the 2020-21 financial year of \$133 billion, Australia's food and grocery manufacturing sector makes a substantial contribution to the Australian economy and is vital to the nation's future prosperity.

The diverse and sustainable industry is made up of over 16,000 businesses ranging from some of the largest globally significant multinational companies to small and medium enterprises. Each of these businesses contributed to an industry-wide \$3.2 billion capital investment in 2020-21.

Food, beverage, and grocery manufacturing together forms Australia's largest manufacturing sector, representing over 32 per cent of total manufacturing turnover in Australia. The industry makes a large contribution to rural and regional Australia economies, with almost 40 per cent of its 272,000 employees being in rural and regional Australia.

It is essential to the economic and social development of Australia, and particularly rural and regional Australia, that the magnitude, significance, and contribution of this industry is recognised and factored into the Government's economic, industrial and trade policies.

Throughout the COVID19 pandemic, the food and grocery manufacturing sector proved its essential contribution to Australian life. Over this time, while our supply chains were tested, they remain resilient but fragile.

The industry has a clear view, outlined in Sustaining Australia: Food and Grocery Manufacturing 2030, of its role in the post-COVID19 recovery through an expansion of domestic manufacturing, jobs growth, higher exports and enhancing the sovereign capability of the entire sector.

This submission has been prepared by the AFGC and reflects the collective views of the membership.

OVERVIEW

The Australian Food and Grocery Council (AFGC) welcomes this opportunity to comment on Food Standards Australia New Zealand's (FSANZ) *Call for submissions – A1247 – D-allulose as a novel food*.

The AFGC understands that FSANZ has assessed an application made by Samyang Corporation to amend the Australia New Zealand Food Standards Code (**the Code**) to permit D-allulose from enzymatic conversion of fructose by D-psicose 3-epimerase (EC 5.1.3.30) from immobilised *Microbacterium foliorum* and has prepared a draft food regulatory measure. It is proposed that D-allulose be added to foods as a low-energy substitute for conventional sugar ingredients, particularly sucrose.

The AFGC has reviewed FSANZ's assessment and supports **permitting the use of the applicant's D-allulose**.

Following an application made by Samyang Corporation to amend the Code, FSANZ has prepared a draft variation to permit the use of D-allulose as a novel food and D-psicose 3-epimerase as an enzyme processing aid. The AFGC membership includes food manufacturers, importers and suppliers that will be directly impacted by the proposed variations to the Code. The submission was prepared following consultation and feedback from a number of AFGC member companies.

The consultation documents have been reviewed and the comments below relate to these specific documents:

- Call for submissions (**CFS**)
- Supporting document 1 (**SD1**) – Technical and Risk assessment

The AFGC presents this submission in two parts:

1. **General comments** which outline the AFGC's position on low-energy sugar substitutes; and
2. **Specific Comments** relating to aspects of the A1247 assessment.

GENERAL COMMENTS

The AFGC welcomes the opportunity to comment on the *Call for submissions – A1247 D-allulose as a novel food*.

The AFGC supports this application proceeding 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. Consumers are the ultimate beneficiaries with greater product choices meeting their needs and assisting them to better lifestyles, better diets, and better health.

Given the current pressures the Australian and New Zealand marketplaces are experiencing with respect to public health policies, specifically targeted to reducing rates of overweight and obesity, the permission to use a low-energy substitute for sugar provides exciting opportunities for the development of innovative alternatives to conventionally used sweeteners in the domestic food and beverage industry. This recognition and support of innovation within the industry will support ongoing benefits to public health and value-add to the Australian and New Zealand economies.

SUPPORT OF D-ALLULOSE USAGE

The AFGC **supports permitting the use of the applicant's** D-allulose in various food categories including but not limited to bakery products, cereals, chewing gum, yoghurt, jams and non-alcoholic beverages.

SPECIFIC COMMENTS

The AFGC wishes to make the following specific comments in relation to this application. For ease of reference, the paragraph numbers and headings refer to sections in the FSANZ's *Call for Submissions* document.

2.1 Risk assessment

The AFGC understands that the applicant's D-allulose is produced by conversion of fructose by the enzyme D-allulose-3-epimerase (also known as D-psicose-3-epimerase), which is naturally present in a non-genetically modified organism, *Microbacterium foliorum* (SYG27B-MF). This enzyme is not currently permitted to be used as a processing aid in the Code. FSANZ has therefore prepared a draft variation to amend Schedule 18 of the Code to permit the use of this enzyme as a processing aid.

The AFGC notes and supports FSANZ's assessment of the food technology aspects, safety, microbiological, nutritional impact and dietary exposure of D-allulose and the D-psicose 3-epimerase enzyme which concluded that:

"No public health or safety concerns were identified in relation to the use of M. foliorum in the production of D-psicose-3-epimerase."

2.1.5 Dietary exposure assessment

The AFGC notes that:

- A short-term dietary intake assessment undertaken by FSANZ identified a number of food categories from which the intake of around 10% of high consumers exceeded the level of D-allulose that causes a laxative effect based on the maximum use levels provided in the application.
- FSANZ then undertook a further assessment to determine what use levels would result in intakes not exceeding the level that causes a laxative effect based on normal food consumption amounts when consumed as one food containing D-allulose per eating occasion. This resulted in lower concentration levels compared to the maximum use levels proposed in the application for some foods.

The AFGC understands that therefore 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).

The AFGC wishes to highlight the significant regulatory burden faced by industry when the maximum permitted levels vary from those in other jurisdictions. The AFGC **recommends** harmonisation of domestic levels with those internationally as much as possible.

For instance, 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 the AFGC understands, the difference in the maximum levels may be attributed to the dietary intake assessment methodology. The AFGC therefore **recommends** FSANZ considers further interrogation and explanation of the dietary modelling to justify any discrepancy from international permitted levels.

Notwithstanding the assessment by FSANZ, some AFGC members have also raised questions regarding the technological and functional roles of D-allulose at the proposed limits for certain food classes. The AFGC, therefore, recommends FSANZ consider:

- a level of **25%** for **sugar confectionery**. This is considered the main potential use of D-allulose, providing the major benefit of targeting a reduced sugar intake and would align with products currently sold in the US market.
- the originally requested level of **10%** for **bakery products and icings and frostings**.
- the originally requested level of **5%** for **Processed cereal products and processed meal products** as the proposed 3.5% limit in the category is considered insufficient to achieve its technological function (to fully replace sugar).
- the originally requested level of 3.5% for beverages.

2.2 Risk management

The AFGC understands that FSANZ has prepared a draft variation to the Code to permit the use of D-allulose as a novel food and D-psicose 3-epimerase as an enzyme processing aid.

The AFGC wishes to make the following comments in relation to the conditions under which D-allulose and D-psicose 3-epimerase are permitted for use.

2.2.3 Proposed conditions of use

The AFGC notes FSANZ's risk management conclusion that:

“As a result of the dietary exposure assessment, the proposed drafting therefore reflects lower maximum use levels when compared to the original application. The applicant also provided examples of products currently being marketed where actual usage levels align with the lower proposed levels of addition.”

The AFGC further notes FSANZ's approach that:

“Schedule 15 food classes are too numerous to be used for the purposes of novel food permissions listed in Schedule 25 of the Code. Doing so may reduce clarity for compliance and enforcement. The novel food permissions proposed in the draft variation therefore use a revised set of food classes based on Schedule 15 to describe the foods to which D-allulose may be added.”

2.2.4 Energy value for D-allulose

The AFGC understands that FSANZ has provided evidence for the inputs to the equation for calculation of energy value in the Nutrition Assessment in Section 3.6 of SD1, and the calculation for the energy factor in the CFS.

The AFGC notes FSANZ's assessment that:

“Based on the equation, the metabolisable energy (ME) calculation for ingested D-allulose is 1.88 kJ/g. FSANZ therefore proposes an energy value of 2 kJ/g for D-allulose (rounded to a whole number) is included in the table to subsection S11—2(3). Rounding the energy value to a whole number is consistent with the listing of other energy factors in the Code.”

The AFGC **supports** the proposed energy value of 2kJ/g as it aligns closely with that prescribed in the USA of 0.4kcal/g (**equivalent to 1.67kJ/g**).

2.2.5 Labelling of foods containing D-allulose

2.2.5.1 Statement of ingredients

The AFGC **supports** FSANZ's preferred approach to declare D-allulose in the statement of ingredients and exempt the listing of the processing aid used to produce D-allulose.

“The existing requirements in the Code for the declaration of D-allulose in the statement of ingredients would enable consumers to make informed food choices.”

“The generic exemption from listing processing aids in the statement of ingredients would apply to foods containing D-allulose which have been produced using this enzyme (processing aid) (see section 1.3.3 above) as no allergens have been identified.”

2.2.5.2 Declaration of energy and nutrients in the NIP

The AFGC understands that FSANZ proposes D-allulose is excluded from the amount of sugars in the nutrition information panel (**NIP**). The amounts of carbohydrate and sugars in the NIP would therefore both exclude D-allulose. The AFGC notes and **supports** FSANZ's position that:

“Adding D-allulose to subsection S11—2(3) would mean that D-allulose is excluded from the amount of carbohydrate listed in the NIP when carbohydrate content is determined using the calculation of available carbohydrate by difference (see subsection S11—3(2)).

Consistent with how other components listed in S11—2(3) are treated, the AFGC **supports** FSANZ's position that if D-allulose is present 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 D-allulose would require separate declaration 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.”

2.2.5.3 Nutrition content and health claims

The AFGC understands that FSANZ proposes foods containing D-allulose are permitted to make nutrition content claims % free, low sugar(s), reduced/lite and no added sugar(s) which otherwise meet existing claim conditions.

The AFGC notes and **supports** FSANZ’s position that:

“If the draft variation is approved, the effect of this proposed amendment would be that the conditions in the table to section S4—3 for a “no added sugars” nutrition content claim would exclude D-allulose from “sugars” because D-allulose is a hexose monosaccharide and so is captured within paragraph (b) of the definition of “sugars” in section 1.1.2—2 of the Code. The words “which may be present” make clear that the presence of D-allulose is not required to make a “no added sugars” nutrition content claim.”*

2.2.7 Exclusivity

The AFGC **supports** in principle the concept of exclusivity as it recognises the investment made in developing the food or ingredient and the need to achieve a return on this investment, thereby supporting innovation.

However, it has general concerns regarding FSANZ’s approach towards exclusivity and its implications on the food industry. The AFGC has previously raised and continues to seek clarity regarding the application of exclusivity and its implications on the food industry to ensure a level playing field.

2.3 Risk Communication

2.3.2 World Trade Organization (WTO)

The AFGC considers that including permissions for a new low-energy sugar substitute in the Code warrants specific WTO notification of these measures. Overseas manufacturers exporting products to Australia or New Zealand should be notified of these measures and provided an opportunity to comment on them if they consider them to be unnecessary trade barriers.

2.4 FSANZ Act assessment requirements

2.4.1.1 Consideration of costs and benefits

Industry

The AFGC notes and **supports** FSANZ’s view 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.”

The AFGC understands that it is up to the applicant to decide the range of food groups to which D-allulose can be added, based on safety considerations.

However, the AFGC is of the view that D-allulose is valuable for use across a broad range of food and beverage classes. Therefore, permitting the use of the ingredient in a broader range of food groups may

- benefit consumers by providing them with more options of foods and beverages
- provide the industry with greater opportunities to create and market new products, which is also consistent with the [Food Regulation System priorities for 2017-2022](#), namely, to maintain a strong, robust and agile food regulation system that not only gives confidence to consumers that their food is safe, but that can also manage new and innovative industry approaches.

The AFGC notes the scope of foods for which the applicant sought permission for use is based on US food class names. The AFGC considers benefits from and recommends the use of D- allulose as a low-energy substitute could be extended to other relevant food class names under S15 including:

- Confectionery (at the primary level, i.e. including fruit filling for confectionery containing not less than 200 g/kg of fruit; chocolate and cocoa products; sugar confection; bubble and chewing gum; low joule chewing gum; icings and frostings)
- Liquid milk products and flavoured liquid milk
- Brewed soft drinks
- Carbonated, mineralised and soda waters
- Fruit and vegetable juices, and fruit and vegetable juice products
- Other foods including snack and nutrition bars.

This would significantly reduce the industry burden from having to make additional application(s) to FSANZ requesting to extend the use of D-allulose as a low-energy substitute to other food classes, allowing for greater consumer choice.

CONCLUSION

The AFGC commends FSANZ on the comprehensive work performed in relation to the evaluation and assessment of D allulose as a novel food and supports the application proceeding.

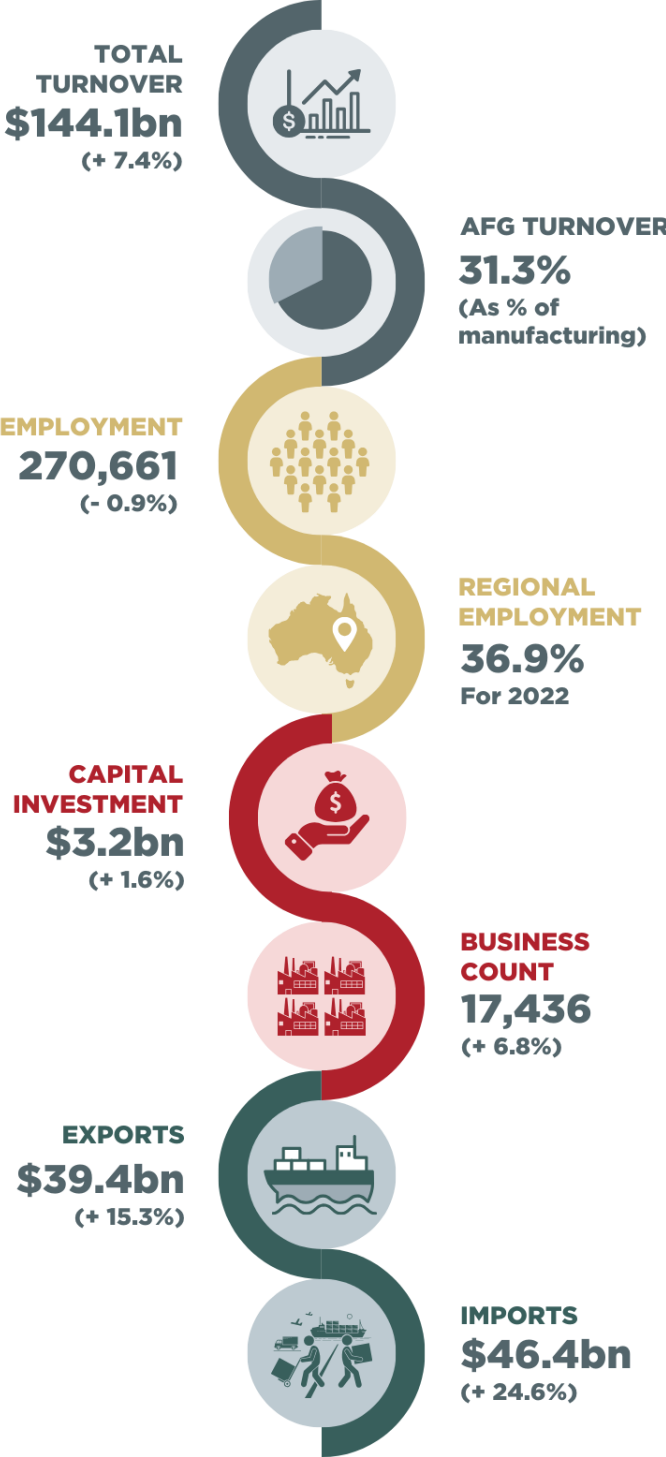
RECOMMENDATION:

The AFGC **supports** permitting the use of D-allulose as a novel food.

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State of Industry 2021-22

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The figures on this page exclude the fresh food sector and are based on 2021-22 ABS data.
 1: This is total number of employees, head count basis and does not include seasonal employees.
 2: Gross fixed capital formation for food, beverage and tobacco manufacturing subsector is taken as indicator of capital investment.