

Application 1247

D-allulose as a novel food – NSW Submission

General Procedure – 1st Call for Submissions

Summary

NSW Food Authority (the Food Authority) appreciates the opportunity to comment on Application 1247 (A1247) – D-allulose as a novel food. The submission does not represent a NSW Government position, which will be a matter for the NSW Government should notification be made by the FSANZ Board to the Food Ministers' Meeting.

While supporting FSANZ assessment that concludes D-allulose has very low acute toxicity, NSW Food Authority considers appropriate measures need to be in place to manage a laxative effect of D-allulose. NSW considers the combination of maximum use levels and a mandatory advisory statement be applied to foods containing D-Allulose to appropriately manage the laxation risk.

A mandatory advisory statement on a laxative effect is particularly important for this application, in that D-Allulose is not well known or understood by Australian and New Zealand consumers. While favourable properties of D-allulose such as low energy content will likely to be advertised by the manufacturer, unfavourable properties such as a laxative effect also need to be provided to consumers to enable informed food choices, and provide advice on appropriate consumption levels.

NSW Food Authority offers further comments below.

Risk management of a laxative effect

FSANZ's assessment has identified a laxative effect of D-allulose, with the lowest dosage associated with gastrointestinal symptoms of 0.4 g/kg bw (400 mg/kg bw; 28 g for a 70 kg adult) as a single dose.

The Food Authority notes the threshold value is based on a review of human tolerance studies on mainly healthy young adults. No studies on children were reviewed in FSANZ's assessment. The Food Authority also notes that FSANZ extrapolated the threshold value to children in the dietary intake assessment of D-allulose based on consumption data for NZ children (5-14 years). Although estimated intakes of added D-allulose tended to be higher for children due to their lower body weight in comparison to adults, it is unknown if the use of the same threshold value is appropriate for children.

Maximum use levels

The Food Authority supports FSANZ's intention to reduce the maximum use levels of D-allulose from the amount originally requested by the applicant to mitigate the risk of laxation. However, the Food Authority requires further information from FSANZ to understand how the proposed maximum levels have been determined.

The results of FSANZ's dietary intake assessment (in Table 7 of SD (page 36)) suggest high consumption of some food categories may still exceed the daily intake limit of D-allulose (0.4 g/kg bw) at the proposed maximum use levels:

- Bakery products

At the maximum limit (5 %w/w) as proposed by FSANZ, they would consume a daily D-allulose intake of:

- 0.465 g/kg bw/day from muffins,
- 1.475 g/kg bw/day from sweet pies and pastries, and
- 0.51 g/kg bw/day from doughnuts.

- Water based flavoured drinks

At the maximum limit (1.5 %w/w) as proposed by FSANZ, consumers would consume a daily D-allulose intake of:

- 0.41 g/kg bw/day from cola-type soft drinks for NZ children
- 0.72 g/kg bw/day from non cola-type carbonated soft drinks for NZ adults
- 0.44 g/kg bw/day from cordial soft drinks for Australians
- 0.86 g/kg bw/day from decaffeinated instant coffee for NZ adults.

The Food Authority also notes the limitation of FSANZ's dietary intake assessment that it '*does not include the possibility of two or more foods being eaten in the same eating occasion or meal*' (SD page 40). As FSANZ discussed it may be unlikely that the same individual consumes high levels of multiple foods containing D-allulose, however, it is possible that the same individual consumes multiple foods containing D-allulose in the same occasion (e.g. dessert + soft drink), that would result in higher intake of D-allulose.

The Food Authority considers setting (reduced) maximum use levels of D-allulose for each food category is important but not sufficient to minimise the risk of a laxative effect. The Food Authority suggests additional measures as discussed below to ensure consumers are aware of the risks incurred if consuming more than the ADI of D-Allulose.

Mandatory advisory statement on a laxative effect of D-allulose

The Food Authority concurs with FSANZ's recommendation that '*control be exercised to limit the consumption of bulk sweeteners, such as D-allulose from all sources to levels below those at which they induce diarrhoea*' (CFS report pages 12-13).

The Policy guideline on the addition of substances other than vitamins and minerals¹ advises '*there needs to be consideration of the cumulative impact of particular substances being added to multiple food products*'.

To discourage excess consumption of foods containing D-allulose from a single or multiple sources, the Food Authority considers it necessary to require an advisory statement on the package to inform consumers of the laxative effect of D-allulose and warn them against excess consumption.

This is consistent with FSANZ Act objectives in Section 18(1) of FSANZ Act:

- (a) the protection of public health and safety; and
- (b) the provision of adequate information relating to food to enable consumers to make informed choices; and
- (c) the prevention of misleading or deceptive conduct.

¹ <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Substances-other-than-Vitamins-and-Minerals>

The advisory statement is particularly important as the risk of the novel food would not be well known among consumers, and other favourable aspects of D-allulose resulting from its low energy factor is likely to be conveyed on the package in the form of the NIP and claims (e.g. sugar/energy claims). The Food Authority considers balanced information should be provided on the package to enable consumers to make informed food choices.

Subsection 1.2.3—2(2) of the Code requires mandatory advisory statements on laxative effects for a food that contains low energy polyols (food additives permitted at GMP) with a threshold of 10 g/100 g or 25 g/100 g.

For maltitol, one of the low energy polyols that the advisory statement is required at a level ≥ 10 g/100 g, previous FSANZ's assessment through Application A537² identified intake levels of maltitol that can cause a laxative effect as 30-50 g/day. Given the identified threshold for laxation of 0.4 g/kg/bw for D-allulose is equivalent to 28 g of D-Allulose consumed by a 70 kg adult, the Food Authority considers the same approach to advisory statements is applied for D-Allulose as was used for maltitol.

FSANZ proposes to permit the use of D-allulose in some categories of foods (e.g. jams and jellies, sugar confectionery) at the level ≥ 10 g/100 g (10 %w/w). For such foods the Food Authority recommends an advisory statement to the effect that 'excess consumption may have a laxative effect' should be required.

The Food Authority also suggests FSANZ consider the accumulative effects of consuming D-allulose and polyols in one setting. Despite limitations in the use of intense sweeteners set out in section 1.3.1—5, combined use of D-allulose and polyols in food is not expressly restricted. Subsection 1.2.3—2(2) requires an advisory statement on a laxative effect for a food that contains a combination of different polyols above certain levels. The Food Authority suggests the same approach for D-allulose as well, requiring the advisory statement for foods containing D-allulose, either alone or in combination with polyols at the level ≥ 10 g/100 g.

Other public health risks

Consumers with diabetes

The Food Authority considers consumers with diabetes are more likely to consume products containing low energy sugar substitutes including D-allulose, however, FSANZ's assessment did not particularly investigate this population group. According to the Australian Institute of Health and Welfare, almost 1.2 million Australian people (about 4.6% of the population) were living with Type 2 diabetes in 2021³. According to Diabetes Australia, there is currently almost 1.5 million Australians (about 5.5% of the population) living with all forms of diabetes and up to 500,000 people living with undiagnosed Type 2 diabetes⁴. Given the significance of diabetes prevalence, the Food Authority encourages FSANZ to monitor consumption pattern of low energy sugar substitutes and potential adverse effects in this population group.

Hereditary fructose intolerance (HFI)

The Food Authority requests commentary from FSANZ about the risk of consumption of D-allulose by population with hereditary fructose intolerance (HFI).

² <https://www.foodstandards.gov.au/food-standards-code/applications/applicationa537reduc2441>

³ https://www.aihw.gov.au/reports/diabetes/diabetes/contents/how-common-is-diabetes/type-2-diabetes#_Toc97889421

⁴ <https://www.diabetesaustralia.com.au/about-diabetes/#:~:text=Facts%20about%20diabetes&text=There%20are%20currently%20almost%201.5,silent%2C%20undiagnosed%20type%20%20diabetes>

FSANZ's assessment identified that D-allulose is mainly absorbed from the small intestine by the same transporters as fructose (SD report page 13). The Food Authority encourages FSANZ to investigate a risk of consumption of D-allulose by the subpopulation with HFI. Currently isomaltulose, tagatose, and sorbitol are mentioned in the FSANZ website that should be avoided by people with disorders in fructose metabolism⁵. The Food Authority suggests updating this advice by reviewing other permitted sugar substitutes and D-allulose.

Potential urinary tract infections (UTIs)

The Food Authority supports FSANZ's proposal to monitor potential health impacts with either *Klebsiella pneumoniae* or incidences of urinary tract infections (UTIs) relating to consumption of D-allulose.

The Food Authority notes people living with diabetes may be more at risk, given UTIs are common in this population group due to a number of factors such as nephropathy, high glucose in the urine and/or changes in the immune system⁶.

Classification of D-allulose in the Code — food (ingredient) or food additive

The Food Authority agrees with the proposed classification of D-allulose as a novel food, as consistent with previous advice from the Advisory Committee on Novel Foods, and prohibition to use D-allulose unless expressly permitted in the Code in accordance with subsections 1.1.1—10(5) and (6).

However, the Food Authority suggests D-allulose has a unique identity being a novel food and low energy sugar and food additive (i.e. a 'triple identity'). D-allulose is captured by the definition of sugars* in the Code as a hexose monosaccharide. D-allulose also performs technological purposes such as intense sweetener and/or bulking agent.

The Food Authority notes D-tagatose also has the same 'triple identity' as D-allulose. D-tagatose is only listed as a novel food in the Code, however, the FSANZ Nutrition Panel Calculator (NPC)⁷ lists D-tagatose as a food additive. The Food Authority suggests FSANZ resolve this misalignment so that users of the Code are in no doubt as to the identity of certain substances.

The Food Authority queries the rationale not to list D-allulose (and D-tagatose) as a food additive in the Code. The purpose of adding D-allulose meets the definition of 'used as a food additive' in the Code. The Code lists all other permitted sugar substitutes such as polyols and intense sweeteners as food additives. If it is FSANZ decision to not list D-Allulose as a food additive, this must be made clear in this application to avoid confusion as to its purpose of addition in foods.

In the EU low energy sugars are regulated as novel food ingredients because '*monosaccharides, disaccharides or oligosaccharides and foods containing these substances used for their sweetening properties*' are explicitly excluded from the definition of a food additive (Article 3 of Regulation (EC) 1333/2008). This explicit clarification as to identity when used in foods removes doubt as to the role of D-Allulose. Without such clarification in the Code, there is concern as to the role, purpose and regulatory identity of sugar substitutes in the Code

⁵ <https://www.foodstandards.gov.au/consumer/generalissues/Isomalt>

⁶ Salari, N., Karami, M.M., Bokaei, S. et al. The prevalence of urinary tract infections in type 2 diabetic patients: a systematic review and meta-analysis. Eur J Med Res 27, 20 (2022). <https://doi.org/10.1186/s40001-022-00644-9>

⁷ <https://www.foodstandards.gov.au/industry/npc/Pages/nutrition-panel-calculator.aspx>

(i.e. are they an ingredient?, are they used as a food additive?). NSW requests that FSANZ clarify the role and purpose of D-Allulose when added to food in the approval report.

From a practical perspective, Schedule 15 of the Code may be more suitable to list maximum permitted levels (MPLs) of D-allulose for individual food categories. This would allow industry to easily compare MPLs of different intense sweeteners, providing an argument to regulate D-Allulose as a food additive.

Listing the maximum use levels of D-allulose in Schedule 15 would also address the ambiguity arising from the following Notes under subsection 1.1.1—10(6):

- *Note 2 There is an overlap between some of these categories. For example, some substances may be used as a food additive or as a nutritive substance. For such substances, there will be different provisions permitting use of the substance for different purposes.*
- *Note 3 In some cases, a provision refers to the total amount of a substance added to a food. In these cases, the total amount applies irrespective of whether the substance was used as a food additive, used as a processing aid or used as a nutritive substance.*

Note 2 suggests the possibility to regulate the same substance under different provisions when used for different purposes. Note 3 does not clarify that maximum permitted use levels set for a novel food would be applicable to the same substance used as a food additive.

If FSANZ decides to regulate D-allulose not as a food additive but as a food (ingredient) by progressing with the proposed listing of maximum use levels of D-allulose in Schedule 25, the Food Authority suggests aligning the listing with other permitted novel foods with conditions (e.g. plant sterols). Existing listings in Schedule 25 refer to relevant Chapter 2 standards for specific compositional requirements when the substance is added. Taking the same approach to D-allulose would maintain consistence in the Code as to compositional requirements for adding a novel food to other food.

The Food Authority also queries if section 1.3.1—5 applies to D-allulose. As this provision only refers to MPLs of intense sweeteners determined in Schedule 15, clarification is required how this provision may apply to D-allulose.

Display in the NIP

The Food Authority notes case-by-case requirements applies to nutrition information for non-traditional sugars and polyols. All substances contribute to the energy content (using respective energy factors), however, conditions vary if a substance needs to be declared as carbohydrate and/or sugars in the NIP (see the table below).

Substance	Display in the NIP			
	Energy	Carbohydrate	Sugars	Individual declaration of the substance
D-allulose	Yes (2 kJ/g)	<ul style="list-style-type: none"> • No if calculated as <i>available carbohydrate by difference</i> • Unclear if calculated as available carbohydrate 	No	Yes
<ul style="list-style-type: none"> • S11 - Low energy Sugars* (monosaccharide) • S25 - Novel food) 				
D-tagatose	Yes (11 kJ/g)	<ul style="list-style-type: none"> • No if calculated as <i>available carbohydrate by difference</i> 	Yes	Yes

<ul style="list-style-type: none"> • S11 - Low energy Sugars* (monosaccharide) • S25 - Novel food 		<ul style="list-style-type: none"> • Unclear if calculated as available carbohydrate 		
Trehalose and isomaltulose <ul style="list-style-type: none"> • Sugars* (disaccharide) • S25 - Novel food 	Yes (17 kJ/g)	Yes	Yes	No
Polyols <ul style="list-style-type: none"> • S11 - Low energy • S15 and S16 - Food additives 	Yes (low energy factors as determined in S11-2(3))	<ul style="list-style-type: none"> • No if calculated as <i>available carbohydrate by difference</i> • Unclear if calculated as available carbohydrate 	No	Yes

The Food Authority notes low energy sugars and polyols are not counted as carbohydrates in the NIP if calculated as *available carbohydrate by difference*. The Food Authority requests clarification from FSANZ as to how low energy sugars and polyols should be calculated as carbohydrate if calculated as *available carbohydrate*. Are they considered as available sugars or starch?

Industry has the ability to choose which method (*available carbohydrate by difference* or *available carbohydrate*) to use to calculate carbohydrate content in the NIP, therefore introducing potential ambiguity in how NIP values are calculated. This seems to present a risk of inconsistency. For example, carbohydrate claim conditions for making comparative claims (i.e. 'reduced or light/lite' and 'increased') in Schedule 4 of the Code involve comparison of carbohydrate content with a reference food. Consumers will not know which method was used to derive the claim.

The Food Authority also notes D-allulose is a monosaccharide but is proposed to be excluded from the listing of sugars in the NIP. Sugars in the NIP would mean *monosaccharides (other than D-allulose) and disaccharides*. Other sugars* permitted as novel foods (i.e. D-tagatose (monosaccharide), trehalose (disaccharide) and isomaltulose (disaccharide)) would continue to be captured as sugars in the NIP.

It may be confusing to impose different requirements for the NIP to different substances with the same function as traditional sugar substitutes. The Food Authority considers there is room for education to assist consumer understanding of the NIP and relevant requirements.

Although low energy sugars and polyols may not be counted as carbohydrate and/or sugars in the NIP, consumers should be informed about the amount of low energy sugars and polyols in the food. The information is particularly important for consumers with disorders in fructose metabolism. It is also important for general consumers to understand the level of intake of substances with a laxative effect. The Food Authority supports the existing requirement in subsection 1.2.8—6(9) to display the amount of low energy sugars and polyols in the NIP if present no less than 5 g/100 g of the food. This provision ensures transparency with the amount of each substance used in the food.

Despite the requirement in section 1.2.8—6, the NIP created using FSANZ NPC does not show special listing of substances listed in S11—2(3). The Food Authority requests FSANZ to address this issue so that the NIP created using NPC will be compliant.

Claims

FSANZ proposes to permit all sugar claims by not counting D-allulose as sugar for the purposes of the NIP and claims, for the rationale that '*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*' (CFS report page 16)

However, other aspects of D-allulose such as cariogenic potential were not assessed in the CFS report. The Food Authority recommends including an assessment on other aspects of D-allulose as sugar (e.g. cariogenic potential, glycemic index) in the approval report in the discussion about sugar claim eligibility.

The Food Authority further requests FSANZ to revise the draft variation at approval to include consequential amendment in Schedule 4 arising from the changes through Proposal P1062 — Defining added sugars for claims.

ENDS

The views expressed in this submission may or may not accord with those of other NSW Government agencies. The NSW Food Authority has a policy which encourages the full range of NSW agency views to be submitted during the standards development stages before final assessment. Other relevant NSW Government agencies are aware of and agree with this policy.

Dated as 13 December 2023

Submitted to Application A1247 D-allulose as a Novel Food
Submitted on 2023-12-13 17:51:43

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Introduction

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

Organisation:
NSW Food Authority

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

Groups to which you belong:
Government

If other please specify:

Who is the contact person for this submission

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