8 November 2023
269-23

Call for submissions – Application A1247

D-allulose as a novel food

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Samyang Corporation to amend the Australia New Zealand Food Standards 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. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at current calls for public comment and how to make a submission.

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published as soon as possible after the end of the submission period.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at information for submitters.

For information on how FSANZ manages personal information when you make a submission, see FSANZ's Privacy Policy.

Submissions should be made using the consultation hub, which FSANZ is trialling for this application. FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices.

There is no need to send a hard copy of your submission if you have submitted it by email. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 20 December 2023

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.
Questions about making a submission or application and proposal processes, including the consultation hub, can be sent to standards.management@foodstandards.gov.au.

Submissions in hard copy may be sent to the following addresses:

Food Standards Australia New Zealand
PO Box 5423
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Supporting document

The following document which informed the assessment of this application is available on the FSANZ website: SD1 Risk and technical assessment report

Executive summary

Samyang Corporation (Samyang) has submitted an application to amend the Australia New Zealand Food Standards Code (the Code) to permit the sale of D-allulose as a novel food. If permitted, D-allulose will be added to foods as a low-energy substitute for sugar. Samyang's D-allulose is manufactured by enzymatic epimerisation of fructose by the D-psicose 3-epimerase enzyme, contained in the organism, *Microbacterium foliorum*. The enzyme, if permitted, will be classed as a processing aid and listed in Schedule 18 of the Code.

D-allulose is of very low acute toxicity. Results of genotoxicity assays were negative, and D-allulose was not associated with carcinogenicity or with adverse reproductive or developmental effects in rats. The lowest single dose of D-allulose associated with gastrointestinal effects was 0.4 g/kg bw (28 g in a 70 kg adult) and to avoid gastrointestinal symptoms, repeated intake should not exceed a total intake of 0.9 g/kg bw/day.

Estimated mean and high chronic dietary intakes of added D-allulose ranged between 150 and 730 mg/kg bw/day based on proposed maximum use levels noted in the application. In the short-term dietary intake assessment, there was the potential for a laxative effect to occur based on normal food consumption patterns of some foods. An assessment was then undertaken to determine what use levels would result in intakes not exceeding the level that causes a laxative effect based on normal food consumption patterns 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. This finding was discussed with Samyang, whereupon they requested that, for these foods, the maximum use levels were reduced from what was requested in the application to mitigate the risk of laxation.

No public health or safety concerns were identified in the microbiological safety assessment of D-allulose and healthy adults. D-allulose intakes for chronic human feeding trials (≥8 weeks duration) were similar to the estimated dietary intakes for single day of consumption. Exclusion criteria for the human feeding studies did not include sub-populations such as diabetics, which may be a potentially sensitive sub-population.

FSANZ determined that the metabolisable energy calculation for ingested D-allulose is 1.88 kJ/g and therefore proposes an energy value of 2 kJ/g for D-allulose if permitted in the Code, rounded to a whole number for consistency with other energy factors in the Code.

FSANZ proposes D-allulose is excluded from the amount of sugars in the NIP and that foods containing D-allulose are permitted to make nutrition content claims about sugars provided other claim conditions are met.

FSANZ's cost benefit considerations assessment concluded that the direct and indirect benefits that would arise from approving this application most likely outweigh the associated costs. However, additional information received from this call for submissions may result in FSANZ arriving at a different conclusion.

FSANZ is satisfied that Samyang is able to produce a final D-allulose ingredient suitable for use in foods as a sugar replacer and consistent with specifications set out in scientific literature. The D-allulose crystalline powder and syrups are stable under typical storage conditions and when contained in a food matrix typical of the proposed end use.

If permitted, the proposed draft variation would confer exclusivity for a period of 15 months, commencing on the date of gazettal.

The enzyme used for the production of D-allulose, D-psicose 3-epimerase, has a five-year history of safe use. FSANZ assessment, based on evidence provided by Samyang, is that there is negligible likelihood of consumer exposure to the production organism, the intact enzyme, or residues from the enzyme in the final D-allulose food ingredient. No significant homology was found with any known toxins or allergens, nor were any microbiological issues identified with the D-psicose 3-epimerase enzyme. Toxicological studies of D-psicose 3-epimerase were therefore not considered necessary. Samyang also provided evidence allowing FSANZ to conclude that the proposed use of D-psicose 3-epimerase as an enzyme used exclusively for the production of D-allulose is justified at a level consistent with Good Manufacturing Practice.

FSANZ seeks submissions on the draft variation.

1 Introduction

1.1 The Applicant

The applicant is Samyang Corporation (Samyang), a food ingredient manufacturer based in South Korea.

1.2 The application

Samyang has submitted an application 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. Samyang's D-allulose is manufactured by enzymatic epimerisation of fructose, however the enzyme used in the manufacture of D-allulose is not currently permitted in the Code. Therefore, this application also requests approval of D-psicose 3-epimerase (also known as D-allulose-3-epimerase) contained in the organism *Microbacterium foliorum* to be used as a processing aid, permitted by Schedule 18 of the Code.

D-allulose does not contribute significant metabolisable energy after consumption when compared to traditional sugars, such as sucrose. To enable the declaration of the energy value of foods containing added D-allulose for labelling purposes, Samyang also requested the establishment of a new energy factor of 1.0 kilojoule per gram (kJ/g) for D-allulose in section S11—2(3) of the Code.

Samyang also requested that D-allulose not be included in the declaration of 'sugars' in the nutrition information panel (NIP) given it would not be included in the declaration of 'carbohydrate' content under Code provisions when the 'available carbohydrate by difference' calculation is used. Additionally, Samyang sought amendment of the Code's requirements for nutrition content claims about sugar(s) for foods containing added D-allulose. According to the Samyang, foods containing added D-allulose as a sugar replacer or substitute will contain less conventional sugars such as sucrose and metabolisable energy than traditionally sweetened counterparts.

Samyang considers that foods containing added D-allulose should be permitted to carry nutrition content claims about sugar(s) listed in the table to section S4—3 (except for *unsweetened* claims), when the content of conventional sugars complies with the conditions listed in column 3 of the table in that section. Recognising there are multiple sections in the Code that relate to the definition of sugar(s) and the conditions for making nutrition content claims about sugar(s), Samyang requested FSANZ investigate the most appropriate amendment to the Code, rather than specifying which section(s) of the Code should be amended.

During the assessment, the brand names for the three Samyang D-allulose products in the application changed as follows:

- Nexweet Crystalline Allulose, previously Crystalline D-allulose (Product 1)
- Nexweet Allulose 95L, previously D-allulose Syrup H (Product 2)
- Nexweet Allulose 10L, previously D-allulose Syrup L (Product 3).

Some levels of addition for particular food classes have also been amended from those included in the application, discussed in section 2.2 below.

Exclusive use of the permission for a period of 15 months from gazettal was requested.

1.3 The current Code requirements

Australia and New Zealand food laws require that food for sale must comply with the Code requirements listed below.

1.3.1 Novel foods

Section 1.1.2—8 describes which foods are novel foods for the purposes of the Code. It defines a 'novel food' as a 'non-traditional food' that requires an assessment of public health and safety considerations having regard to:

(a) the potential for adverse effects in humans; or
(b) the composition or structure of the food; or
(c) the process by which the food has been prepared; or
(d) the source from which it is derived; or
(e) patterns and levels of consumption of the food; or
(f) any other relevant matters.

A 'non-traditional' food is defined in the Code as, among other things, a food that does not have a history of human consumption in Australia or New Zealand.

Paragraphs 1.1.1—10(5)(b) and 1.1.1—10(6)(f) of the Code provide that, unless expressly permitted by the Code, a food offered for retail sale must not be a novel food or have a novel food as an ingredient.

Section 1.5.1—3 provides that a novel food is permitted by the Code if the novel food is listed in the table to section S25—2 and any conditions of use specified in that table are complied with.

The table to section S25—2 (sale of novel foods) lists permitted novel foods together with their conditions for use including use levels, restrictions on use and labelling requirements.

Novel foods must undergo pre-market assessment and approval by FSANZ before they can be listed in the table to section S25—2.

D-allulose is not currently listed in the above table as a permitted novel food.

The Advisory Committee on Novel Foods (ACNF) was asked by industry in 2020 to provide the Committee's view on whether D-allulose was a novel food for Code purposes.[1] The ACNF concluded that, in its view, D-allulose was a novel food and therefore required assessment and approval before D-allulose or a food containing D-allulose could be offered for retail sale in Australia and New Zealand. The ACNF also considered there was a potential for adverse effects in humans at high levels of intake.

[1] Further information on the ACNF's role and function is at https://www.foodstandards.gov.au/industry/novel/Pages/default.aspx

1.3.2 Processing aids

Paragraph 1.1.1—10(6)(c) of the Code provides that food for sale cannot contain, as an ingredient or component, a substance 'used as a processing aid' unless that substance's use as a processing aid is expressly permitted by the Code.

Section 1.1.2—13 provides that a substance 'used as a processing aid' in relation to a food is a substance used during the course of processing that meets all of the following conditions:

- it is used to perform a technological purpose during the course of processing
- it does not perform a technological purpose in the food for sale, and
- it is a substance listed in Schedule 18 or identified in section S16—2 as an additive permitted at Good Manufacturing Practice (GMP).

Standard 1.3.3 and Schedule 18 of the Code list the permitted processing aids.

Enzymes of microbial origin permitted to be used as processing aids are listed in the table to subsection S18—4(5) or in the table to subsection S18—9(3) of Schedule 18, depending on whether a technological purpose has been specified. Enzymes of microbial origin listed in the table to subsection S18—4(5) are permitted for use as a processing aid to perform any technological purpose if the enzyme is derived from the corresponding source specified in the table. The table to subsection S18—9(3) lists those substances, including enzymes derived from particular sources, that are permitted to be used as processing aids for specific technological purposes in relation to:

- if a food is specified—that food; or
- if no food is specified—any food.

Additionally, paragraph 1.3.3—11(c) specifies that the substance may only be used as a processing aid if it is not present in the food at greater than the maximum permitted level for that substance indicated in the table to section S18—9.

Samyang's D-allulose production utilises several substances as processing aids. With one exception, all are currently permitted under the above provisions for use as processing aids. The exception is the main production enzyme, D-psicose 3-epimerase.

1.3.3 Contaminant and natural toxicant requirements

Subsection 1.1.1—10(3) of the Code requires food for sale to comply with all relevant composition requirements in the Code for that food. This includes requirements imposed by Standard 1.4.1 and Schedule 19 of the Code in relation to the maximum levels of contaminants and natural toxicants that may be present in food.

1.3.4 Identity and purity requirements

Section 1.1.1—15 of the Code requires that, when added to food in accordance with this Code, or sold for use in food, a substance that is a novel food or a processing aid must comply with any relevant identity and purity specifications set out in Schedule 3 of the Code.

Schedule 3 sets specifications by listing a relevant specification in that Schedule itself or by applying a specification included in an international publication listed in sections S3—2 and S3—3 of that Schedule.

Schedule 3 does not contain an identity and purity specification for D-allulose, however, Food Chemicals Codex (FCC 2020), within S3—2 Substances with specifications in primary sources, sets specifications for “Allulose”, as does The Merck Index, 15th Edition (O’Neil et al 2013), being a secondary source within S3—3, sets a specification for D-psicose. Either specification is suitable for the D-allulose which is the subject of this application.

1.3.5 Labelling

Subsection 1.1.1—10(8) provides that food for sale must comply with all relevant labelling requirements imposed by the Code for that food.

Standard 1.2.4 requires packaged food products to be labelled with a statement of ingredients unless exempt. Ingredients must be included in the statement of ingredients using either a name by which the ingredient is commonly known, a name that describes the true nature of the ingredient, or a generic name if one is specified in Schedule 10.

Paragraphs 1.2.4—3(2)(d) and (e) exempt processing aids from the requirement to be declared in the statement of ingredients, unless other requirements apply.

Subsection 1.2.3—4(3) requires certain foods and substances (e.g. allergens) to be declared when present as ingredients in a food for sale.

Standard 1.2.7 sets out the requirements and conditions for voluntary nutrition, health and related claims made about food. Section S4—3 lists the conditions for making nutrition content claims about sugars including *low*, *reduced* or *light/lite,* and *no added sugar(s).*

Standard 1.2.8 requires most packaged food products to be labelled with a nutrition information panel (NIP). Subsection S11—2(3) prescribes energy factors for specific food components, including low energy sweeteners, to be used when calculating the amount of energy to declare in a NIP.

Section 1.1.2—2 provides that, when used in Standard 1.2.7, Standard 1.2.8 and Schedule 4, the term ‘sugars’ means monosaccharides and disaccharides - except where that term appears in those Standards with an asterisk (i.e., as ‘sugars*’). In that case, ‘sugars*’ means any of the following products derived from any source:

(i) hexose monosaccharides 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;

but does not include:

(i) malt or malt extracts; or
(ii) sorbitol, mannitol, glycerol, xylitol, polydextrose, isomalt, maltitol, maltitol syrup, erythritol or lactitol.

1.3.6 Identity and purity requirements

Novel foods permitted by section 1.5.1—3 and S25—2 must also meet any relevant identity and purity specifications set out in section S3—2. Section S3—2(1)(a) and the table to section S3-2 includes a list of substances and provisions.

1.4 International Standards

There are no international standards for novel foods or for the use of D-allulose as a food and food ingredient. However, D-allulose is approved for use in a number of other regions, including the United States of America (USA), Japan and Korea, the requirements of each being outlined below.

Similarly, there are no international standards for the calculation of energy factors for food components such as D-allulose, which is not metabolised like other simple carbohydrates. The Codex Alimentarius Guidelines on Nutrition Labelling (CAC/GL 2-1985) includes guidance on calculation of energy for carbohydrates (17 kJ/g), protein (17 kJ/g), fat (37 kJ/g) and alcohol (29 kJ/g), and organic acid (13 kJ/g).

1.4.1 USA

Several sources of D-allulose have a Generally Recognised as Safe (GRAS) status. The United States Food and Drug Administration (FDA) has issued 'no questions' letters for four GRAS notifications related to food uses of D-allulose (GRN 400; GRN 498; GRN 693 and GRN 828). In these GRAS notifications, toxicity-related studies on D-allulose from the literature were presented that support the safety of use of D-allulose. The FDA did not question the acceptability and suitability of these studies to establish the safety of D-allulose for the proposed food uses. The FDA did not have questions on the summary of safety, concluding that D-allulose intake of less than 0.5-0.6 g/kg bw/day is safe. Samyang's D-allulose from *M. foliorum* is the subject of GRN 828 which received FDA's no question letter. *M. foliorum* (SYG27B-MF) harbouring D-allulose-3-epimerase enzyme activity does not require separate approval in the USA.

1.4.2 South Korea

D-allulose is permitted to be marketed in South Korea. *M. foliorum* harbouring D-allulose-3-epimerase enzyme activity has been approved in South Korea. D-allulose is considered to be a zero-energy carbohydrate in South Korea, that is, the energy value to be used for labelling of foods containing D-allulose is zero (0) kcal/g; as set out in the Ministry of Food And Drug Safety's 'Foods Labelling Standards' (MFDS 2016 – p157).

1.4.3 Japan

D-allulose has been marketed in Japan without the need for regulatory approval. D-allulose's energy factor for food labelling purposes in Japan is also 0 kcal/g.

1.5 Reasons for accepting application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act)
- it related to a matter that warranted the variation of a food regulatory measure.

1.6 Procedure for assessment

The application is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Risk assessment

FSANZ has undertaken an assessment of the food technology aspects, safety, microbiological, nutritional impact and dietary exposure of D-allulose and the D-psicose 3-epimerase enzyme. A summary of these assessments is provided below.

2.1.1 Food technology assessment

D-allulose:

FSANZ is satisfied that Samyang is able to produce a final D-allulose ingredient suitable for use in foods as a sugar replacer and consistent with specifications set out in scientific literature. Samyang's manufacturing plant operates in accordance with standard Good Manufacturing Practice (GMP), under International Standards Organisation (ISO) 9001:2000 and Hazard Analysis and Critical Control Point (HACCP) certification.

Stability studies provide assurance that the D-allulose crystalline powder and syrups are stable under typical storage conditions and when contained in a food matrix typical of the proposed end use.

D-psicose 3-epimerase enzyme:

FSANZ concludes that the proposed use of D-psicose 3-epimerase as an enzyme exclusively for the production of D-allulose is justified. The evidence presented to support the proposed use provides adequate assurance that the use of the enzyme, in the form and requested amount (i.e. at a level consistent with GMP) is technologically justified and has been demonstrated to be effective in achieving its stated purpose. There are relevant identity and purity specifications for the enzyme in the Code. The applicant provided evidence that the enzyme meets these specifications.

D-psicose 3-epimerase performs its technological purpose during the production of D-allulose and is not performing a technological purpose in the final food. It is therefore appropriately categorised as a processing aid as defined in the Code. D-psicose 3-epimerase enzyme will not be present in D-allulose when sold as a food, or used as an ingredient in other foods.

2.1.2 Toxicological assessment

D-allulose

Most (80%) of an oral dose of D-allulose is rapidly absorbed from the small intestine, but rapidly excreted in the urine. There is some metabolism of D-allulose by microbiota in the large intestine, but it appears that most D-allulose that reaches the large intestine is excreted unchanged in the faeces.

D-allulose is of very low acute toxicity, with an acute oral LD50 in the rat of approximately 16 g/kg bw. A No Observed Adverse Effect Level (NOAEL) of 5000 mg/kg bw/day, the highest dose tested, was identified in a 90-day rat study. Results of genotoxicity assays were negative, and D-allulose was not associated with carcinogenicity in an 18-month chronic study in rats. D-allulose was not associated with adverse reproductive or developmental effects in rats.

Laxative effects, attributed to the osmotic effect of D-allulose that is not absorbed from the gastrointestinal tract, have been observed in laboratory animals and in humans. The lowest single dose of D-allulose associated with gastrointestinal effects was 0.4 g/kg bw (28 g in a 70 kg adult) and repeated intake should not exceed a total consumption of 0.9 g/kg bw/day, according to a non-randomized controlled trial on gastrointestinal tolerance of D-allulose in healthy and young adults (Han et al 2018b).

D-psicose-3-epimerase

It is concluded that 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. D-psicose 3-epimerase has a five-year history of safe use for the production of D-allulose, and the applicant has provided evidence that there is negligible likelihood of consumer exposure to the production organism, the intact enzyme or residues from the enzyme. No significant homology was found with any known toxins or allergens. Toxicological studies of D-psicose 3-epimerase are not considered to be necessary. An Acceptable Daily Intake (ADI) “not specified” is appropriate for D-allulose.

2.1.3 Microbiological assessment

D-allulose

No public health or safety concerns were identified in the microbiological safety assessment of D-allulose and healthy adults. D-allulose intakes for chronic human feeding trials (≥8 weeks duration) were similar to the estimated dietary intakes for single day of consumption. Intakes for older adults (65 years and above) were less than the 15-64 years group. Exclusion criteria for the human feeding trials highlighted that no microbiological safety data is available for sub-populations such as diabetics. The high percentage of absorption of untransformed D-allulose in the small intestine through the kidneys to urine does flag potential issues with urinary tract infections. Uro-pathogenic bacteria such as *Klebsiella pneumoniae* are able to metabolise D-allulose. The microbiological safety of subpopulations, such as diabetics, exposed to D-allulose has not been established.

D-psicose-3-epimerase

No public health and safety risks were identified to be associated with the use of *M. foliorum* in the production of D-psicose 3-epimerase.

2.1.4 Nutrition assessment

FSANZ considered the available evidence for calculation of the components of the equation for metabolisable energy of D-allulose. It is concluded that:

Gross energy (GE) = 15.7 kJ/g
Urinary energy (UE) = 80% of gross energy
Fecal energy (FE) = 3% of gross energy
Gaseous energy (GaE) = 5% of gross energy
Surface area energy (SE) = 0% of gross energy

No evidence was identified to indicate that D-allulose consumption would affect the absorption of other nutrients.

2.1.5 Dietary exposure assessment

Estimated mean and high chronic dietary intakes of added D-allulose ranged between 150 and 730 mg/kg bw/day across the Australian and New Zealand population groups and scenarios assessed based on proposed maximum use levels noted in the application. Estimated dietary intakes from naturally occurring sources of D-allulose were very low compared to intakes from added sources (≤11 mg/kg bw/day). It is concluded that 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.

In the short-term dietary intake assessment to evaluate potential laxative effects, there were less than 10% of consumers of most food categories that had intakes above the level that causes a laxative effect (0.4 g/kg bw/ day), and some food categories with above 10% of consumers for some population groups, indicating the potential for a laxative effect to occur based on normal food consumption patterns. The foods leading to the potential for laxative effects for all population groups assessed were in the categories of water based flavoured drinks, desserts and sweet bakery products. There was a higher proportion (>10%) of 5-14 year old New Zealand children who had estimated intakes of the added D-allulose above 0.4 g/kg bw/ day, mainly due to their lower body weight. An assessment was then undertaken to determine what use levels would result in intakes not exceeding the level that causes a laxative effect based on normal food consumption patterns 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. Therefore FSANZ proposed lower maximum use levels for those foods/food classes than the maximum use levels originally proposed by the applicant (see Table 1 for details).

D-psicose-3-epimerase

Due to Samyang's specific manufacturing process including the purification steps, the presence of D-psicose-3-epimerase in the final D-allulose products is expected to be negligible. The analytical results of the commercial D-allulose preparations have confirmed that the protein content was below the limit of quantification (LOQ) of 0.625 mg/g (limit of detection (LOD): 0.1 mg-N/g), indicating that residual protein could not be detected in the samples. Therefore, the likelihood of consumer exposure to the D- psicose 3-epimerase enzyme is considered to be negligible through the consumption of D-allulose manufactured using this unique method. Therefore, no dietary exposure to the enzyme would be expected

from the final foods and based on this, FSANZ has not undertaken a dietary exposure assessment for D- psicose-3-epimerase.

2.2 Risk management

2.2.1 Risk management options

The risk management options available to FSANZ after assessment were to either:

- reject the application, or
- prepare a draft variation of the Code.

2.2.2 Preferred Risk management approach

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 conditions under which D-allulose and D- psicose 3-epimerase are permitted for use are described below.

2.2.3 Proposed conditions of use

No scientific evidence was identified in the nutrition risk assessment linking D-allulose consumption to a potential decrease in the bioavailability or intake of essential micronutrients. No risks were identified based on the conclusion of the risk assessments.

The microbiological risk assessment concluded that a 12 week study commissioned by the applicant provided evidence that consumption of D-allulose at an average of 0.20 g/kg/bw day, did not induce significant changes in the microbiome or level of pathogens, including *K. pneumoniae*. This, combined with the potentially low levels of dietary exposure intake to any populations, including sub-populations such as diabetics, FSANZ propose that no risk management measures are required with regards to *K. pneumoniae*.

FSANZ also notes the potential issues with urinary tract infections as identified as a potential issue in the microbiological assessment. Noting that no public health or safety concerns were identified in the microbiological safety assessment of D-allulose for healthy adults, FSANZ does not propose any specific risk management. FSANZ also consider that the MPL's proposed for each food class are adequate to manage the risk to vulnerable subpopulations. However, FSANZ will monitor any developments regarding potential issues with either *K. pneumoniae* or incidences of urinary tract infections stemming from the consumption of D-allulose through our routine horizon scanning programme, which monitors international developments.

A dietary intake assessment was carried out using the maximum use levels % (w/w) requested in the application for the various food classes. 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 (28 g for a 70 kg adult), as shown in the Han et al 2018b study, based on normal food consumption patterns. A report of the Scientific Committee for Food concerning sweeteners (SCF 1985) noted that some bulk sweeteners (substances with a sweetness "value" similar to sucrose) cause laxation and flatulence. The general nature of the laxative effect, sometimes known clinically as "osmotic diarrhoea", indicates that the condition results from osmosis across the intestinal wall owing to the presence in the lumen of unabsorbed bulk sweetener and its metabolites. The amounts of the various sweeteners required to cause laxation depends upon the sweetener, whether the dose is spread over a number of meals or consumed all at once, whether the person or animal receiving the dose is fasting or not, and on individual differences in susceptibility to the laxative effect of these sweeteners. FSANZ recommends

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.

The risk of laxation arising from consumption of D-allulose in excess of the threshold for laxation was discussed with the applicant, whereupon they requested that, for these food classes, the maximum use levels for those food classes were reduced to mitigate this risk. As a result of the dietary exposure assessment at section 2.1.5 above, 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.

Dietary intake of D-allulose was calculated using food groups listed in the application. These food groups are loosely based on the food classes listed in Schedule 15 of the Code. However, FSANZ considers that the 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 prepared by FSANZ therefore use a revised set of food classes based on Schedule 15 to describe the foods to which D-allulose may be added. It is envisaged that this approach will provide clarity to the extent that the food classes used are similar to recognised food classes currently listed in Schedule 15 of the Code. The revised food class names do not impact on the accuracy of the dietary exposure assessment. The revised food class names and maximum usage levels, up to which D-allulose can be added, are shown in Table 1.

Table 1 Adjustments to food class names and maximum permitted levels of D-allulose from those requested in the application

Food classes as requested in application	**Revised food class names (based on S15)**	**Proposed maximum levels (%w/w) with original requested levels in brackets where applicable**
Beverages (water based, non-alcoholic); low- and reduced energy, low- and reduced sugar (including sweetened teas, instant coffees but not including cereal/nut/legume-based milk analogues)	Water based flavoured drinks	1.5 (3.5)
Gelatins, pudding and fillings; low- and reduced energy, low- and reduced sugar	Fruit filing for confectionery containing not less than 200g/kg of fruit	3 (10)
Breakfast cereals and cereal based bars; ***regular*** Breakfast cereals and cereal bars; reduced energy; ***reduced sugar***	Processed cereal products and processed meal products	3.5 (5)
Frozen dairy desserts (ice cream, soft serve, sorbet); low- and reduced- energy and low- and reduced sugar	Ice cream and edible ices	4 (5)
Yogurt and frozen yogurt; low- and reduced energy; low- and reduced sugar	Fermented milk products and rennetted milk products	4 (5)

Food classes as requested in application	Revised food class names (based on S15)	Proposed maximum levels (%w/w) with original requested levels in brackets where applicable
Bakery products (bread rolls, cakes, cake-type rolls, pastries, doughnuts, biscuits (including cookies, shortbread, butter milk and whole wheat biscuits, crackers)); reduced energy	Bakery products (including bread)	5 (10)
Fat-based cream (used in modified fat/energy cookies, cakes, pastries, and pie)	Dairy based dessert products and fat based dessert products. Dips and snacks	5
Icings and frostings	Icings and Frostings	5
Jams and jellies	Fruit spreads (including related products such as fruit jams or chutneys) Vegetable spreads(including related products such as vegetable jams or chutneys) Jelly products	10
Dressings for salads Sweet sauces and syrups; low- and reduced- energy, low- and reduced sugar	Sauces and toppings (including mayonnaises and salad dressings)	10
Hard candies/confectionery; low- and reduced energy Soft candies/confectionery; low- and reduced energy (not including chocolate)	Sugar confectionery	10 (50)
Chewing gum	Bubble gum and chewing gum	30 (50)
Sugar substitutes	Tabletop sweeteners	100

2.2.4 Energy value for D-allulose

Standard 1.2.8 defines ‘energy factor’ based on metabolisable energy and lists factors, expressed as kJ/g, for a large number of energy yielding components in Schedule 11. Energy factors are used in the calculation of a food’s energy content, and components that are recognised as contributing significantly to the energy content of a food (e.g. macronutrients) are assigned values for this purpose. Other food components can contribute to energy intake in a more moderate way and may be assigned an energy factor where there is sufficient supporting evidence.

As D-allulose is proposed for use as a sugar substitute, and is not an unavailable carbohydrate, the default energy factor would be 17 kJ/g. However the applicant has submitted data that enables derivation and listing of a more accurately estimated energy factor.

Section 3.2.5.B.2 of the FSANZ Application Handbook sets out the equation that must be used in establishing or varying the energy factor for a food. This equation (set out below) has been used as the basis for FSANZ's calculation of the energy value of D-allulose.

ME = GE – FE – UE – GaE – SE where:

ME means metabolisable energy
GE means gross energy (as measured by bomb calorimetry)
FE means energy lost in faeces
UE means energy lost in urine
GaE means energy lost in gases produced by fermentation in the large intestine
SE means energy content of waste products lost from surface areas.

Evidence for the inputs to the equation is set out in the Nutrition Assessment in Section 3.6 of SD1, and the calculation for the energy factor is provided below.

The Gross energy (GE) for D-allulose, based on bomb calorimetry of fructose, is 15.7 kJ/g.
The faecal energy (FE) for ingested D-allulose is 0.47 kJ/g.
The urinary energy (UE) for ingested D-allulose is 12.56 kJ/g.
The gaseous energy (GaE) for ingested D-allulose is 0.79 kJ/g.
The surface area energy (SE) for ingested D-allulose is 0 kJ/g.

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.

2.2.5 Labelling of foods containing D-allulose

The addition of D-allulose to food will be subject to existing generic labelling requirements in the Code which will provide information to enable consumers to make informed choices.

2.2.5.1 Statement of ingredients

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 (see section 1.3.3 above).

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

As noted in section 1.3.3, Standard 1.2.8 generally requires most packaged food products to be labelled with a nutrition information panel (NIP).

Energy must be declared in the NIP and subsection S11—2(3) of Schedule 11 includes energy factors for specific approved food components including low energy substitutes for

sugar ingredients. As it is proposed to include an energy factor of 2 kJ/g for D-allulose in subsection S11—2(3) of Schedule 11 (section 2.2.4), this energy factor would need to be applied in the calculation of the average energy content of a food containing D-allulose (section S11—2).

As discussed by the applicant, 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)).

Based on the definition of sugars in the Code (section 1.1.2—2), should D-allulose be permitted for use, the sugars amount listed in the NIP would include D-allulose. As most D-allulose is absorbed intact from the small intestine and therefore not metabolised (section 2.1.2 and SD1) which is different to conventional mono- and disaccharides which affect blood glucose and insulin levels, FSANZ proposes D-allulose is excluded from the amount of sugars in the NIP. The amounts of carbohydrate and sugars in the NIP would therefore both exclude D-allulose.

The proposed approach differs to requirements for the Nutrition Facts Label (NFL) in the USA as D-allulose has to be included in the total carbohydrate amount. This is because the regulations generally require that total carbohydrate include such components as sugar alcohols and dietary fibre. In contrast, the amount of carbohydrate in the NIP specifically excludes such components. The FDA has stated that a discretionary approach will be taken in relation to the exclusion of D-allulose from the declaration of total sugars in the NFL.

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

In response to the applicant's request, FSANZ has considered whether it is appropriate to permit the nutrition content claims *% free*, *low sugar(s), reduced/lite* and *no added sugar(s)* on foods that contain D-allulose and otherwise meet existing claim conditions. For example, a food displaying a *low sugar* claim must have a sugars concentration of no more than 2.5 g/100 mL for liquid food or 5 g/100 g for solid food.

As discussed previously, 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. For these reasons FSANZ proposes foods containing D-allulose are permitted to make nutrition content claims about sugars (as listed above) provided other claim conditions for sugars are met.

FSANZ notes there are two general level health claims about dental health in section S4—5 of the Code. As it is proposed to permit the use of D-allulose in chewing gum and confectionery, these claims may be of interest. However, such foods containing D-allulose up to the permitted maximum levels would need to meet the claim conditions.

2.2.6 Specification

Section 1.1.1—15 requires that a substance *used as a novel food* must comply with any relevant specification set out in Schedule 3. As explained in section 1.3 above, there are no specifications for D-allulose in Schedule 3, however it is covered by relevant international specifications in the primary and secondary sources listed in sections S3—2 and S3—2 of that Schedule. These sources are the Food Chemicals Codex (FCC 2020) and the Merck Index, 15th Edition, (O'Neil et al 2013), which set specifications for Allulose and D-psicose respectively.

The three forms of Samyang's D-allulose, the Nexweet Crystalline Allulose, Nexweet Allulose 95L and Nexweet Allulose 10L only differ in composition relative to the amount moisture contained within them. As such, FSANZ consider that as the active ingredient within each of Samyang's three products, the D-allulose itself, is covered by are Food Chemicals Codex and the Merck Index, an individual specification for each of the three forms of the applicant's D-allulose products would not be required in Schedule 3.

2.2.7 Exclusivity

An applicant may request an exclusive use permission to use and sell a novel food for a certain period of time to recognise the investment made in developing that novel food and the need to achieve return on this investment, thereby supporting innovation.

The applicant has requested an exclusive use permission for Samyang's D-allulose for a period of 15 months on the basis that they have invested significantly in the technology development and safety studies.

FSANZ is proposing to permit D-allulose use as a novel food subject to the condition that 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, if approved. Once this period ends, this exclusive use permission will revert to a general permission, meaning that the D-allulose novel food permission will apply to and permit any and all brands of D-allulose that comply with the Code.

An exclusive use permission does not, and cannot, prevent approval of second or subsequent applications under the Code, either within the exclusive use period or during the progression of an application, for the use of the same food or ingredient by other food companies, providing the application process is undertaken.

2.2.8 D-psicose 3-epimerase enzyme

FSANZ has prepared a draft variation to the Code permitting the use of D-psicose 3-epimerase enzyme contained in the organism *M. foliorum* to be used as a processing aid, permitted by Schedule 18 of the Code, only to manufacture D-allulose. If approved, this permission would be subject to the condition that the maximum permitted level or amount of enzyme used in the food must be consistent with GMP.

The conclusions from the risk and technical assessment were that the proposed use of the enzyme is technologically justified and there were no safety concerns associated with its proposed use.

Other risk management considerations for this application are related to the enzyme and source microorganism nomenclature, specifications and labelling. These are discussed in section 1.3.3 above.

2.2.8.1 Regulatory approval for enzymes

As stated above, FSANZ has prepared a draft variation to permit the use of the enzyme as a processing aid for its stated purpose. The express permission for the enzyme to be used as a processing aid will also provide the permission for its potential presence in the food for sale.

2.2.8.2 Enzyme and source microorganism nomenclature

The International Union of Biochemistry and Molecular Biology (IUBMB) uses the accepted name 'D-psicose 3-epimerase and is the name used in the proposed draft variation. The organism *M. foliorum* is not currently listed within Schedule 18 of the Code.

2.2.9 Risk management conclusion

Having considered all aspects of the assessment against the statutory requirements, including relevant Ministerial Policy Guidelines, FSANZ has prepared a draft variation to the Code to permit Samyang's D-allulose as a novel food and the use of D-psicose 3-epimerase enzyme as a processing aid in the manufacture of D-allulose.

In preparing the proposed draft variation, FSANZ had regard to, among other things, safety data for acute and long term D-allulose intake, consideration of the food technology aspects, microbiological, nutritional impact and dietary exposure of D-allulose and the D-psicose 3-epimerase enzyme used to produce it.

If the draft variation is approved, the addition of D-allulose would be subject to relevant requirements and conditions in the Code, which include entries for:

- a novel food permission and conditions of use of D-allulose listed in Schedule 25 of the Code;
- an energy value of 2 kJ/g for D-allulose included in the table to subsection S11—2(3);
- an exclusive use period of 15 months for Samyang's Nexweet brand of D-allulose, commencing on the date of gazettal;
- a permission in Schedule 18 for the use of the D-psicose 3-epimerase enzyme as a processing aid in the production of D-allulose;
- excluding D-allulose from the amount of sugars in the NIP;
- permitting foods containing D-allulose to make nutrition content claims about sugars provided other claim conditions are met.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a standard communication strategy to this application.

All calls for submissions are notified via the FSANZ Notification Circular, media release, through FSANZ's social media channels and Food Standards News.

The applicant and individuals and organisations that make submissions will be notified at each stage of the assessment.

The process by which FSANZ considers standards development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views

of interested parties on the draft variation.

2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

Amending the Code to permit the voluntary addition of the applicant's D-allulose as proposed, is unlikely to have a significant effect on international trade as the use of D-allulose is voluntary and permissions to use D-allulose vary across different countries. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

When assessing this application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

2.4.1 Section 29

2.4.1.1 Consideration of costs and benefits

The Office of Best Practice Regulation (OBPR), now called the Office of Impact Analysis (OIA), exempted FSANZ from the need to undertake a formal Regulation Impact Statement (RIS) in relation to the regulatory change proposed in response to this application (OBPR correspondence dated 6 May 2022, OBPR Reference: OBPR22-02203). That is because the OBPR considered the application is unlikely to have a more than minor regulatory impact.

FSANZ, however, has given consideration to the potential costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29 (2)).

The purpose of this consideration is to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo. This analysis considers permitting the sale of D-allulose as a novel food. FSANZ is of the view that no other realistic food regulatory measures exist, however information received may result in FSANZ arriving at a different outcome.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures. In fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo by permitting the sale of D-allulose as a novel food.

Costs and Benefits to:

Industry
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. Industry would also have the option to use the 'D-psicose 3-epimerase' enzyme to make the D-allulose in the longer-term and after the

exclusivity period granted to the applicant finishes. Different businesses may take-up one or both these options if a net benefit existed for them. Given the range of low-energy substitute for sugars as food and drink ingredients already in the market, permitting this voluntary D-allulose is not expected to significantly impact market dynamics.

Should this application be approved, the price of D-allulose may be significantly higher than the price of standard sugar after being first permitted in Australian and New Zealand-made or imported products. Therefore if permitted, certain businesses may initially benefit from use of D-allulose in niche products. If commercially successful, use of D-allulose may gradually expand across the product range, particularly if the price of D-allulose reduces over time.

D-allulose products are already permitted for sale in the United States (US), Japan, and South Korea. The European Union is also considering whether to permit use of D-allulose products. Hence, permitting use of D-allulose in Australia and New Zealand may facilitate international trade. This may include greater competition from imported products also containing D-allulose.

Consumers
Permitting D-allulose may increase the choice and numbers of products available to consumers, particularly to consumers who seek lower-calorie alternatives to sugars ingredients.

FSANZ is currently unaware of any health or safety concerns to consumers, associated with permitting the use of D-allulose proposed in this application and will continue to monitor the evidence base.

Government
Approving this application may result in a small cost to government in terms of an addition to the current range of ingredients and enzymes that are monitored for compliance if the use of D-allulose increases the choice and numbers of lower-energy products, eventually lead to small, unquantified benefits to public health such as a reduction in obesity rates.

Conclusions from cost benefit considerations
FSANZ's assessment is that the direct and indirect benefits that would arise from approving this application most likely outweigh the associated costs. However, additional information received from this Call for Submissions may result in FSANZ arriving at a different conclusion.

2.4.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the application.

2.4.1.3 Any relevant New Zealand standards

The proposed regulatory measures apply in both Australia and New Zealand. There are no other relevant New Zealand Standards.

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2 Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.4.2.1 Protection of public health and safety

FSANZ has completed food technology, nutrition, microbiological, toxicology and dietary exposure assessments, which are summarised in sections 2.2.1 to 2.2.5 above. FSANZ's conclusion, based on the best available scientific evidence, was that use of D-allulose as a novel food in the manner proposed would pose low risk, particularly given the low levels of dietary exposure. FSANZ did not identify any public health and safety concerns risks in relation to the D-psicose 3-epimerase enzyme.

2.4.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

The application of existing generic labelling requirements will provide information to enable consumers to make informed choices about the presence of D-allulose in a food. The proposed specific energy factor for D-allulose in the Code will provide consumers with information about the energy content of a food containing D-allulose. Additionally, excluding D-allulose from the determination of carbohydrate and sugars amounts in the NIP, and permitting certain nutrition content claims about sugars on foods with D-allulose will assist consumers to make informed food choices.

2.4.2.3 The prevention of misleading or deceptive conduct

There are no issues identified with this application relevant to this objective.

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ has used the best available scientific evidence to conduct the risk analysis, which is summarised in SD1. The applicant submitted a dossier of scientific studies as part of the application. FSANZ had regard to this dossier, together with other technical information including scientific literature, in assessing the application.

- **the promotion of consistency between domestic and international food standards**

FSANZ considered the promotion of consistency between domestic and international food standards and the desirability of an efficient and internationally competitive food industry. D-allulose is permitted in several overseas jurisdictions. The proposed permission would promote consistency between domestic and some international food standards.

- **the desirability of an efficient and internationally competitive food industry**

The proposed permission would support an internationally competitive food industry.

- **the promotion of fair trading in food**

No issues were identified for this application relevant to this objective.

- **any written policy guidelines formulated by the Forum on Food Regulation**

FSANZ has had regard to both high order and specific policy principles in relevant Ministerial Policy Guidelines. One Ministerial Policy Guideline specifically applied to this application:

- Regulation of Novel Foods

Noting the assessment in SD1 and the assessment above of FSANZ Act requirements, FSANZ considers this Policy Guideline would be met by the proposed permission, if approved.

3 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

4 References

FCC (2020). Allulose. In: Food Chemicals Codex, Twelfth Edition. Rockville (MD): United States Pharmacopeial Convention, pp. 1773 (accessed 7 December 2022)

Han Y, Choi BR, Kim SY, Kim S-B, Kim YH, Kwon E-Y and Choi M-S (2018b) Gastrointestinal tolerance of d-allulose in healthy and young adults. A non-randomized controlled trial. Nutrients 10: 2010

Merck Index: An Encyclopedia of Chemicals, Drugs, and Biological, 15th Edition, O'Neil et al (2013).

SCF (1985) Report of the Scientific Committee for Food concerning sweeteners (opinion expressed 14 September 1984). Accessed 27 April 2023.

Attachments

A. Draft variations to the Australia New Zealand Food Standards Code
B. Draft Explanatory Statement

Attachment A – Draft variation to the Australia New Zealand Food Standards Code

Food Standards (Application A1247 – D-allulose as a novel food) Variation

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[Insert Delegate's name and position title]
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1247 – D-allulose as a novel food) Variation*.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

Standard 1.1.2—Definitions used throughout the Code

[1] Subsection 1.1.2—2(3) (paragraph (a) of the definition of "*sugars*")

Repeal the paragraph, substitute:

(a) in Standard 1.2.7, Standard 1.2.8 and Schedule 4 (except where it appears with an asterisk as 'sugars*')—means monosaccharides (other than D-allulose) and disaccharides; and

Standard 1.2.7—Nutrition, health and related claims

[2] Section 1.2.7—2 (Note 1, definition of "*sugars*")

Repeal the definition, substitute:

sugars, in Standard 1.2.7, Standard 1.2.8 and Schedule 4 (except where it appears with an asterisk as 'sugars*')—means monosaccharides (other than D-allulose) and disaccharides. (Elsewhere in the Code it has a different definition).

Standard 1.2.8—Nutrition information requirements

[3] Section 1.2.8—4 (Note 1, definition of "*sugars*")

Repeal the definition, substitute:

sugars, in Standard 1.2.7, Standard 1.2.8 and Schedule 4 (except where it appears with an asterisk as 'sugars*')—means monosaccharides (other than D-allulose) and disaccharides. (Elsewhere in the Code it has a different definition).

Standard 2.6.2—Non-alcoholic beverages and brewed soft drinks

[4] Section 2.6.2—2 (Note 1, paragraph (a) of the definition of "*sugars*")

Repeal the paragraph, substitute:

(a) in Standard 1.2.7, Standard 1.2.8 and Schedule 4 (except where it appears with an asterisk as 'sugars*')—means monosaccharides (other than D-allulose) and disaccharides; and

Schedule 2—Units of measurement

[5] Section S2—2 (table, after item dealing with 'w/v')

Insert:

w/w	weight per weight

Schedule 4—Nutrition, health and related claims

[6] Section S4—2 (Note, paragraph (a) of the definition of "*sugars*")

Repeal the paragraph, substitute:

(a) in Standard 1.2.7, Standard 1.2.8 and Schedule 4 (except where it appears with an asterisk as 'sugars*')—means monosaccharides (other than D-allulose) and disaccharides; and

[7] Section S4—3 (table item dealing with nutrition content claims in relation to 'sugars or sugars')

Omit "contains no added sugars*", substitute **"**contains no added sugars* with the exception of D-allulose which may be present, and no".

Schedule 11—Calculation of values for nutrition information panel

[8] Subsection S11—2(3) (table, above item dealing with 'erythritol')

Insert:

D-allulose	2

Schedule 18—Processing aids

[9] Subsection S18—9(3) (table)

Insert:

D-psicose 3-epimerase (EC 5.1.3.30) from immobilised *Microbacterium foliorum*	**For use in the manufacture of D-allulose**	**GMP**

Schedule 25— Permitted novel foods

[10] Section S25—2 (table)

Insert:

D-allulose	1. May only be added to a food listed in condition 3. 2. Must not be present in a food listed in condition 3 in an amount or at a level greater than the limit specified in condition 3 for that food. 3. The permitted foods are: (a) water based flavoured drinks (limit: 1.5% (w/w)); (b) fruit filling for confectionery containing not less than 200g/kg of fruit (limit: 3% (w/w)); (c) processed cereal products (limit: 3.5% (w/w)); (d) processed meal products (limit: 3.5% (w/w)); (e) ice cream (limit: 4% (w/w)); (f) edible ices (limit: 4% (w/w)); (g) fermented milk products (limit: 4% (w/w)); (h) rennetted milk products (limit: 4% (w/w)); (i) bakery products (including bread) (limit: 5% (w/w)); (j) dairy based dessert products (limit: 5% (w/w)); (k) fat based dessert products (limit: 5% (w/w)); (l) dips (limit: 5% (w/w)); (m) snacks (limit: 5% (w/w)); (n) icings (limit: 5% (w/w)); (o) frostings (limit: 5% (w/w)); (p) fruit spreads (including related products such as fruit jams or chutneys) (limit: 10% (w/w)); (q) vegetable spreads (including related products such as vegetable jams or chutneys) (limit: 10% (w/w)); (r) jelly products (limit: 10% (w/w)); (s) sauces and toppings (including mayonnaises and salad dressings) (limit: 10% (w/w)); (t) sugar confectionery (limit: 10% (w/w)); (u) bubble gum and chewing gum (limit: 30% (w/w)); (v) tabletop sweeteners (limit: 100% (w/w)). 4. During the exclusive use period, only D-allulose sold under the brand Nexweet may be added to food in accordance with conditions 1, 2 and 3 above. 5. For the purposes of condition 4 above, **exclusive use period** means the period commencing on the date of gazettal of the *Food Standards (Application A1247 – D-allulose as a novel food) Variation* and ending 15 months after that date.

Attachment B - Draft Explanatory Statement

DRAFT EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1247 – D-allulose as a novel food) Variation

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

The Authority accepted Application A1247 which seeks to permit food offered for retail sale to consist of, or have as an ingredient, D-allulose, as a novel food. D-allulose will be permitted in a range of foods based on the food classes listed in Schedule 15 of the Code to provide clarity for compliance and enforcement to the extent that the food classes used are similar to recognised food classes currently listed in Schedule 15 of the Code.

The risks of D-allulose altering the human gut microbiome or D-allulose selectively favouring the growth of *Klebsiella* spp., such as *K*. *pneumoniae*, were also assessed. Noting that there is insufficient information to determine any risk surrounding *K. pneumoniae*, combined with the low levels of dietary exposure intake, no risk management measures are required. However FSANZ will monitor any developments in this area through our routine horizon scanning programme.

Schedule 2 of the Code will be amended by inserting ‘w/v’ (weight per volume) into the table to section S2—2 to clarify the levels up to which D-allulose is permitted to be added by Schedule 25. Schedule 2 requires amendment because it does not currently contain a meaning for that symbol.

Based on the metabolisable energy calculation for ingested D-allulose of 1.88 kJ/g, calculated by FSANZ, it is therefore proposed 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 definition of “sugars in Standard 1.2.7, Standard 1.2.8 and Schedule 4 (except where it appears with an asterisk as ‘sugars*’)—means monosaccharides (other than D-allulose) and disaccharides. (Elsewhere in the Code it has a different definition).” D-allulose will be excluded from the definition of “sugars” for the purposes of Standard 1.2.7, Standard 1.2.8 and Schedule 4.

The table to section Schedule 18—9(3) of the Code will be amended by inserting, in alphabetical order “D-psicose 3-epimerase (EC 5.1.3.30) from immobilised *Microbacterium foliorum*” as an enzyme permitted to be used as a processing aid for use in the manufacture of D-allulose. The enzyme will be permitted at a level consistent with GMP.

The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation - the *Food Standards (Application A1247 – D-allulose as a novel food) Variation*.

2. Variation will be a legislative instrument

If approved, the draft variation would be a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and be publicly available on the Federal Register of Legislation (www.legislation.gov.au).

If approved, this instrument would not be subject to the disallowance or sunsetting provisions of the *Legislation Act 2003.* Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunsetting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the Food Ministers Meeting (FMM). The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has prepared a draft variation that amends Standards 1.1.2, 1.2.7, 1.2.8, 2.6.2 and Schedules 2, 4, 11, 18 and 25 to permit food offered for retail sale to consist of, or have as an ingredient, this 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.

4. Documents incorporated by reference

The approved draft variation does not incorporate any documents by reference.

However, existing provisions of the Code incorporate documents by reference that will prescribe identity and purity specifications for the D-allulose and D-psicose 3-epimerase to be permitted by the approved draft variation. Section 1.1.1—15 of the Code requires substances used as novel foods and processing aids to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code.

For D-allulose, section S3—2 of Schedule 3 incorporates by reference the specifications listed in the Food Chemicals Codex (FCC 2020) for Allulose.

For the D-psicose 3-epimerase enzyme, section S3—2 of Schedule 3 incorporates by reference the specifications listed in:

- the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications (FAO JECFA Monographs 23 (2019)); and
- the United States Pharmacopeial Convention (2020) Food Chemicals Codex (12th edition).

These include general specifications for the identity and purity of enzyme preparations used in food processing.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of application A1247 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) will be open for a 6-week period.

The Office of Best Practice Regulation (OBPR), now called the Office of Impact Analysis (OIA), exempted FSANZ from the need to undertake a formal Regulation Impact Statement (RIS) in relation to the regulatory change proposed in response to application A1247 (OBPR correspondence dated 6 May 2022, OBPR Reference: OBPR22-02203). That is because the OBPR considered the proposed change is unlikely to have a more than minor regulatory impact.

6. Statement of compatibility with human rights

If approved, this instrument would be exempt from the requirements for a statement of compatibility with human rights as it would be a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

Clause 1 provides that the name of the variation is the *Food Standards (Application A1247 – D-allulose as a novel food) Variation.*

Clause 2 provides that the Code is amended by the Schedule to the variation.

Clause 3 provides that the variation will commence on the date of gazettal of the instrument.

Item [1]

Item [1] of the Schedule to the draft variation would amend paragraph (a) of the definition of "sugars" in subsection 1.1.2—2(3) of the Code by repealing the paragraph and substituting it with the following new paragraph (a):

"(a) in Standard 1.2.7, Standard 1.2.8 and Schedule 4 (except where it appears with an asterisk as 'sugars*')—means monosaccharides (other than D allulose) and disaccharides; and"

If the draft variation is approved, the effect of this amendment would be to expressly exclude D-allulose from the definition of "sugars" for the purposes of Standard 1.2.7, Standard 1.2.8 and Schedule 4.

Items [2] – [4], and [6] of the Schedule to the draft variation would amend the Code as a consequence of the proposed amendment in item [1].

Item [2]

Item [2] of the Schedule to the draft variation would amend the definition of "sugars" in Note 1 of section 1.2.7—2 by repealing the definition and substituting it with the following new definition:

"***sugars***, in Standard 1.2.7, Standard 1.2.8 and Schedule 4 (except where it appears with an asterisk as 'sugars*')—means monosaccharides (other than D-allulose) and disaccharides. (Elsewhere in the Code it has a different definition)."

This amendment reflects the proposed amendment in item [1] above.

Item [3]

Item [3] of the Schedule to the draft variation would amend the definition of "sugars" in Note 1 of section 1.2.8—4 by repealing the definition and substituting it with the following new definition:

"***sugars***, in Standard 1.2.7, Standard 1.2.8 and Schedule 4 (except where it appears with an asterisk as 'sugars*')—means monosaccharides (other than D-allulose) and disaccharides. (Elsewhere in the Code it has a different definition)."

This amendment also reflects the proposed amendment in item [1] above.

Item [4]

Item [4] of the Schedule to the draft variation would amend paragraph (a) of the definition of "sugars" in Note 1 of section 2.6.2—2 by repealing the paragraph and substituting it with the following new paragraph (a):

"(a) in Standard 1.2.7, Standard 1.2.8 and Schedule 4 (except where it appears with an asterisk as 'sugars*')—means monosaccharides (other than D-allulose) and disaccharides; and"

This amendment mirrors the proposed amendment in item [1] above.

Item [5]

Item [5] of the Schedule to the draft variation would amend Schedule 2 of the Code by inserting the following entry into the table to section S2—2 after table item dealing with 'w/v' (weight per volume):

"w/w weight per weight"

Schedule 2 sets out the meanings of certain symbols used in the Code. This amendment is proposed because the proposed amendment in item [10] below refers to "w/w", but Schedule 2 does not currently contain a meaning for that symbol.

Weight per weight (w/w) refers to when the weight of each component is used when calculating levels of addition, irrelevant of whether either is a solid or a liquid. If a liquid, then the volume is ignored and the weight of that liquid is used in the calculation.

Item [6]

Item [6] of the Schedule to the draft variation would amend Schedule 4 of the Code by repealing paragraph (a) of the definition of "sugars" in the Note to section S4—2 and substituting it with the following new paragraph (a):

"(a) in Standard 1.2.7, Standard 1.2.8 and Schedule 4 (except where it appears with an asterisk as 'sugars*')—means monosaccharides (other than D-allulose) and disaccharides; and"

This amendment mirrors the proposed amendment in item [1] above.

Item [7]

Item [7] of the Schedule to the draft variation would amend Schedule 4 of the Code by omitting "contains no added sugars*" in the table item dealing with nutrition content claims in relation to 'sugars or sugars' in the table to section S4—3; and substituting that text with:

"contains no added sugars* with the exception of D-allulose which may be present, and no".

If the draft variation is approved, the effect of this proposed amendment would 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.

Item [8]

Item [8] of the Schedule to the draft variation would amend Schedule 11 of the Code by inserting the following new entry into the table to subsection S11—2(3) (above the table item dealing with 'erythritol'):

"D-allulose	2"

If the draft variation is approved, the effect of this proposed amendment would that D-allulose would have an energy factor of 2 kJ/g when calculating "average energy content" for the purposes of this Schedule and Standard 1.2.8.

Item [9]

Item [9] of the Schedule to the draft variation would amend Schedule 18 of the Code by inserting, in alphabetical order, the following new entry into the table to subsection S18—9(3):

- "D-psicose 3-epimerase (EC 5.1.3.30) from immobilised *Microbacterium foliorum*" in column 1 (enzyme permitted to be used as a processing aid);
- "For use in the manufacture of D-allulose" in column 2 (specific technological purpose for this enzyme); and
- "GMP" in column 3 (the maximum permitted level above which this enzyme must not be present in the food for sale.

This table lists substances permitted to be used as processing aids for specific technological purposes.

If the draft variation is approved, the effect of this amendment would be to permit the proposed use of this enzyme in accordance with the Code.

Item [10]

Item [10] of the Schedule to the draft variation would amend Schedule 25 of the Code by inserting a new entry in to the table to section S25—2.

The new entry would in effect permit D-allulose as a novel food to be a food for retail for sale or to be present as an ingredient in a food for retail for sale.

Paragraphs 1.1.1—10(5)(b) and 1.1.1—10(6)(f) of the Code provide that, unless expressly permitted by the Code, a food offered for retail sale must not be a novel food or have a novel food as an ingredient. Section 1.5.1—3 of the Code provides that a novel food is permitted by the Code if the novel food is listed in the table to section S25—2 and any conditions of use specified in that table are complied with. The table to section S25—2 of the Code lists permitted novel foods together with their conditions for use.

The new entry would impose five conditions of use in relation to D-allulose as a permitted novel food.

Condition 1 would provide that D-allulose may only be added to a food listed in condition 3 of the proposed permission. D-allulose must not be added to a food which is not listed in condition 3.

Condition 2 would provide that D-allulose must not be present in a food listed in condition 3 in an amount greater than the limit specified for that food by condition 3.

Condition 3 lists the foods to which D-allulose may be added and the maximum permitted amount or level for D-allulose in each food. As explained above, condition 2 would require that the amount of D-allulose present in the relevant food not exceed that specified limit.

Condition 4 would provide that, during the exclusive use period, only D-allulose sold under the brand *Nexweet* may be added to food in accordance with the above conditions.

Condition 5 would provide that, for the purposes of condition 4, the exclusive use period is the period commencing on the date of gazettal of the *Food Standards (Application A1247 – D-allulose as a novel food) Variation* and ending 15 months after that date. On the expiry of the exclusive use period, condition 4 will automatically cease to have effect. At that point, the D-allulose novel food permission provided by the new entry would apply to and permit any and all brands of D-allulose that comply with the Code.