FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

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301-24

Approval report – 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 the sale of D-allulose produced from the enzymatic conversion of fructose by D-psicose 3-epimerase (EC 5.1.3.30) contained in *Microbacterium foliorum*.

On 8 November 2023, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 16 submissions.

FSANZ approved the draft variation on 7 August 2024. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 19 August 2024.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

[1] Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation

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Supporting document

The following document, which informed the assessment of this application, is available on the FSANZ website:

SD1 Technical and risk assessment

Executive summary

Samyang Corporation (Samyang) 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. D-allulose would be added to specified foods as a lower-energy substitute for sugar ingredients. Samyang's D-allulose is produced from enzymatic epimerisation of fructose by D-psicose 3-epimerase, contained in *Microbacterium foliorum*. Samyang has requested permission in the Code for D-psicose 3-epimerase as it is not currently permitted for use as a processing aid.

Approach at Call for Submissions

D-allulose

FSANZ considered D-allulose a novel food, being used as a replacement for regular sugar in foods, providing similar functionality when used as an ingredient. Samyang's D-allulose conformed with specifications for D-allulose established in the United States Pharmacopeial Convention and the Merck Index and would be incorporated by reference in the Code.

The microbiological safety assessment concluded there are no public health or safety concerns in healthy adults. It was noted that uropathogenic bacteria such as *Klebsiella* species could use D-allulose as a food source if present in urine. While this could lead to the proliferation of such species, there are no reports that either establish or specifically investigate if this occurs or would lead to adverse health effects, especially in sensitive subpopulations, such as diabetics. Noting the history of safe use of D-allulose internationally, the weight-of-evidence suggests adverse microbiological effects are unlikely.

No toxicological concerns were identified in studies in laboratory animals or clinical studies in humans. The critical health endpoint identified in the human health risk assessment was the potential for D-allulose to cause a laxative effect due to the osmotic effect of D-allulose that is not absorbed from the gastrointestinal tract. To manage the risk of a laxative effect, FSANZ recommended that consumption of D-allulose should not exceed 0.4 g/kg body weight (bw) in a single serving, or 0.9 g/kg bw on a daily basis.

Estimated mean and high chronic dietary intakes of added D-allulose ranged between 160 and 730 mg/kg bw/day based on proposed MPLs noted in the application. In the short-term dietary intake assessment, there was the potential for a laxative effect to occur based on normal consumption patterns of some foods. As such, further assessments were undertaken to determine what use levels mitigate a laxative effect. This resulted in lower concentration levels compared to those requested in the application for some foods. Samyang agreed that, for these foods, the proposed MPLs could be reduced from those originally requested. The draft variation at the call for submissions therefore contained reduced MPLs for these particular foods.

D-allulose would be added to specified foods as a lower-energy substitute for sugar. FSANZ determined that the metabolisable energy for D-allulose is 1.88 kJ/g and the approved variation contains a (rounded) energy factor of 2 kJ/g. The energy factor of 2 kJ/g will be used for including the energy contribution from D-allulose in the declaration of average energy content in the nutrition information panel (NIP).

D-psicose 3-epimerase

The use of D-psicose 3-epimerase for the production of D-allulose is justified at a level consistent with Good Manufacturing Practice (GMP). D-psicose 3-epimerase has a history of safe use, with no significant homology found with any known toxins or allergens. On the basis of the available data the likelihood of consumer exposure to the production organism, the enzyme, or residues from the immobilized cell system in the final D-allulose food ingredient is negligible. As such, FSANZ concluded that there were no safety concerns associated with the use of D-psicose 3-epimerase in the production of D-allulose.

Submissions on the draft variation

Following assessment and the preparation of the draft variation, FSANZ called for submissions regarding the draft variation. FSANZ received 16 submissions.

Approach at Approval

D-allulose

On consideration of the submissions received, FSANZ amended the approved variation to revert to the D-allulose MPLs originally requested and to add a new clause to requiring the labelling of a food containing D-allulose to display an advisory statement to manage the risk of a laxative effect from high intakes of some foods.

FSANZ also revised the food classes to more closely align with the foods requested in the application, allowing innovation and regulatory harmonisation whilst providing certainty for compliance and enforcement purposes.

FSANZ confirmed the energy factor of 2 kJ/g for D-allulose, which is included in the approved draft variation for the purposes of calculating the energy content of food containing D-allulose.

In the approved draft variation, D-allulose is excluded from the average quantity of sugars declared in the NIP and FSANZ confirmed the approach at CFS to permit foods containing D-allulose to make nutrition content claims about sugars including no added sugar(s), provided existing claim conditions are met.

For reasons set out in this report, FSANZ has approved a draft variation to the Code. In summary, the approved draft variation will provide an exclusive permission for the use of Samyang’s Nexweet brand of D-allulose as a novel food for a period of 15 months, commencing on the date of gazettal.

1 Introduction

1.1 The applicant

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

1.2 The application

1.2.1 D-allulose and associated enzyme used in its production

Samyang 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 would be added to foods as a low-energy substitute for conventional sugar ingredients, particularly sugar. The requested levels and the food classes in the application are set out in Table 1, in below.

Table 1 Food classes and levels requested the in the application

Food classes requested in application	MPLs (% w/w) requested in application
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)	3.5
Gelatins, pudding and fillings; low- and reduced energy, low- and reduced sugar	10
Breakfast cereals and cereal based bars; ***regular*** Breakfast cereals and cereal bars; reduced energy; ***reduced sugar***	5
Frozen dairy desserts (ice cream, soft serve, sorbet); low- and reduced-energy and low- and reduced sugar	5
Yogurt and frozen yogurt; low- and reduced energy; low- and reduced sugar	5
Bakery products (bread rolls, cakes, cake-type rolls, pastries, doughnuts, biscuits (including cookies, shortbread, butter milk and whole wheat biscuits, crackers)); reduced energy	10
Fat-based cream (used in modified fat/energy cookies, cakes, pastries, and pie)	5
Icings and frostings	5
Jams and jellies	10
Dressings for salads	5
Sweet sauces and syrups; low- and reduced- energy, low- and reduced sugar	10
Hard candies/confectionery; low- and reduced energy	50
Soft candies/confectionery; low- and reduced energy (not including chocolate)	25
Chewing gum	50
Sugar substitutes	100

Samyang's D-allulose is manufactured by enzymatic epimerisation of fructose, utilising a D-psicose 3-epimerase contained in *M. foliorum*. There is no permission in the Code for a D-psicose 3-epimerase enzyme, therefore the application also requested permission for the use of this enzyme as a processing aid.

1.2.2 Metabolizable energy

D-allulose does not contribute significant metabolizable energy after consumption when compared to sugar. In order to include the energy contribution from D-allulose in the declaration of average energy content in the nutrition information panel (NIP), Samyang requested the establishment of a new energy factor of 1.0 kilojoule per gram (kJ/g) for D-allulose in subsection S11—2(3) of the Code.

1.2.3 Labelling requirements

Samyang requested that D-allulose not be included in the declaration of 'sugars' in the 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 Samyang, foods containing added D-allulose as a sugar replacer or substitute will contain less conventional sugars - such as sucrose and metabolizable energy - than traditionally sweetened counterparts.

Samyang considered 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.

Samyang requested an exclusive use permission for D-allulose as a novel food for a period of 15 months from gazettal. The brand names for the three Samyang D-allulose products are Nexweet Crystalline Allulose, Nexweet Allulose 95L and Nexweet Allulose 10L.

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.**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.

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 MPL 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 enzyme used to produce D-allulose, 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.

D-allulose

Subsection S3—2(1) incorporates by reference the United States Pharmacopeial Convention (2022) Food chemicals codex (13th edition), which establishes specifications for 'Allulose'. It also incorporates by reference The Merck Index, 15th Edition, being a secondary source within S3—3, which establishes a specification for D-psicose (O'Neil et al 2013).

In addition, section S3—4 requires that if there is no relevant specification under section S3—2 or S3—3, or if the monographs referred to in those sections do not contain a specification for identity and purity of a substance relating to arsenic or heavy metals, the specification is that the substance must not contain on a dry weight basis more than:

(a) 2 mg/kg of lead; or
(b) 1 mg/kg of arsenic; or
(c) 1 mg/kg of cadmium; or
(d) 1 mg/kg of mercury.

D-psicose 3-epimerase

Of relevance to D-psicose 3-epimerase, subsection S3—2(1) 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 26 (2021)), and the United States Pharmacopeial Convention (2022) Food chemicals codex (13th edition). These include general specifications for enzyme preparations used in food processing for identity and purity parameters.

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—2 sets out requirements for an advisory statement to the effect that excess consumption may have a laxative effect for foods containing specified substances above certain concentrations.

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).* Changes to conditions for *no added sugar(s)* claims were gazetted in December 2023 from Proposal P1062 – Defining added sugars for claims.

Standard 1.2.8 requires most packaged food products to be labelled with a 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.

Subsection 1.2.8—6(9) requires that if one or more components (other than organic acids) listed in subsection S11—2(3) is present in the food, singly or in combination, in an amount of no less than 5 g/100 g; and if either the *available carbohydrate by difference* method is used (and any of those components have been subtracted in the calculation); or the *available carbohydrate* method is used (and any of those substances have been quantified or added to the food), then the NIP must include individual declarations of those substances.

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 and, when used elsewhere in the Code, 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.

1.4 International standards

In developing food regulatory measures, FSANZ must have regard to the promotion of consistency between domestic and international food standards. In terms of food safety, the relevant international standard setting body is the Codex Alimentarius Commission (Codex).

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 used in a number of regions, including the United States of America (USA), Japan and Korea. The requirements of each are 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 seven GRAS notifications related to food uses of D-allulose (GRN 400; GRN 498; GRN 693; GRN 828; GRN 1024; GRN 1029; GRN 1057). Samyang's D-allulose from *M. foliorum* was the subject of GRN 828. The energy value to be used for labelling of foods containing D-allulose in the USA is 1.7 kJ/g.

1.4.2 South Korea

D-allulose is permitted in South Korea. *M. foliorum* with D-allulose-3-epimerase activity has been approved in South Korea to produce D-allulose. 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 was assessed under the General Procedure in the FSANZ Act.

1.7 Decision

The draft variation as proposed following assessment was approved with amendments, as explained below in sections 2.3.2.3 and 2.3.3.2. The approved draft variation as amended after consideration of submissions is at Attachment A. The approved draft variation takes effect on the date of gazettal.

The related 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.

The draft variation on which submissions were sought is at Attachment C.

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions on the draft variation to the Code from 8 November to 20 December 2023. Sixteen submissions were received - four from government, ten from industry and two from individual submitters. FSANZ's responses to issues raised in submissions are provided in Appendix 1.

The majority of submitters provided support for permitting the voluntary addition of D-allulose as a novel food, some of those subject to it being widened to additional food categories. Several issues were raised, including the proposed MPLs, the range of foods which may contain D-allulose, the exclusive use permission and the dietary intake assessment conclusions.

Labelling matters such as excluding D-allulose from sugars in the NIP, permitting foods containing D-allulose to make no added sugar(s) claims, aligning requirements for D-allulose with those for D-tagatose and an advisory statement about a laxative effect were also raised.

Four submitters expressed support for using D-psicose 3-epimerase in the production of D-allulose. No submitter raised concerns about the use of D-psicose 3-epimerase.

2.2 Risk assessment

FSANZ has undertaken a food technology and risk assessment of both the D-allulose and the D-psicose 3-epimerase contained in the organism *M. foliorum*, which is used to manufacture Samyang's D-allulose. A summary of these assessments is provided below.

2.2.1 D-allulose

2.2.1.1 Food technology assessment

Samyang has demonstrated an ability to produce D-allulose through numerous batch records, which conform with specifications set out in Food Chemicals Codex (FCC 2020) and the Merck Index, 15th Edition, (O'Neil et al 2013) which have specifications for Allulose and D-psicose, respectively. Therefore, no specification will be inserted into the Code, rather the above specifications will be referenced by S3—2 and S3—3 of the Code.

Samyang's manufacturing plant operates in accordance with 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 (Nexweet Crystalline Allulose) and syrups,(Nexweet Allulose 95L and Nexweet Allulose 10L) are stable under typical storage conditions and when contained in a food matrix typical of the proposed end use.

2.2.1.2 Toxicological assessment

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 was of very low acute toxicity in laboratory animals. Results of genotoxicity assays were negative, and D-allulose was not associated with carcinogenicity or 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. To avoid a laxative effect, consumption of D-allulose should not exceed 0.4 g/kg body weight (bw) at one time, or 0.9 g/kg bw/day.

2.2.1.3 Dietary intake assessment

Estimated mean and high chronic dietary intakes of added D-allulose ranged between 160 and 730 mg/kg bw/day based on proposed MPLs noted in the application. In the short-term dietary intake assessment, there was the potential for a laxative effect to occur based on normal 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 class or combination of similar food classes containing D-allulose per eating occasion. This resulted in lower levels compared to the proposed MPLs in the application for some foods. The assessments included the intake from brewed soft drinks that was included at approval following a request made during the public consultation at call for submissions (CFS).

2.2.1.4 Microbiological assessment

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.

The microbiological safety assessment concluded there are no public health or safety concerns in healthy adults. It was noted that uropathogenic bacteria such as *Klebsiella* species could use D-allulose as a food source if present in urine. While this could lead to the proliferation of such species, there are no reports that either establish or specifically investigate if this occurs or would lead to adverse health effects, especially in sensitive subpopulations, such as diabetics. Noting the history of safe use of D-allulose internationally, the weight-of-evidence suggests adverse microbiological effects are unlikely.

2.2.1.5 Nutrition assessment

No evidence was identified to indicate that D-allulose consumption would affect the absorption of other nutrients. Details regarding the calculation of an energy factor for D-allulose are covered below in section 2.3.6.

2.2.2 D-psicose 3-epimerase

No public health or safety concerns were identified in relation to the use of *M. foliorum* in the production of D-psicose-3-epimerase. It is neither pathogenic nor toxigenic. D-psicose 3-epimerase has a history of safe use for the production of D-allulose, and the applicant has provided analytical evidence that there is negligible likelihood of consumer exposure to the production organism, the intact enzyme, or residues from the immobilized cell system. No significant homology was found with any known toxins or allergens.

The proposed use of D-psicose 3-epimerase 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.

D-psicose 3-epimerase performs its technological purpose during the production of D-allulose. The enzyme functions as a processing aid for the purposes of the Code and does not perform a technological purpose in the food for sale. There are relevant identity and purity specifications for the enzyme in the Code.

2.3 Risk management

2.3.1 Risk management options

Following assessment, FSANZ prepared a draft variation and called for submissions on that draft variation for a period of six weeks.

The risk management options available to FSANZ following the CFS are to either:

- approve the draft variation proposed following assessment, or
- approve that draft variation subject to such amendments as FSANZ considers necessary, or
- reject that draft variation.

FSANZ had regard to the requirements of the FSANZ Act (see section 2.5 below) in developing the proposed regulatory measure. For the reasons set out in this report, and after consideration of submissions, FSANZ considers it appropriate to approve an amended version of the draft variation proposed following assessment. The reasons for amending the draft variation proposed in the CFS are outlined in Section 2.3.2.3 below.

The approved draft variation will permit:

- the use of D-allulose as a novel food
- D-psicose 3-epimerase to be used as a processing aid in the production of D-allulose.

Further details on the permissions and associated conditions are provided below.

2.3.2 Permission for D-allulose as a novel food and MPLs

2.3.2.1 Approach in the CFS

In the CFS, the draft variation contained a permission for D-allulose as a novel food in certain food classes, subject to MPLs for each food class. The proposed draft variation included lower MPLs of D-allulose than those requested in the application, for the following reasons.

The dietary intake assessment using the MPLs requested in the application identified a risk of a laxative effect for some food classes. As outlined in Section 2.2.1.2 above and SD1, this would have occurred where the intake of D-allulose was above the threshold of 0.4 g/kg/bw (28 g for a 70 kg adult) or 0.9 g/kg bw/day, based on normal food consumption patterns.

The risk of a laxative effect arising from consumption of D-allulose in excess of the threshold was discussed with the applicant, whereupon they agreed that, for these food classes, the MPLs be reduced to mitigate this risk. The applicant also provided examples of products being marketed where actual usage levels align with the lower proposed levels of addition.

2.3.2.2 Decision and rationale

Having had regard to the submissions received and for the reasons stated in this report, FSANZ has decided to amend the Code to permit D-allulose as a novel food when offered for retail sale as a tabletop sweetener or used as an ingredient in manufactured foods. The permission for use of D-allulose as an ingredient is limited to certain food classes and is subject to MPLs.

FSANZ considers that regulation of D-allulose as a novel food, rather than a food additive, is appropriate. Although D-allulose adds sweetness, this is not its sole function, as would be the case with a food additive (intense sweetener). It is used as a replacement for sugar in foods, providing similar functionality when used as an ingredient, including as a bulking agent, providing mouthfeel, browning capability, and depression of freeze point. It would typically be added as an ingredient in amounts considerably higher than most food additives, in particular in comparison to intense sweeteners. Approval as a novel food provides consistency with the regulatory approach for other sugar replacements such as D-tagatose and trehalose, both being novel foods.

After having regard to the submissions, FSANZ amended the draft variation to increase the MPLs for D-allulose in the permitted foods to the levels requested in the application (see Table 2). In particular, FSANZ notes comments from submitters that the higher MPLs are more aligned with the use of D-allulose as a sugar replacer, offering advantages in terms of sensory and flavour profiles and provide greater international harmonisation.

In the dietary intake assessment, FSANZ identified the risk of a laxative effect associated with consuming foods containing D-allulose in some food classes based on the MPLs requested by the applicant. Those MPLs, when specified in the Code will limit this risk, including for both a single eating occasion and repeated intake across a day.

The MPLs have also been used as the basis for further risk management decisions to be made in response to the identified risks. Discussion on the labelling requirements for foods containing D-allulose can be found in section 2.3.7.

2.3.3 Food classes

2.3.3.1 Approach in the CFS

At the CFS, the draft variation permitted the addition of D-allulose to food classes based on food classes in Schedule 15 – Substances that may be used as food additives. The specific food class names referred to in the application were not used in the draft variation but the foods were broadly captured to provide certainty for compliance and enforcement purposes. The proposed revised food class names and MPLs up to which D-allulose could be added, were shown in Table 1 of the CFS.

A number of submitters requested the permitted food classes be expanded to include additional foods, citing the benefit to industry and potential positive impact addition of D-allulose to foods, could have on obesity. One government submitter considered that if D-allulose is regulated as a novel food, the drafting should align with the permissions for other novel foods which refer to names in relevant Chapter 2 standards.

2.3.3.2 Decision and rationale

Following the CFS and having had regard to submitter comments, FSANZ has decided to amend the draft variation to revise the food classes permitted to have added D-allulose (Table 2) to more closely align with the foods requested in the application (Table 1). There are no requirements however, relating to levels of sugar or energy content, or associated claims/representations, as referred to by the applicant. This is because such an approach may result in a very narrow range of foods (for example, food meeting conditions for low energy only) or require the making of a claim or particular representation in order to be enforceable (for example a 'reduced sugar' claim). It is considered that using D-allulose as a sugar replacer does not necessarily mean a food will meet the conditions for low or reduced energy/sugar claims. The food classes are appropriate without additional criteria for sugar and/or energy content.

Where applicable, the food classes align with those in Schedule 15 and/or with foods defined in the Code and which are subject to specific Chapter 2 standards, for example, ice cream. It was not always possible to align the requested foods with defined foods in the Code, as the food class requested by the applicant was broader than the defined food. For example, the term 'bakery products' rather than bread (a defined food) is used.

It is also noted that the food for sale must comply with any other compositional and labelling requirements in the Code. For example, 'fruit spreads' rather than jam is used in the approved draft variation, noting that a fruit spread made with D-allulose as a replacement for sugar may not meet the compositional requirements for a food sold as jam.

Table 2 Food classes and MPLs for D-allulose at approval

Food class names in the approved draft variation	Approved MPLs (%w/w)
Non-alcoholic water based flavoured drinks[1]	3.5
Desserts (with or without gelatine)	10
Breakfast cereals	5
Cereal bars	5
Ice cream	5
Edible ices (including sorbet)	5
Yoghurt	5
Bakery products	10
Imitation cream	5
Icing	5
Frostings	5
Fruit spreads (but not chutney)	10
Salad dressings	5
Sweet sauces	10
Syrups	10
Confectionery (but not chocolate)	50
Chewing gum	50
Bubble gum	
Tabletop sweeteners	No limit

1 (a) includes: brewed soft drinks; non-brewed soft drinks; cola type drinks; formulated caffeinated beverages; fruit drinks; tea beverages; coffee beverages; powdered drink concentrates; and liquid drink concentrates; and
(b) does not include: milk analogues; fruit juices; vegetable juices; formulated beverages; electrolyte drinks; and electrolyte drink bases.

2.3.4 Specification

There are relevant identity and purity specifications in primary and secondary sources of specifications listed in Schedule 3 of the Code for 'Allulose' and 'D-psicose respectively (refer to section 2.2.1.1 above). D-allulose would need to meet the relevant specification when added to food as an ingredient or sold as a tabletop sweetener. Section S3—4 contains additional MPLs for arsenic and heavy metals for any substance, including D-allulose:

- 2 mg/kg of lead; or
- 1 mg/kg of arsenic; or
- 1 mg/kg of cadmium; or
- 1 mg/kg of mercury.

2.3.5 Exclusivity

An applicant may request an exclusive use permission to use and sell a novel food for up to 15 months. Further information is available on the FSANZ website[2].

The applicant requested an exclusive use permission for their brand of D-allulose for a period of 15 months on the basis that they have invested significantly in the technology development, safety studies and the preparation of the application.

FSANZ determined that this request was justified and decided to provide the applicant with a 15 month exclusive use period for the use of D-allulose as a novel food. The approved draft variation includes a condition that, for a limited period of 15 months from gazettal of the draft variation, only D-allulose under Samyang's brand name 'Nexweet' may be added to food in accordance with the specified conditions. 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.

If other brands of D-allulose are produced using an enzyme that is not permitted under the Code, approval is required for that enzyme, via the FSANZ application process.

2.3.6 Energy factor for D-allulose

The *average energy content of food is calculated according to factors, expressed as kJ/g, for general and specific energy yielding components as listed 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.

The applicant submitted data that enabled derivation and listing of an 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 ingredient. This equation (set out below) has been used as the basis for FSANZ's calculation of the energy factor 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.

[2] Exclusivity of use for novel foods and nutritive substances | Food Standards Australia New Zealand

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) for ingested D-allulose is 1.88 kJ/g. FSANZ therefore proposed that an energy factor 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 factor to a whole number is consistent with the other energy factors in the Code.
Some submitters noted their support of the proposed energy factor whereas others suggested a lower level in order to align more closely with international markets.

FSANZ has decided to retain the energy factor of 2 kJ/g for D-allulose in the approved draft variation, for the purposes of calculating the energy content of food containing D-allulose. This is based on the assessment outlined above and noting that there is no consistency in energy factors used in other countries.

2.3.7 Labelling of foods containing D-allulose

Foods containing D-allulose are subject to existing generic labelling requirements in the Code which provide information to enable consumers to make informed choices (see section 1.3.5). As the approved draft variation includes an energy factor of 2 kJ/g for D-allulose in subsection S11—2(3), this energy factor will need to be applied in the calculation of the average energy content of a food containing D-allulose for the NIP (section S11—2).

2.3.7.1 Declaration of sugars and carbohydrate in the NIP

2.3.7.1.1 Approach at CFS

At the CFS, FSANZ proposed D-allulose be excluded from the average quantity of sugars declared in the NIP. Most D-allulose is absorbed intact from the small intestine and not metabolised (section 2.2.1.1 in this report and section 3.2 in SD1). This is different to conventional monosaccharides and disaccharides which affect blood glucose and insulin levels.

FSANZ stated in the CFS that under existing provisions in the Code (section S11—3), D-allulose would not be included in carbohydrate declarations in the NIP. The amounts of carbohydrate and sugars in the NIP would therefore both exclude D-allulose.

2.3.7.1.2 Decision and rationale

FSANZ's decision is to maintain the approach at CFS. In the approved draft variation, D--allulose is excluded from the average quantity of sugars declared in the NIP.

Industry submitters who commented on this matter supported the approach.

Government submitters suggested labelling requirements for low energy sugars should be consistent to avoid confusion for consumers. While excluding D-allulose from sugars in the NIP differs to requirements in the Code for D-tagatose, the only other permitted low energy sugar, FSANZ considers labelling requirements are best considered on a case-by-case basis taking into account all relevant information. As noted above, excluding D-allulose from

sugars in the NIP is also aligned with existing requirements for carbohydrate declarations in the NIP.

In response to a government submitter request for clarification on requirements for carbohydrate declarations in the NIP, FSANZ notes section S11—3 sets out two methods for determining the amount of carbohydrate: *calculation of available carbohydrate* and the *calculation of available carbohydrate by difference.* Either method excludes D-allulose as the *calculation of available carbohydrate by difference* specifically excludes those substances listed in subsection S11—2(3) and the *calculation of available carbohydrate* only includes *available sugars.* D-allulose is not considered an 'available' sugar compared with traditional sugars as it is largely excreted unchanged.

2.3.7.2 Nutrition content claims

2.3.7.2.1 Approach at CFS

At the CFS, FSANZ proposed foods containing D-allulose would be permitted to make nutrition content claims about sugars (*% free*, *low sugar(s), reduced/lite*, *no added sugar(s)* but not *unsweetened*) provided other claim conditions for sugars are met. FSANZ considered such permissions were appropriate given most D-allulose is not metabolised in the human body and has a low energy factor of 2 kJ/g.

2.3.7.2.2 Decision and rationale

FSANZ's decision is to maintain the approach at CFS to permit foods containing D-allulose to make nutrition content claims about sugars, including *no added sugar(s),* provided existing claim conditions are met. Since the CFS was publicly released, FSANZ has gazetted changes to the conditions for *no added sugar(s)* claims in section S4—3 arising from Proposal P1062 -Defining added sugars for claims. The draft variation at CFS relating to the permission for foods containing D-allulose to display *no added sugar(s)* claims has therefore been amended at approval (see item 8 at Attachment 1) to maintain the approach.

Under Proposal P1062, conditions for *unsweetened* claims were amended to not permit such claims on foods containing low energy sugars, as ingredients, listed in subsection S11—2(3). Therefore foods containing D-allulose will not be permitted to display *unsweetened* claims.

While industry submitters who commented on this matter supported permitting claims about sugars, government submitters did not support the permission for foods containing D-allulose to make *no added sugar(s)* claims. Government submitters considered consumers could be misled from such claims and that D-allulose and D-tagatose should be treated similarly with respect to claims as a different approach could be confusing for consumers. In addition, government submitters stated a different approach for D-allulose and D-tagatose could create an unfair competitive advantage when similar products have different requirements and may be considered inconsistent with fair trading legislation.

FSANZ maintains that as most D-allulose is not metabolised and has a very low energy factor, it is appropriate to regulate D-allulose differently to traditional sugars and permit *no added sugar(s)* claims. The applicant who sought permission to use D-tagatose (Application A472 – D-tagatose as a novel food) did not request permission to make nutrition content claims about sugars and therefore FSANZ did not specifically consider the matter at that time. The recently completed Proposal P1062 maintained the existing approach in the Code to not permit foods containing D-tagatose to make *no added sugar(s)* claims because of the energy factor of 11 kJ/g which is 65% of the energy content of traditional monosaccharides and disaccharides (17 kJ/g in the Code). It appears there has been minimal use of D-tagatose in foods for sale in Australia and New Zealand since it was approved in 2004.

FSANZ considers claim permissions for foods containing low energy sugars are best considered on a case-by-case basis at the time applications for permission to add are assessed. This will ensure all relevant information is considered, noting that energy factors and metabolic impacts may vary. FSANZ can prepare information for consumers to explain labelling requirements for low energy sugars.

2.3.7.3 Risk of a laxative effect from excess consumption of foods containing added D-allulose

2.3.7.3.1 Approach at CFS

As discussed in section 2.3.2, the draft variation at the CFS stage prescribed lower MPLs for D-allulose in certain food classes than the applicant originally requested, in order to mitigate the risk of a laxative effect from some food classes. Consequently, FSANZ did not need to consider whether an advisory statement about the risk of a laxative effect should be required.

2.3.7.3.2 Decision and rationale

Based on the outcomes from the risk assessment about a potential laxative effect from D-allulose at a dosage exceeding 0.4 g/kg bw and the dietary intake assessment based on the applicant's original MPLs for D-allulose in certain food classes, FSANZ's decision is to amend the draft variation to require an advisory statement about the risk of a laxative effect for some food classes (see Table 3). Consistent with the advisory statement required for foods with polyols and other substances listed in section 1.2.3—2, a statement to the effect that excess consumption may have a laxative effect, is required for certain food classes as discussed below. This statement will alert consumers to a possible laxative effect at high intakes of the foods, thereby providing information for informed choice.

Table 3 Food classes required and not required to have an advisory statement about a laxative effect

Food classes for which an advisory statement[1] IS required	**Food classes for which an advisory statement[1] is NOT required**
Bakery products	Cereal bars
Bubble gum	Icings
Breakfast cereals	Frostings
Chewing gum	Fruit spreads
Confectionery (excluding chocolate)	Imitation cream
Desserts (with or without gelatine)	Salad dressings
Edible ices (including sorbet)	Sweet sauces
Ice cream	Syrups
Non-alcoholic water based flavoured drinks	Tabletop sweeteners
Yoghurt	

[1] statement to the effect that excess consumption may have a laxative effect.

Dietary intakes of D-allulose in at least one of the three population groups were estimated to be over 0.4 g/kg bw for the following food classes (Table 7 in SD1): bakery products, bubble gum and chewing gum, breakfast cereals, desserts (with or without gelatine), ice cream and edible ices, non-alcoholic water based flavoured drinks and yoghurt, including frozen yoghurt. Foods containing D-allulose in these classes are therefore required to display an advisory statement about a laxative effect. Where there was at least one dietary intake estimate of D-allulose over 0.4 g/kg bw for individual food classifications (e.g. fancy breads and cakes within the 'bakery products' class), FSANZ decided to take a conservative approach and require the advisory statement on all foods in the class e.g. bakery products.

For breakfast cereals, a similar approach was taken given the dietary estimate of D-allulose for porridge was determined to be over 0.4 g/kg bw. Additionally, FSANZ considers that even though the dietary estimate for ready-to-eat breakfast cereals for New Zealand children aged 5-14 years was 0.39 g/kg bw, requiring the statement for these cereals is justified given the estimate is very close to the 0.4 g/kg bw threshold and children are a vulnerable population.

Dietary intakes of D-allulose were estimated to be 0.4 g/kg bw or below for the following food classes (Table 7 in SD1): cereal bars, fruit spreads, icings and frostings, salad dressings and tabletop sweeteners. Foods containing D-allulose in these classes are therefore not required to display an advisory statement about a laxative effect.

Food classes that required a specific assessment based on the data available for them for the dietary intake were confectionery (excluding chocolate), imitation cream and sweet sauces & syrups. Additional analysis was undertaken to determine the maximum amount of D-allulose that could be added before causing a laxative effect (see section 3.5.2.6 in SD1). For confectionery, it was determined that a D-allulose concentration of 10% could cause a laxative effect. Given the MPL of D-allulose in confectionery (excluding chocolate) is 50%, FSANZ has decided an advisory statement about a possible laxative effect is required. For sweet sauces & syrups, it was determined that a D-allulose concentration of 15% could cause a laxative effect. Given the MPL of D-allulose in this food class is 10%, FSANZ has decided an advisory statement about a possible laxative effect is not required. For imitation cream, it was determined that an excessive amount would need to be consumed before exceeding a D-allulose intake of 0.4 g/kg bw (see section 3.5.2.6 in SD1). Consequently, FSANZ has decided an advisory statement about a possible laxative effect is not required for imitation cream.

In response to the CFS, government submitters suggested the existing approach for requiring advisory statements for food containing maltitol and other polyols could be applied to foods containing D-allulose. Current provisions require an advisory statement for foods containing specified polyols, either alone or in combination, at a concentration of 10% or more (subsection 1.2.3—2(2)). FSANZ decided not to apply an approach for the advisory statement similar to that for maltitol, because the dietary intake assessment indicated there was no consistent concentration across all food classes that posed a risk of a laxative effect (see Table 8 in SD1).

In summary, FSANZ decided to amend the draft variation to require an advisory statement for food classes shown to pose a risk of a laxative effect at high intakes.

2.3.8 D-psicose 3-epimerase

2.3.8.1 Approach at CFS

The conclusions from the risk and technical assessment were that the proposed use of D-psicose 3-epimerase contained in *M. foliorum* is technologically justified and there were no safety concerns associated with its proposed use.

In the CFS, the draft variation contained a permission for the use of D-psicose 3-epimerase *M. foliorum* as a processing aid, with no concerns from submitters raised on that approach.

2.3.8.2 Decision and rationale

As stated above, FSANZ has approved a draft variation to the Code to permit the D-psicose 3-epimerase enzyme contained in *M. foliorum* to be used as a processing aid to manufacture D-allulose. The permission is subject to the condition that the MPL or amount of the enzyme that may be present in D-allulose must be an amount consistent with GMP.

However, the draft variation has been amended to remove the statement that the enzyme within *M. foliorum* is 'immobilised'. FSANZ decided, after further consideration, that there was no reason to limit the permission for the use of D-psicose 3-epimerase enzyme contained in *M. foliorum* to immobilised forms only. This is in line with previously assessed enzymes which have been immobilised prior to use.

Other risk management considerations for this aspect of the application are related to the enzyme and source microorganism nomenclature, specifications and labelling, as follows.

The International Union of Biochemistry and Molecular Biology (IUBMB) uses the accepted name 'D-psicose 3-epimerase' and this is the name used in the approved draft variation.

Nomenclature for the organism *M. foliorum* is in accordance with accepted international norms.

There are relevant identity and purity specifications in primary sources of specifications listed in Schedule 3 for enzyme preparations used in food processing (refer to section 1.3.4 above).

The generic exemption in the Code from listing processing aids in the statement of ingredients applies to food containing D-allulose which have been produced using D-psicose 3-epimerase as no allergens have been identified.

2.3.9 Risk management conclusion

Having considered all aspects of the assessment against the statutory requirements, including having regard to submitter comments and relevant Ministerial Policy Guidelines, FSANZ has approved a variation to the Code to permit D-allulose as a novel food for retail sale as a tabletop sweetener; or as an ingredient in certain manufactured foods. The permission for use of D-allulose as an ingredient is limited to certain food classes and is subject to MPLs and relevant requirements and conditions. The approved amended draft variation includes provisions as follows:

- a novel food permission and conditions of use for D-allulose listed in Schedule 25
- a permission in Schedule 18 for the use of the D-psicose 3-epimerase as a processing aid in the production of D-allulose
- an energy factor 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 requirement for an advisory statement about the risk of a laxative effect for some food classes in Standard 1.2.3.
- excluding D-allulose from the definition of sugars for the purposes of nutrition labelling and certain claims about sugars
- permitting food containing D-allulose to make nutrition content claims about *no added sugar(s)* provided other conditions are met.

2.3.10 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 Food Standards Notification Circular, media release, FSANZ's social media channels and Food Standards News.

The process by which FSANZ considers standards development matters is open, accountable, consultative and transparent. Public submissions were called to assist consideration of the draft variation to the Code. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application.

The draft variation was considered for approval by the FSANZ Board having regard to all submissions made during the CFS period.

2.3.11 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 not substantially the same as existing international standards and the proposed measure may have a significant effect on trade.

To date, there are few relevant overseas standards on the use of D-allulose in foods and no international standard. However, there may be differences in permitted food classes, levels at which D-allulose is permitted to be added, the energy factor used for labelling and labelling about a laxative effect amongst the USA, South Korea, Japan and Australia and New Zealand. These differences may require overseas manufacturers to vary product composition and labelling specifically for the Australian and New Zealand markets as would be needed for other markets given the lack of consistency across countries.

A notification to the WTO under Australia's and New Zealand's obligations as a part of the WTO Technical Barriers to Trade agreement has been made to enable WTO members to comment on the amendments to the Code.

2.4 FSANZ Act assessment requirements

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.

In relation to the assessment of processing aids, the OIA have previously advised FSANZ that a RIS is not required for applications relating to these substances. This is because applications relating to permitting the use of processing aids, such as D-psicose 3-epimerase, that have been determined to be safe are considered to be minor and deregulatory in nature, as their use will be voluntary if the draft variation concerned is approved.

FSANZ, however, gave 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)(a)).

The purpose of this consideration was 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 considered permitting the sale of D-allulose as a novel food, and permitting the use of D-psicose 3-epimerase to be used as a processing aid to manufacture D-allulose. FSANZ is of the view that no other realistic food regulatory measures exist.

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 food offered for retail sale to be, or have as an ingredient, D-allulose as a novel food, and permitting D-psicose 3-epimerase to be used as a processing aid.

2.4.1.1.1 Costs and benefits to:

Industry

Approving the draft variation would give industry an extra option for a low-energy substitute for sugar as an ingredient in the foods that D-allulose would be permitted. Industry may also benefit from the permission for D-psicose 3-epimerase to be used as a processing aid to manufacture D-allulose. Different businesses may take-up this option if a net benefit existed for them. Given the range of low-energy substitutes for sugars as food ingredients already in the market, permitting this voluntary use of D-allulose is not expected to significantly impact market dynamics.

D-allulose products are already permitted for sale in the USA, 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. That is particularly the case given FSANZ would permit MPLs that are consistent with levels permitted in other jurisdictions. That may benefit exports containing D-allulose and also lead to greater competition from imported products containing D-allulose.

Granting an exclusive use permission will prevent D-allulose from other businesses (i.e. that are not Nexweet brand) from being added to food in the short-term. However, granting of the exclusive use permission does not preclude any other business from applying to amend the Code to permit the use of their own brand of D-allulose. Therefore, the market for supplying D-allulose could be opened during the 15 month exclusive use period for any other business willing to make an application. At the end of the exclusive use period all businesses will experience the same benefits in offering D-allulose for retail sale or using brands other than ‘Nexweet’ as an ingredient in accordance with the specified conditions that D-allulose may be added to food.

Consumers

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

The requirement of an advisory statement about the risk of a laxative effect for some food classes will alert consumers to a possible laxative effect at high intakes of the foods, thereby providing information for informed choice.

A large range of low-energy alternatives to sugar are already on the market and would compete with D-allulose. Therefore, granting the exclusive use permission to the applicant (where only D-allulose under the brand name ‘Nexweet’ may be added to food in accordance with the specified conditions) is not expected to result in notably higher food prices for consumers during the period than if exclusive use was not granted.

Government

Approving this draft variation 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, that may 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 the draft variation most likely outweigh the associated costs. No further information was provided during the consultation process that changed that assessment.

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, summarised in sections 2.2.1 to 2.2.3 above. FSANZ's conclusion, based on the best scientific evidence, was that use of D-allulose as a novel food in the manner proposed would pose no public health and safety concerns.

FSANZ did not identify any public health and safety concerns in relation to the use of the D-psicose 3-epimerase enzyme as a processing aid to manufacture D-allulose.

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

The labelling requirements relevant to this application are discussed above in section 2.3.7 of this report.

2.4.2.3 The prevention of misleading or deceptive conduct

There were 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. 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**

There are relevant international specifications for D-allulose and enzyme preparations as referred to in section 1.3.4 of this report, with which D-allulose and D-psicose 3-epimerase would have to comply. In addition, there is a Codex guideline - Guidelines on Substances used as Processing Aids (CAC/GL 75-2010) - which sets out general principles for the safe use of substances used as processing aids, including that substances used as processing aids shall be used under conditions of GMP.

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

Australia and New Zealand will remain competitive with other international markets, where approval for D-allulose is already in place or occurs in the future. This will also help foster continued innovation and improvements in food manufacturing techniques and processes. The conclusion of the risk assessment is that there are no public health and safety concerns associated with the proposed use of D-allulose. It is therefore appropriate that Australian and New Zealand food industries are given the opportunity to benefit from the use of D-allulose for the applications proposed by the applicant.

- **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 Food Ministers' Meeting**

FSANZ must have regard to any written policy guidelines formulated by the Food Ministers' Meeting. There are two policies relevant to this application:

- Policy Guidelines on Novel Foods
- Policy Guideline on the Addition to Food of Substances other than Vitamins and Minerals.

FSANZ has had regard to these two policy guidelines as detailed in the following sections. In addition, the high order principles in both guidelines reflect FSANZ's statutory objectives in subsections 18(1) and 18(2) in the FSANZ Act. FSANZ's assessment in relation to these objectives is described in sections 2.5.2 and 2.5.3 above.

D-allulose

Policy Guideline on Novel Foods

The 'Ministerial Council Policy Guidelines on Novel Foods' also includes the high order principle *'be consistent with and complement Australian and New Zealand national policies and legislation including those relating to nutrition and health promotion'*. With respect to that principle, FSANZ considers the addition of D-allulose to the food classes as approved, is consistent with national nutrition policies in Australia and New Zealand that recommend limiting added sugars intake (NHMRC, 2013; MoH 2020).

The Specific Principles in this guideline are:

- To ensure that public and industry confidence in the food system is maintained.
- To provide an assessment process that aims to protect commercially sensitive information and recognise industry's intellectual property to the maximum extent possible.
- To ensure consumers are not misled by novel foods or food ingredients, which appear similar to existing foods but may differ in terms of nutrition or function.

Following assessment as outlined in this report and SD1, FSANZ has determined that permitting the addition of D-allulose to the food classes as approved is consistent with the above Specific Principles.

Policy Guideline on the Addition to Food of Substances other than Vitamins and Minerals.

The 'Policy Guideline Addition to Food of Substances other than Vitamins and Minerals' includes Specific Order Policy Principles for substances added for a technological function as well as for any other purpose. This application falls under 'any other purpose' and therefore regard has been given to these policy principles in the assessment of this application. These principles state that the addition of substances other than vitamins and minerals to food should be permitted where:

a) the purpose for adding the substance can be articulated clearly by the manufacturer (i.e. the 'stated purpose')
b) the addition of the substance to food is safe for human consumption
c) the substance is added in a quantity and a form which is consistent with delivering the stated purpose
d) the addition of the substance is not likely to create a significant negative public health impact to the general population or sub population
e) the presence of the substance does not mislead the consumer as to the nutritional quality of the food.

Following assessment as outlined in this report and SD1, FSANZ has determined that permitting the addition of D-allulose to certain foods as approved is consistent with the above principles.

This policy guideline also includes a section on implementation. The points under that section are covered as outlined above in sections 2.3.2 and 2.3.3.

D-psicose 3-epimerase

The 'Ministerial Policy Guideline Addition to Food of Substances other than Vitamins and Minerals'[3] includes specific order policy principles for substances added to achieve a solely technological function, such as processing aids. These specific order policy principles state that permission should be granted where:

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e., the 'stated purpose')
- the addition of the substance to food is safe for human consumption
- the amounts added are consistent with achieving the technological function
- the substance is added in a quantity and a form which is consistent with delivering the stated purpose
- no nutrition, health or related claims are to be made regarding the substance.

FSANZ determined that permitting the proposed use of D-psicose 3-epimerase is consistent with these specific order policy principles for 'Technological Function'. All other relevant requirements of the policy guideline are similarly met.

3 References

FAO/WHO (2020). Chapter 6: Dietary exposure assessment of chemicals in food. Second Edition 2020. In *Environmental Health Criteria 240. Principles and Methods for the Risk Assessment of Chemicals in Food.*
https://www.who.int/docs/default-source/food-safety/publications/chapter6-dietary-exposure.pdf

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

FDA United States Food and Drug Administration: (2020) The Declaration of Allulose and Calories from Allulose on Nutrition and Supplement Facts Labels: Guidance for Industry.

FSANZ (2009), Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes.
https://www.foodstandards.gov.au/sites/default/files/publications/Documents/Principlespractices%20exposure%20assessment%202009.pdf

MOH (2020) Eating and Activity Guidelines for New Zealand Adults: Updated 2020. Wellington: Ministry of Health.

NHMRC (2013) Australian Dietary Guidelines. Canberra: National Health and Medical Research Council. Canberra, Australia

O'Neil et.al. (2013).The Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals, 15th Edition, Royal Society of Chemistry, Great Britain.

Appendix

Summary of submitter comments and FSANZ response

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

Attachments

A. Approved draft variation to the *Australia New Zealand Food Standards Code*
B. Explanatory Statement
C. Draft variation to the *Australia New Zealand Food Standards Code* (call for submissions)

Appendix 1 – Summary of submitter comments and FSANZ responses

Submitters to the A1247 call for submission are listed below, with a summary of issues raised by submitters and FSANZ responses listed in Table 1.

List of submitters

- Ai Group
- Australian Beverages Council (ABC)
- Australian Food & Grocery Council (AFGC)
- Australian Institute of Food Science and Technology (AIFST)
- Buderim Foods
- Calorie Control Council
- New Zealand Beverage Council (NZBC)
- New Zealand Food and Grocery Council (NZFGC)
- Nutrishus Brands
- Queensland Health
- New South Wales Food Authority (NSWFA)
- New Zealand Food Safety (NZFS)
- Victorian Departments of Health and Energy, Environment and Climate Action (Vic DoH and DEECA)
- Senchai
- Two individual submitters

Table 1 Summary of submissions and FSANZ response

Topic of submission	Raised by	FSANZ response (including any amendments to drafting)
Food classes Requested expanding the food categories to include all beverage types as classified under the Code to benefit innovation and consumer options and align with the Food Regulation System priorities 2017-2022. Expanding the food categories would provide clarity for enforcement and reduce the burden on industry to make further applications to amend the Code. Some submitters stated that a limited number of categories would negate benefit to industry. Recommended aligning categories with S15 and listing the category number to reduce ambiguity and confusion. Noted that the applicant's scope was based on the US food class names and recommended FSANZ extend these to other food class names: broader range of confectionery, liquid milk products and flavoured liquid milk, brewed soft drinks, carbonated, mineralised and soda waters, fruit and vegetable juices, fruit and vegetable juice products, other foods including snack and nutrition bars.	NZBC, ABCL, Buderim, AFGC, AIFST	FSANZ has decided to widen the food classes permitted in the draft variation to maintain consistency with foods requested by the applicant to enable innovation, regulatory harmonisation and provide clarity for compliance and enforcement purposes. Brewed soft drinks are also included as a non-alcoholic water based beverage.
D-allulose should be broadly permitted in the food supply (no exclusivity) as it has the potential to reduce obesity if used instead of sugar.		FSANZ has only assessed the addition of D-allulose to the foods requested by the applicant. Therefore, the permission must be limited to those foods.

Topic of submission	Raised by	FSANZ response (including any amendments to drafting)
MPLs Higher levels should be permitted, based on the self-limiting nature of D-allulose (flavour profile) and its similarity to fructose and polyols. Recommended either no MPL set or revert to the levels requested in the application, or levels overseas for reasons of technological function, harmonisation and to provide trade benefits.	ABCL, AIFST, AFGC, Buderim, Individual, Ai Group, NZBC	For the reason stated in this report, FSANZ has decided to amend the draft variation to • increase the MPLs to those originally requested by the applicant • require an advisory statement for certain foods where a risk of a laxative effect is present (summarised in Table 8, SD1).
Preferred unit of measurement Recommended units of milligrams per kilogram (mg/kg) for measurement in line with established treatment of other MPLs in the Code.	ABCL	FSANZ considers a percentage (% w/w) to be the most appropriate measurement since the amounts of D-allulose used in production are generally larger than other substances to which MPLs apply.
Drafting – novel food vs food additive Agreed with classification of D-allulose as a novel food Notes D-allulose is captured by the definition of sugars* in the Code as a hexose monosaccharide and performs technological purposes such as intense sweetener and/or bulking agent. ***D-tagatose*** Noted D-tagatose is only listed as a novel food in the Code, however, the FSANZ Nutrition Panel Calculator (NPC) lists it as a food additive. Suggests FSANZ resolve this misalignment so that users of the Code are in no doubt as to the identity of certain substances. Questioned the rationale not to list D-allulose (and D-tagatose) as a food additives under Standard 1.3.1. The purpose of adding D-allulose meets the definition of 'used	NSWFA	FSANZ considers the novel food standard to be the most appropriate for the regulation of D-allulose. The food classes to which D-allulose may be added, as listed in the approved amended draft variation, now align more closely with the approach used for the regulation of similar foods rather than for food additives. *D-tagatose* FSANZ acknowledges NSWFA for pointing out that D-tagatose is described as a food additive in the NPC. This will be corrected when the NPC is next updated. FSANZ does not agree. See section 2.3.2.2 of this report

Topic of submission	Raised by	FSANZ response (including any amendments to drafting)
as a food additive' in the Code. The Code lists all other permitted sugar substitutes such as polyols and intense sweeteners as food additives. Queried 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.		*Section 1.3.1—5* The application of section 1.3.1—5 of the Code is a matter for the jurisdictions whose legislation give effect to the Code. FSANZ notes that section 1.3.1—5 applies to a substance used as a food additive to perform the technological purpose of an intense sweetener. As explained in section 2.3.2.3 of this report, FSANZ's assessment is that D-allulose is not being used in this case as a food additive. Nor is it an intense sweetener (as it is only 70% as sweet as sugar).
Laxative effect Foods with D-allulose could be labelled with information about the risk of a laxative effect if there was a broad permission. Supported FSANZ's decision to lower the maximum percentage limit of D-allulose to mitigate laxative effect. FSANZ's assessment identified a laxative effect of D-allulose, with the lowest dosage associated with gastrointestinal symptoms of 0.4 g/kg bw as a single dose. Noted the threshold value was based on a review of human tolerance studies on mainly healthy young adults and no studies on children were reviewed. NSWFA also noted 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. NZFS noted there is limited human research to inform the levels at which a laxative effect occurs. The tolerance	NSWFA, NZFS	Please see above comments for FSANZ's rationale for the change back to the originally requested MPLs. FSANZ considers the required labelling measures (section 2.3.7 above) sufficiently manage the risk of a laxative effect. As part of the hazard assessment of D-allulose, FSANZ conducted a literature review to identify any studies, case reports or reviews not included in the application. Several studies of the effects of D-allulose in patients with either Type 1 or Type 2 diabetes, or in rodent models of diabetes, were found. No information in the peer-reviewed scientific literature concerning the risk of a laxative effect in the other subpopulations was found. In the studies on patients with diabetes, no adverse clinical effects of the consumption of D-allulose were identified in any of those studies. Beneficial effects on blood glucose and on insulin tolerance were reported. Since the risk assessment was first released for submissions, one study of tolerance of D-allulose in children has been published. This study has been reviewed and added to the SD1. No gastrointestinal effects were observed in children, and there is no evidence that children are more sensitive to D-allulose than adults. FSANZ is therefore not aware of scientific evidence establishing a greater risk to people with irritable bowel syndrome, diabetes or other chronic diseases. However FSANZ has amended the draft variation to require an advisory statement to the effect that excess consumption may have a laxative effect for certain food classes and considers this is sufficient to minimise the risk of a

Topic of submission	Raised by	FSANZ response (including any amendments to drafting)
studies involved healthy participants consuming D-allulose with no other food, or with a meal not described beyond macronutrient composition. There is no laxative effect hazard assessment specific to children, or to people with irritable bowel syndrome, diabetes or other chronic diseases. Additionally, D-allulose and fructose compete for transport across the small intestine, so simultaneous consumption reduces absorption of D-allulose, and this may increase the risk of laxative effects due to a higher proportion of D-allulose reaching the large bowel. Due to the limited data, NZFS suggested additional risk management via a mandatory advisory statement. NZFS also noted the dietary intake assessment did not consider the scenario of D-allulose being consumed alongside other sugar substitutes including sugar alcohols, which may add to the laxative effects of consuming D-allulose. The threshold value is based on a study on healthy young adults. This evidence doesn't consider limits for children or people who are not 'healthy' (e.g., people with diabetes or with gastrointestinal conditions). Also noted adverse effects were sometimes described as 'severe' in the threshold studies.		laxative effect including when being consumed alongside other sugar substitutes. See labelling section in this table for more details. FSANZ also notes that for those consumers wanting to avoid low energy sugars, D-allulose will be listed in the statement of ingredients. It would be very difficult to undertake a dietary intake assessment on products containing D-allulose consumed alongside foods that also have the potential to cause a laxative effect. FSANZ is confident that an advisory statement on such products will provide consumers with a choice as to whether they consume these foods together. Any such ingredient will also be listed in the ingredient list on foods.
Dietary intake assessment Recommend further interrogation and explanation of the dietary modelling to justify any discrepancy with international permitted levels. Noted that the United States Food and Drug Administration (FDA) considers D-allulose intake of less than 0.5-0.6 g/kg bw/day as safe, which closely aligns with FSANZ's assessment of 0.4 g/kg bw/day. However, as AIFST understands, this difference in the maximum levels may be attributed to the dietary intake assessment methodology and notes the food consumption data used	AFGC, Buderim Foods, AIFST	The short-term dietary intake of added D-allulose was estimated following international best practice (FAO/WHO, 2020) and is appropriate to assess the risk of a laxative effect for high consumers (P97.5) for this assessment. This assessment resulted in proposing lower MPLs for some food classes than the those originally requested by the Applicant at Call For Submissions. Any discrepancies from differences to international intake assessments and associated permitted levels might be attributed to the country/region based consumption data and body weight data used, concentrations used and/or the methodology followed. For instance, when determining the maximum use concentration to not exceed the level that can cause a laxative effect, New Zealand children aged 5-14 years represented the worst-case scenario

Topic of submission	Raised by	FSANZ response (including any amendments to drafting)
is up to 20 years old.		because of the lower body weights for that age group in comparison to the other two population groups assessed, which tend to result in higher estimates of intake per kilogram of body weight. Another factor is the typically higher food consumption per kilogram of body weight for children due to their growth and development. Furthermore there were some uncertainties in the data and information used for this assessment. Hence FSANZ used conservative assumptions (as described in the A1247 SD1, section 3.5.2.5) to ensure that the estimated dietary intake was not an underestimation and was therefore representative of the worst case scenario. This is a general practice as outlined in FSANZ's Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes (FSANZ, 2009). A detailed description of the dietary intake assessment is provided in section 3.5 of the SD. The consumption data used for the dietary intake assessment may not reflect changes in the consumption of some food categories assessed (e.g., foods containing low- and reduced-energy/sugar) since it was collected. This will be reflected in future national nutrition surveys. FSANZ used consumption data available from the latest Nutrition surveys in Australia and New Zealand for this assessment. FSANZ has previously evaluated differences in consumption amounts between national nutrition surveys. It was found that for the majority of food groups, consumption amounts do not differ greatly, however there may be some variation in consumption of more specific or niche types of foods. The consumption amounts derived for food classes from national nutrition survey data available for use in this assessment will be representative of typical consumption amounts of current consumers. There will always be some variation in consumption amounts within a population.
Supported FSANZ's intention to reduce the MPLs of D-allulose from the amount originally requested by the applicant to mitigate the risk of a laxative effect. However, requested information to understand how the proposed levels were determined. The results of FSANZ's dietary intake assessment (in	NSWFA	FSANZ initially conducted a short-term assessment (assessment of potential laxative effects) based on the MPLs originally proposed by the applicant (Table 5, SD1). The results provided in Table 7, SD1, indicated that consumption of some food categories may exceed the threshold limit for a laxative effect (0.4 g/kg bw). As a result an additional analysis was undertaken to determine the maximum amount of D-allulose (%w/w) that could be added to each food category before causing a laxative effect as explained in the section '*Maximum*

Topic of submission	Raised by	FSANZ response (including any amendments to drafting)
Table 7 of SD (page 36)) suggested high consumption of some food categories may still exceed the daily intake limit of D-allulose (0.4 g/kg bw) at the proposed MPLs.		*use concentration to not exceed the level that can cause laxative effects'* in SD1. For this estimation where possible, similar food categories were combined to derive a high (P97.5) consumption value in order to determine a single maximum possible concentration. This was undertaken for the entire category such as 'biscuits, cakes and pastries' and 'water based flavoured drinks' etc as indicated in Table A2.1. in SD1. The modelling was used to determine the highest use level that would result in the laxative effect level not being exceeded. The exposure estimates provided in this submission are based on the consumption amounts estimated for each sub food category that were considered under combined/major categories by FSANZ for this estimation (Table A2.1., SD1). For the food category 'coffee based beverages' that included 'coffee beverage, decaffeinated, instant powder/granules', the added D-allulose to cause a laxative effect was estimated to be 0.7 %(w/w) and it was rounded to 1 % (w/w) according to FSANZ's standard rounding procedure and presented in Table 8, SD1. Please also note the comments above for details on the amendments made to the MPLs for D-allulose in the draft variation.

Topic of submission	Raised by	FSANZ response (including any amendments to drafting)
Noted 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)'. NSWFA considered setting (reduced) MPLs of D-allulose for each food category to be important but not sufficient to minimise the risk of a laxative effect and suggested additional measures to ensure consumers are aware of the risks incurred if consuming more than the ADI of D-allulose, i.e., mandatory advisory statement of a laxative effect, monitoring of low sugar product consumption patterns in subpopulations such as diabetics and those with hereditary fructose intolerance (HFI). NZFS noted there may be some sub-groups, such as people with type 2 diabetes, who could be more likely to replace numerous food items with low-sugar or low-energy alternatives, and therefore may consume multiple foods containing D-allulose at one time.	NSWFA, NZFS	FSANZ conducted chronic and short-term dietary intake assessments for added D-allulose. The chronic dietary intake assessment included intake from all the proposed food categories containing added-D-allulose, and does take into account where consumers ate more than one food containing added D-allulose in a day. The short-term dietary intake estimates were used to represent the high food consumer (P97.5) and a high intake, from a single food or food category, from one meal or over one day. These are the standard methods and internationally accepted best practices. Although it is standard practice, consideration of only one food category/food is a limitation of the short term assessment as noted in section 3.5.2.2 in the SD1. However, where possible, similar food categories were combined together or a higher level/ major food category was used to derive a high consumption value in order to determine a single maximum possible concentration for the entire/ combined category as explained in the section '*Maximum use concentration to not exceed the level that can cause laxative effects'* in the SD1 to address this limitation to a certain extent and minimise any potential risk '. The application of advisory labelling about possible laxative effects will enable consumers to make informed choices about whether to consume more than one food that could cause a laxative effect in one meal or over one day. See section 2.3.7.3 of this report for further discussion on the requirements for an advisory statement. For the short-term assessment, FSANZ is currently not aware of any potential adverse effects with subpopulations from the intake from other sugar substitutes.
FSANZ risk assessment – vulnerable subpopulation Considered 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. Given the significance of diabetes prevalence, encourage FSANZ to monitor consumption patterns of low energy sugar substitutes and potential adverse effects in	NSWFA	As part of the hazard assessment of D-allulose, FSANZ conducted a literature review to identify any studies, case reports or reviews not included in the Application. Several studies of the effects of D-allulose in patients with either Type 1 or Type 2 diabetes, or in rodent models of diabetes, were found. No adverse clinical effects of the consumption of D-allulose were identified in any of those studies at the doses employed. Beneficial effects on blood glucose and on insulin tolerance were reported (see SD1). FSANZ is currently not aware of any potential adverse effects of low energy sugar substitutes on this

Topic of submission	Raised by	FSANZ response (including any amendments to drafting)
this population group**.**		subpopulation.
Supported 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. Some submitters noted 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 system and noting that this subpopulation may be more likely to seek out low energy and low sugar foods. Considered that the maximum levels of use for each food category may help to mitigate the possible microbiological risk of high consumption.	NSWFA, NZFS, NZFGC	As part of the hazard assessment of D-allulose, FSANZ conducted a literature review to identify any studies, case reports or reviews not included in the application. Several studies of the effects of D-allulose in patients with either Type 1 or Type 2 diabetes, or in rodent models of diabetes, were found. In the studies on patients with diabetes, no adverse clinical effects of the consumption of D-allulose were identified in any of those studies.
Requested commentary from FSANZ about the risk of consumption of D-allulose by population with hereditary fructose intolerance (HFI). FSANZ's assessment identified that D-allulose is mainly absorbed from the small intestine by the same transporters as fructose (SD report page 13). Encouraged 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 metabolism. Suggested updating this advice by reviewing other permitted sugar substitutes and D-allulose.	NSWFA	There is no information in the peer-reviewed scientific literature concerning consumption of D-allulose by people with HFI. FSANZ notes that the metabolic defect in HFI is a deficiency of aldolase B, which is responsible for breaking down fructose-1-phosphate to glyceraldehyde and dihydroxyacetone phosphate. Since D-allulose does not undergo any significant metabolism, but is excreted unchanged, a lack of aldolase B would not be expected to affect the kinetics of D-allulose.

Topic of submission	Raised by	FSANZ response (including any amendments to drafting)
FSANZ risk assessment – risk to those with renal conditions FSANZ's safety assessment only included studies of D-allulose consumption in healthy adults as a result of study exclusion criteria which consistently removed participants with diabetes, hepatic and renal function disorders, and those that were pregnant or lactating. Submitters were concerned about the lack of data to establish microbiological safety in these subpopulations, particularly in individuals with renal conditions given it has been demonstrated that a high proportion of D-allulose is passed through and excreted via the kidneys, and in diabetic populations as they may be large consumers of foods containing low energy sugar substitutes. The departments also note that while several microorganisms were identified as carrying D-allulose metabolism genes (and therefore presenting potential risk for bacterial urinary tract infection), the clinical studies included in the safety assessment only considered *K. pneumoniae.* The VicDoH and DEECA suggested further consideration of microbiological risks and mitigation, including across uro-pathogenic bacteria and in potentially vulnerable consumer subpopulations, is required to establish safety. NZFS suggested the risk could be monitored via FSANZ's routine horizon scanning programme.	Vic DoH and DEECA, NZFS	FSANZ's assessment was based on the best available scientific evidence as required by the FSANZ Act. FSANZ is not aware of any evidence of a microbiological risk. There is no information in the peer-reviewed scientific literature concerning the consumption of D-allulose in trial participants with diabetes, hepatic and renal function disorders, during pregnancy or who were lactating. There is also no information in the peer-reviewed scientific literature concerning excretion of D-allulose in patients with renal insufficiency. Nor, were relevant studies on any other uro-pathogenic bacteria were identified.

Topic of submission	Raised by	FSANZ response (including any amendments to drafting)
Energy factor for D-allulose Considered that future evidence could strengthen the accuracy of FSANZ's calculation of metabolisable energy from D-allulose. Noted only two studies (one published, one unpublished) were used to estimate the proportion of D-allulose excreted in urine, and that urinary excretion varies according to the dose of D-allulose and appears to vary between individuals (based on the large standard deviations). However, despite limitations in the available data to inform energy calculations, the energy contribution of D-allulose is very low.	NZFS	FSANZ's assessment was based on the best available scientific evidence as required by the FSANZ Act.
To align more closely with international markets (USA: D-allulose energy factor 1.672 kJ/g; Korea and Japan 0 kJ/g) and to address potential disparities resulting from rounding, recommend either the adoption of the applicant's suggested value of 1.0 kJ/g or the allowance of rounding to one decimal place. It is important to align with global practices to mitigate potential trade implications and to facilitate greater export market access for Australian products. Rounding energy factor to a whole number can significantly impact outcomes, particularly when dealing with initial values that are very small compared to the majority of other energy factors.	ABCL, NZBC	FSANZ has assessed the energy factor for D-allulose using the equation set out in section 3.2.5.B.2 of the FSANZ Application Handbook and the scientific evidence as described in section 3.6 of SD1. Using this equation, FSANZ determined that the energy factor for D-allulose is 1.88 kJ/g, rounded to 2 kJ/g. There is no consistency with the energy factor for D-allulose internationally and so it is not possible to achieve global alignment. Rounding of energy factors for determining the energy content for the NIP was established before the joint Food Standards Code was developed and this practice has been consistently applied to new factors. FSANZ's decision is to maintain this approach. Rounding to 1.9 kJ/g instead of 2 kJ/g would have a minimal effect on the energy content listed in the NIP for foods with ingredients contributing fat, carbohydrate and/or protein which have much higher energy factors than D-allulose. Likewise, rounding the energy factor to one decimal place would have minimal impact on the energy value for foods with ingredients contributing little or no additional energy such as a zero sugar beverage with D-allulose.
Supports the proposed energy factor of 2 kJ/g. The value aligns closely with that prescribed in the USA of 0.4 kcal/g (equivalent to 1.67 kJ/g).	AFGC, AIFST, Buderim	Noted.

Topic of submission	Raised by	FSANZ response (including any amendments to drafting)
Labelling - Sugar and carbohydrate declarations in the NIP Low energy sugars and polyols are not included in the carbohydrate declaration in the NIP when determined using the *calculation of available carbohydrate by difference* set out in subsection S11—3(2). Seeks clarification as to whether the low energy sugars and polyols are included in carbohydrate declarations if using the *calculation of available carbohydrate* method. Industry has the ability to choose which method (available carbohydrate by difference or available carbohydrate) to use to calculate carbohydrate content for 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. D-allulose is a monosaccharide but is proposed to be excluded from the listing of sugars in the NIP. 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. Suggests there is room for education to assist consumer understanding of the NIP and relevant requirements.	NSWFA	D-allulose would not be included in the average amount of carbohydrate declared in the NIP when either method for determining carbohydrate concentration set out in section S11—3 is used. See section 2.3.7 for further discussion. Reviewing the methods for determining carbohydrate content of a food for the NIP is out of scope for this application. When adding the *calculation of available carbohydrate* method to the Code was considered in Proposal P247 (Definition of carbohydrate) in 2001, FSANZ noted there was on average, about 1.4% difference between analysed carbohydrate and carbohydrate by difference over a broad range of foods. Under fair trading laws information on food labels including claims should not be misleading or deceptive. FSANZ considers labelling requirements for low energy sugars are best considered on a case-by-case basis taking into account all relevant information. Trehalose, isomaltulose, low energy sugars and traditional sugars all have different properties, noting trehalose and isomaltulose are not low energy sugars.

Topic of submission	Raised by	FSANZ response (including any amendments to drafting)
It is important the requirements for calculation of sugars in the NIP for D-allulose is consistent with other low energy sugars such as D-tagatose. From nutritional perspective health professionals are concerned that D-allulose will not be included in the calculation of sugars in the NIP unless there is 5 g/100g or more present in the food.	QLDH	The provision in subsection 1.2.8—6(9) requires the amount of D-allulose to be declared in the NIP if it is present in a food (with or without other substances listed in subsection S11—2(3), except for organic acids) in an amount no less than 5 g/100 g. This requirement is not about sugars declaration in the NIP. FSANZ's decision is to exclude D-allulose in the sugars declaration in the NIP, as discussed in section 2.3.7.1 of the report. Labelling requirements for low energy sugars are best considered on a case-by-case basis, noting due to differing properties there may be reasons to vary labelling requirements.
Labelling - Nutrition content claims Requests FSANZ revise the draft variation at approval and confirm how D-allulose will be aligned in the new definition of 'sugars', as per the recent gazettal of proposal P1062 - Defining added sugars for claims. Given specified nutrition content claims will be allowed, requests D-allulose be excluded from the added sugars definition.	ABCL, NZBC, NSWFA	The draft variation has been amended in view of changes made to the *no added sugar(s)* claim conditions from Proposal P1062. See section 2.3.7.
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. 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.	NSWFA	FSANZ notes that as part of the FDA's consideration of D-allulose for nutrition and energy labelling purposes, a review of the scientific evidence related to the cariogenic potential, metabolism, and caloric value of, and glycemic response to, allulose was undertaken. The FDA concluded D-allulose does not promote dental caries due to its low cariogenic potential. It was also concluded that allulose produces only a negligible increase in glycemic and insulinemic responses (FDA, 2020). While FSANZ did not assess cariogenic potential or glycemic index for this application, permitting foods containing D-allulose to make claims about sugars does not appear to be inconsistent with the low cariogenic potential and minimal impact of D-allulose on glycemic response.

Topic of submission	Raised by	FSANZ response (including any amendments to drafting)
Considers there is potential for consumers to be misled by no added sugar claims or there to be confusion by a health halo concept that may promote some items as a healthier choice. This is inconsistent with a key priority of the food regulation system (Priority 2) to support the public health objectives to reduce chronic disease related to overweight and obesity. Suggest FSANZ consider the recent World Health Organization guideline 'Use of non-sugar sweeteners' which suggests that non-sugar sweeteners should not be used as a means of achieving weight control. As a low-energy substitute for conventional sugar ingredients, it appears it may be appropriate for nutrition content claims for energy to be used in relation to D-allulose. However, with a proposed energy factor of 2 kJ/g (200 kJ/100 g), it appears products containing D-allulose may not qualify for the energy nutrition content claims 'low' (energy) and 'diet'. It is inappropriate for an 'unsweetened' nutrition content claim to be used for D-allulose and is not supported because it is misleading. D-allulose has approximately 70% of the sweetness of sucrose and therefore significantly contributes to sweetness. Similar to D-tagatose, if D-allulose was included in the definition of 'sugars*' it would not be permitted to include a nutrition content claim for *unsweetened*.	QLDH	Permission for foods containing D-allulose to display nutrition content claims such as *no added sugar(s)* is consistent with the *Policy Guideline on Nutrition, Health and Related Claims*. FSANZ had regard to this guideline in the development of claim permissions and conditions under Proposal P293 – Nutrition, health and related claims. More recently FSANZ amended conditions for *no added sugar(s)* claims to ensure they aligned with dietary guidelines in Australia and New Zealand to better inform food choice (Proposal P1062 – Defining added sugars for claims). As low energy sugars such as D-allulose and D-tagatose are specifically excluded from the WHO guideline on the use of non-sugar sweeteners, FSANZ has not considered the guideline for this application. Foods containing D-allulose would need to meet existing conditions in Section S4—3 for *low energy* and *diet* claims. For example, a beverage containing D-allulose could display a *low energy* claim if the beverage has an average energy content of no more than 80 kJ/100 mL. Given the approved draft variation permits D-allulose to be added to water based flavoured drinks up to a maximum of 3.5% w/w, such a product is likely to meet claim conditions provided D-allulose plus any other ingredients do not contribute more than 80 kJ/100 mL. There are requirements in addition to the maximum energy content for *diet* claims as set out in Section S4—3. FSANZ agrees that foods containing low energy sugars such as D-allulose (and D-tagatose) should not be permitted to display *unsweetened* claims, however this was not explicit in the Code when submissions were called on the draft variation. The amendments made to the *unsweetened* claim conditions from Proposal P1062 prohibit foods containing low energy sugars, as ingredients, listed in subsection S11—2(3) of Schedule 11 from making such claims. See section 2.3.7.2 of this report for further discussion.

Topic of submission	Raised by	FSANZ response (including any amendments to drafting)
There is limited available evidence demonstrating that the energy contribution from D-allulose varies according to the amount consumed and likely according to whether it is eaten concurrently with fructose. Suggests further consideration is needed for an energy cut-off at which a low-sugar sweetener can be considered an added sugar.	NZFS	While evidence suggests the energy contribution from D-allulose may vary depending on whether D-allulose is consumed with or without fructose, it is likely that in both situations the energy contribution will be small (see section 3.2.1.5 of SD1). FSANZ considers claim permissions for foods containing low energy sugars are best considered on a case by case basis at the time applications for permission to add are assessed. This will ensure all relevant information is considered, noting that energy factors and metabolic impacts may vary.
Requests that in the first Note in Section S4—2 (i.e. the definition of *sugars* in Section 1.1.2—2), 'hexose monosaccharide (other than D-allulose)' is in parts (a) and (b)(i), not just in part (a).	ABCL	Not supported. The application sought an amendment to the Code to permit the nutrition content claims *% free, low sugar(s), reduced/lite* and *no added sugar(s)* on foods that contain added D-allulose. For the reasons listed in the CFS and this report, FSANZ's assessment is to permit such claims provided certain conditions are met. The amendment in question implements that outcome. The latter does not require the change to the Code requested by the submitter. Additionally the submitter's suggested Code change is not required to exclude D-allulose from sugars declarations in the NIP (see responses above).
Suggests a typographical error in the drafting is corrected. The second 'sugars' in the title of Item 7 [Section S4—3 (table item dealing with nutrition content claims in relation to 'sugars or sugars') should be sugars*.	QLDH	FSANZ agrees there is a typographical error in the title of Item 7 in the drafting in the CFS but sugars* is not correct. It should read: 'table item dealing with nutrition content claims in relation to 'sugar or sugars'. This amendment has been made in the approved draft variation (see item 8 at Attachment A).

Topic of submission	Raised by	FSANZ response (including any amendments to drafting)
Labelling - Declaration of D-allulose in the NIP Seek clarification on whether the inclusion of D-allulose in the NIP from requirements in subsection 1.2.8—6(9) would impact carbohydrate/sugar values and consequently influence nutrition content claims related to sugar. Suggests D-allulose be labelled in the NIP akin to sugar alcohols, positioned under sodium at the bottom of the NIP. This would minimise consumer confusion arising from assumptions about its metabolic properties. The current regulatory framework presents a dual perspective: while there is no obligation to disclose D-allulose on the label, except through an inclusion in the ingredient statement, a contradictory provision exists. When D-allulose is utilised singly or in combination with substances outlined in subsection S11—2(3) (excluding organic acids) and the value surpasses 5g/100g, there is a requirement for identification in the NIP. This duality poses challenges and may contribute to consumer confusion, undermining the objective of facilitating informed choices. The ABCL contends that consumers can make informed decisions based on the ingredient statement, as per established requirements.	ABCL, NZBC	FSANZ's decision is to exclude D-allulose from the average quantity of sugars declared in the NIP as most D-allulose is not metabolised (see section 2.2.5.2 in the CFS). As discussed above, based on provisions in Section S11—3, D-allulose would also not be included in carbohydrate declarations in the NIP. A declaration of D-allulose in the NIP (in accordance with subsection 1.2.8—6(9)) would not affect nutrition content claims about carbohydrate or sugar(s). If required from subsection 1.2.8—6(9), D-allulose must be listed in the NIP in accordance with provisions set out in Schedule 12 of the Code. The requirement in subsection 1.2.8—6(9) to declare D-allulose when used singly or in combination with other substances listed in subsection S11—2(3) (except for organic acids) at a concentration over 5 g/100 g was intended to provide information to consumers who may be sensitive to a laxative effect from excess consumption of polyols, isomalt and/or polydextrose. The advisory statement about a laxative effect is required when such substances are present either alone or in combination at a concentration of 10g/100g or 25 g/100g depending on the substance concerned. The degree of a laxative effect from D-allulose will vary amongst individuals with some having a greater sensitivity than others. FSANZ therefore considers it is appropriate to require the average quantity of D-allulose to be declared in the NIP in accordance with existing provisions in subsection 1.2.8—6(9) to support informed choice.
Despite the requirement in Section 1.2.8—6(9), the NIP created using Nutrition Panel Calculator does not show special listing of substances listed in subsection S11—2(3). Requests FSANZ addresses this issue so that the NIP created using the calculator will be compliant.	NSWFA	When the Nutrition Panel Calculator was developed, it focussed exclusively on the seven mandatory components in a NIP. Expansion to include additional components as listed items in the NIP would be resource intensive and require significant redevelopment of the current system.

Topic of submission	Raised by	FSANZ response (including any amendments to drafting)
Agrees that if D-allulose and other substances listed in subsection S11—2(3) are present in an amount of no less than 5 g/100 g and if carbohydrate content is determined using the available carbohydrate by difference calculation, then D-allulose would require separate declaration in the NIP. This provision ensures transparency with the amount of each substance used in the food.	AFGC NSWFA	FSANZ notes subsection 1.2.8—6(9) requires that if D-allulose (with or without other substances listed in subsection S11—2(3), except for organic acids) is present in a food in an amount no less than 5 g/100 g, then D-allulose would need to be listed in the NIP if carbohydrate content is determined using the *calculation of available carbohydrate by difference* or the *calculation of available carbohydrate* as set out in Section S11—3.
Advisory statement about laxative effect 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 are likely to be conveyed on the package in the form of the NIP and claims (e.g. sugar/energy claims). Consider balanced information should be provided on the package to enable consumers to make informed food choices.	NSWFA	Following consideration of the outcomes of the dietary intake assessment on a potential laxative effect from foods containing D-allulose at the applicant's proposed MPLs, FSANZ has decided to amend the draft variation to require an advisory statement to the effect that excess consumption may have a laxative effect for certain food classes, irrespective of the D-allulose concentration in the food (see section 2.3.7.3 of the report).

Topic of submission	Raised by	FSANZ response (including any amendments to drafting)
Suggest there should be consideration of the need for a mandatory advisory statement under Section 1.2.3 – 2 related to the risk of a laxative effect because D-allulose is only partially absorbed from the gastrointestinal tract, and there is evidence that this creates an osmotic laxative effect at moderate intake levels. Maximum limits are determined on the assumption that only one D-allulose containing food is consumed at one time. Concerned that setting MPLs as proposed by FSANZ may still result in intake of D-allulose above the threshold level to cause a laxative effect in high consumers e.g. by consuming dessert and a soft drink both containing D-allulose in one occasion, or for anyone who is replacing many foods with low-energy, low-sugar alternatives. This is due to the lack of evidence to inform the threshold for requiring the mandatory advisory statement, so a mandatory advisory statement would be the most conservative option. While the proposed MPLs for D-allulose are below the level that would require the mandatory labelling under Section 1.2.3 – 2 for most foods, there are a small number of categories that pose a risk for laxative effect due to higher permitted levels (chewing gum, sugar substitutes).	VIC DoH and DEECA NZFS QLDH	As noted above FSANZ has decided to amend the draft variation to require an advisory statement for certain food classes irrespective of D-allulose concentration (see section 2.3.7.3 of the report). The dietary intake assessment undertaken to determine the risk of a laxative effect takes into account not only the MPLs for the food class but also the amount of the food typically consumed. Therefore, a food with a higher concentration of D-allulose doesn't necessarily pose a risk of a laxative effect if a small amount is consumed.

Topic of submission	Raised by	FSANZ response (including any amendments to drafting)
Suggests FSANZ considers requiring a maximum one-day intake statement for tabletop sweeteners. This could mitigate the risk of an individual consuming a quantity far above what has been assessed in threshold studies. We note the animal studies indicate that extremely high levels of intake may cause gastrointestinal haemorrhaging, but there is no information on unsafe levels of intake in humans.	NZFS	The evidence suggests that it is unlikely that an individual would consume more than 28 g D-allulose (0.4 g/kg bw) from a tabletop sweetener during one day. The dietary intake assessment indicated a very low intake of D-allulose from such a product (see Table 7 in SD1).
Many food categories will contain less than 5 g/100g of D-allulose (as per Section S25—2), and for these foods, the D-allulose content will not be required in the NIP. For individuals who are more sensitive to non-digestible carbohydrates, one of two labelling options may assist in providing clear information – either requiring the mandatory advisory statement at any level of D-allulose or requiring that the NIP includes D-allulose at concentrations below 5 g/100g.		As discussed above, FSANZ has decided to amend the draft variation to require the advisory statement for certain food classes, irrespective of D-allulose concentration.
WTO Notification Recommended FSANZ notify the WTO of this application to ensure harmonisation with international markets and so that member states have the opportunity to respond.	ABCL, AFGC, NZBC	A notification to the WTO under Australia's and New Zealand's obligations as a part of the WTO Technical Barriers to Trade agreement has been made to enable WTO members to comment on the amendments to the Code.
Public health benefit of D-allulose Outright support for D-allulose in Australia and New Zealand due to taste and benefit to public health (diabetes and metabolic (illnesses).	Individual	FSANZ notes this comment.

Topic of submission	Raised by	FSANZ response (including any amendments to drafting)
Concern that FSANZ has not acknowledged the magnitude of the potential impact of allulose on reducing obesity rates. FSANZ has a duty of care to consider these more serious risks as part of the National Obesity Strategy 2022-2032. Provided a number of papers relating to carbohydrate reduction and obesity management (see submission) and provided an alternative solution: • Secure the latest enzyme that allows for continuous allulose manufacture at a lower price point. • Require product manufacturers to adequately label their product packaging with laxative information. • Work with the sugar cane industry to convert their materials to allulose. • Allow self-regulation as there is only so much allulose that can be added for product performance and taste before it becomes cost prohibitive. Set the FSANZ application fee to be a nominal amount in recognition of the public health service that Samyang Corporation has done for the broader benefits of health.	Individual	FSANZ is supportive of reducing overweight and obesity-related illnesses in populations, especially populations that are more at-risk of such illnesses and effects. FSANZ limited its assessment to the specific request from the application, in accordance with the FSANZ Act, therefore can only assess: • the specific enzyme used by Samyang to manufacture their D-allulose. • Laxative effect with regards to labelling (see section 2.3.7.3 of the report). FSANZ will consider applications relating to the use of a different technology or enzyme(s) for the manufacture of D-allulose or to permit its broader use in food. An applicant is able to make an unpaid application.

Topic of submission	Raised by	FSANZ response (including any amendments to drafting)
In the application, FSANZ has not established a significant, fatal health risk that warrants the allulose limits. There is no mention of even having considered laxative product labelling as a cost effective alternative risk management solution. Instead, the misguided dosage regulation being suggested represents the worst case scenario 'for 50 different products across 15 broad food classifications'. This will significantly hinder allulose from practically being enabled in product formulations, as a sugar substitute. By limiting the role that allulose can play in mitigating obesity related fatalities, justified based on managing non-fatal risks and exceptional scenarios, FSANZ is failing in their legal duty of care to protect the health of people in ANZ.	Individual	FSANZ has only assessed the addition of D-allulose to the foods requested by the applicant. Therefore, the permission must be limited to those foods. FSANZ notes also that it is required to assess this application to amend the Code in accordance with the FSANZ Act.
Exclusivity Supported the exclusivity period as it recognises the investment made in developing the application, food and/or ingredient thereby supporting innovation. Some submitters however, had general concerns regarding FSANZ's approach towards exclusivity and sought clarity regarding the application of exclusivity and its implications on the food industry to ensure a level playing field.	ABCL, NZBC, AFGC	Exclusive permissions for novel foods were introduced in 2007 under Proposal P305 - Permission for Exclusivity of Use of Novel Foods. This followed requests from the food regulation ministers for FSANZ to consider: • the capacity for including a specific provision for exclusivity of use for novel foods in Standard 1.5.1, and • a limit on the period of exclusive permission as a novel food for a particular brand of up to 15 months, after which any exclusive permissions revert to a generic permission at the expiration of the approved period of exclusivity. The above is reflected in the current Food Regulation Policy guideline on novel foods, which includes the following specific policy principle: To provide an assessment process that aims to protect commercially sensitive information and recognise industry's intellectual property to the maximum extent possible.

Topic of submission	Raised by	FSANZ response (including any amendments to drafting)
Exclusivity is likely to result in barriers to trade for products already on the market outside of Australia and New Zealand. Companies who wish to take up the opportunity to incorporate D-allulose in their existing or new products will have only one supply option which will potentially reduce the number of new products available if companies are nervous about continuity of supply from a single company.	AIFST	See above response.
The length of the exclusivity period will create personal and societal costs that are significant with major impacts on society, the economy, natural resources and ecosystems. Is an anti-competitive move which prevents anyone else selling existing products with a different brand of allulose. This is a breach of Trans-Tasman anti-trust legislation and counter to making healthier food choices more accessible particularly to indigenous people. Stated the exclusivity section in the CFS was 'poorly worded and not clear enough for sufficient consultation'. Questioned the costs incurred to Samyang: • Samyang have already had 9 years of selling allulose • multiple GRAS notes have already been approved • no new technology has been developed specifically for the FSANZ approval process • test results in the application were not funded by Samyang • similar wording is used across the USA, FSANZ and European applications. Suggested: • Set the FSANZ application fee to be a nominal amount in recognition of the public health service	Individual	Any applicant for a novel food can legally request an exclusive use period available option. Whether or not FSANZ should accept an exclusive use period or mandate a length of that period is out of scope for this application. See the response above for further information about exclusivity. This permission is deregulatory in nature, meaning that Food Ministers, when approving a relevant regulatory measure proposed by FSANZ, are permitting addition to food of a substance that was not previously permitted. Application fees or charges are set or fixed by the FSANZ Act, not FSANZ. FSANZ is required to comply with that Act in this regard. In this case, the Act required the fees in question to be imposed and paid. An exclusive use permission in the Code does not prevent approval of subsequent applications 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. The period of exclusive permission as a novel food or nutritive substance for a particular brand is limited at up to 15 months from the time of gazettal, after which any exclusive permissions would revert to a generic permission at the expiration of the approved period of exclusivity. An exclusive use permission in the Code does not prevent approval of subsequent applications 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.

Topic of submission	Raised by	FSANZ response (including any amendments to drafting)
that Samyang Corporation has done for the broader benefits of health. • 4 month exclusivity to only the ingredient supply and not the products that it's made in. This Application sets a precedent which prevents product innovation as the nature of the applicant's business is sweetener manufacturing, not product manufacturing. FSANZ risks accepting actions under one piece of legislation aimed to encourage innovation, with the effect of being illegal under the *Commerce Act 1986* (NZ) which prohibits a contract/arrangement that has the purpose, or of substantially lessening competition in the market. Australia also has the *Competition and Consumer Act 2010*.		
Noted a new innovation developed since the US GRAS application and stated the applicant's technology was obsolete. Industry will have to experience 15 months of inflated allulose prices but benefit will be negated as the enzyme production methods available now are more innovative than the one requested by Samyang.	Individual	FSANZ appreciates that there may be other methods for producing D-allulose, but must assess the method requested by the applicant as required by the FSANZ Act. The granting of an exclusive use permission does not preclude anyone else from applying to amend the Code in relation to the sale or production of D-allulose, including permission for the use of a different enzyme(s) for its manufacture or an alternative specific method of production, within or following the 15 month exclusive use period. See comments above.
Enforcement Questioned how the exclusivity permission would be enforced at the border since the source (supplier) of D-allulose in a product would not be obvious at the point of entry.	AIFST	Noted. This is a matter for the Department of Agriculture, Fisheries and Forestry at the relevant border under the Imported Food Inspection Scheme and Ministry for Primary Industries in New Zealand. FSANZ notes that no regulator raised this as an issue.
Other The submitter also raised several concerns regarding the applicant's commercial activities in the marketplace.	Individual	These concerns are outside the scope of this application and FSANZ's assessment.

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.

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 immediately after the commencement of the *Food Standards (Proposal P1063 – Code Revision (2024) – Added Sugar(s) Claims) Variation*.

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—means monosaccharides (other than D-allulose) and disaccharides; and

Standard 1.2.3—Information requirements – warning statements, advisory statements and declarations

[2] Paragraph 1.2.3—2(2)(c)

Repeal the paragraph, substitute:

(c) one or more of the substances listed in paragraph (a), in combination with one or more of the substances listed in paragraph (b), at a level of or in excess of 10 g/100 g; or

(d) added D-allulose as an ingredient and the food is one of the following:

(i) a bakery product;

(ii) bubble gum;

(iii) chewing gum;

(iv) breakfast cereal;

(v) confectionery (but not chocolate);

(vi) a dessert (with or without gelatine);

(vii) ice cream;

(viii) edible ice;

(ix) a non-alcoholic water based flavoured drink (as defined in the table to section S25—2);

(x) yoghurt.

Standard 1.2.7—Nutrition, health and related claims

[3] 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—means monosaccharides (other than D-allulose) and disaccharides. (Elsewhere in the Code it has a different definition).

Standard 1.2.8—Nutrition information requirements

[4] 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—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

[5] 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—means monosaccharides (other than D-allulose) and disaccharides; and

Schedule 2—Units of measurement

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

Insert:

w/w	weight per weight

Schedule 4—Nutrition, health and related claims

[7] 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—means monosaccharides (other than D-allulose) and disaccharides; and

[8] Section S4—3 (table entry dealing with "Sugar or sugars", descriptor of 'No added' in column 3, subparagraph (f)(i) in column 4)

Omit "hexose monosaccharides and disaccharides", substitute "hexose monosaccharides (other than D-allulose) and disaccharides"

Schedule 11—Calculation of values for nutrition information panel

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

Insert:

D-allulose	2

Schedule 18—Processing aids

[10] Subsection S18—9(3) (table)

Insert:

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

Schedule 25— Permitted novel foods

[11] Section S25—2 (table)

Insert:

D-allulose	1. May only be a food for retail sale if that food is a tabletop sweetener. 2. May only be added to a food listed in condition 4. 3. A food listed in condition 4 must not contain added D-allulose in an amount or at a level greater than the limit, if any, specified in that condition for that food. 4. The listed foods are: (a) bakery products (limit: 10% w/w); (b) bubble gum (limit: 50% w/w); (c) breakfast cereals (limit: 5% w/w); (d) cereal bars (limit: 5% w/w); (e) chewing gum (limit: 50% w/w); (f) confectionery (but not chocolate) (limit: 50% w/w); (g) desserts (with or without gelatine) (limit: 10% w/w); (h) edible ices (including sorbet) (limit: 5% w/w); (i) frostings (limit: 5% (w/w)); (j) fruit spreads (but not chutney) (limit: 10% w/w); (k) ice cream (limit: 5% w/w); (l) icings (limit: 5% w/w); (m) imitation cream (limit: 5% w/w); (n) non-alcoholic water based flavoured drinks (limit: 3.5% w/w); **Note** See the definition of 'a non-alcoholic water based flavoured drink' in condition 5 below. (o) salad dressings (limit: 5% w/w); (p) sweet sauces (limit: 10% w/w); (q) syrups (limit: 10% w/w); (r) tabletop sweeteners (limit: 100% w/w); (s) yoghurt (limit: 5% w/w); **Note** An advisory statement to the effect that excess consumption may have a laxative effect is required for certain foods for sale containing D-allulose. See subsection 1.2.3—2(2) 5. For the purposes of this permission, a **non-alcoholic water based flavoured drink:** (a) includes: a brewed soft drink; a non-brewed soft drink; a cola type drink; a formulated caffeinated beverage; a fruit drink; a tea beverage; a coffee beverage; a powdered drink concentrate; and a liquid drink concentrate; and (b) does not include: a food standardised in Part 2.9 of the Code; a dairy analogue; a fruit juice; a vegetable juice; a formulated beverage; an electrolyte drink; and an electrolyte drink base. 6. During the exclusive use period, only D-allulose sold under the brand Nexweet may be a food for retail sale in accordance with condition 1 or added to food in accordance with conditions 2 to 5 above. 7. For the purposes of condition 6 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 – Explanatory Statement

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 sought to amend the Code to permit the use of D-allulose as a novel food from enzymatic conversion of fructose by D-psicose 3-epimerase contained in *M. foliorum*. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation - the *Food Standards (Application A1247– D-allulose as a novel food) Variation* (the approved draft variation).

Following consideration by the Food Ministers' Meeting (FMM), Section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the approved draft variation.

2. Variation is a legislative instrument

The approved draft variation is a legislative instrument for the purposes of the *Legislation Act 2003* (see Section 94 of the FSANZ Act) and is publicly available on the Federal Register of Legislation (www.legislation.gov.au).

This instrument is not 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 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 approved a draft variation to amend Standards 1.1.2, 1.2.3, 1.2.7, 1.2.8, 2.6.2 and Schedules 2, 4, 11, 18 and 25 to permit, subject to certain specified conditions: the sale and use of D-allulose as a novel food; and the use of a particular enzyme – the D-psicose 3-epimerase from *M. foliorum* - as a processing aid in the production of D-allulose.

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.

Subsection S3—2(1) incorporates by reference the United States Pharmacopeial Convention (2022) Food chemicals codex (13th edition), which establishes specifications for 'Allulose'.

Subsection S3—3(g) incorporates by reference The Merck Index, 15th Edition, being a secondary source within S3—3, which establishes a specification for 'D-psicose' (O'Neil et al 2013).

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 26 (2021)); and in the United States Pharmacopeial Convention (2022) Food Chemicals Codex (13th edition). Both include general specifications for the identity and purity of enzyme preparations used in food processing. These will be relevant for D-psicose 3-epimerase.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of application A1247 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 8 November 2023 for a 6-week consultation 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 was unlikely to have a more than minor regulatory impact.

6. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under Section 44 of the *Legislation Act 2003*.

7. Variation

Clause 1 provides that the name of the approved draft 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 approved draft variation will commence and take effect immediately after the commencement of the *Food Standards (Proposal P1063 – Code Revision (2024) – Added Sugar(s) Claims) Variation* (the P1063 variation). The P1063 variation amends many of the same provisions that the approved draft variation amends. The P1063 variation removes a redundant term from those provisions. For that reason, clause 3 provides that the approved draft variation shall take effect immediately after the P1063 variation takes effect.

Items [1] to [11] of the Schedule of the approved draft variation amend the Code.

Item [1]

Item [1] amends paragraph (a) of the definition of "sugars" in subsection 1.1.2—2(3) of the Code. It repeals the paragraph and substitutes it with the following new paragraph (a):

"(a) in Standard 1.2.7, Standard 1.2.8 and Schedule 4—means monosaccharides (other than D allulose) and disaccharides; and"

The effect of this amendment is 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.

The amendments made to the Code by Items [3] – [5], and [7] are as a consequence of this amendment.

Item [2]

Item [2] amends Section 1.2.3—2 of the Code. It repeals paragraph 1.2.3—2(2)(c) and substitutes it with the following new paragraphs:

(c) one or more of the substances listed in paragraph (a), in combination with one or more of the substances listed in paragraph (b), at a level of or in excess of 10 g/100 g; or

(d) added D-allulose as an ingredient and the food is one of the following:
    (i) a bakery product;
    (ii) bubble gum;
    (iii) chewing gum;
    (iv) breakfast cereal;
    (v) confectionery (but not chocolate);
    (vi) a dessert (with or without gelatine);
    (vii) ice cream;
    (viii) edible ice;
    (ix) a non-alcoholic water based flavoured drink (as defined in the table to section S25—2);
    (x) yoghurt.

Section 1.2.3—2 of the Code provides that the labelling of certain foods must include certain statements in accordance with Standard 1.2.1. Subsection 1.2.3—2(2) lists the foods that, in accordance with Standard 1.2.1, must have an advisory statement to the effect that excess consumption may have a laxative effect. The amendment made by Item [2] will in effect require such an advisory statement to appear on or in the labelling of a food for sale in accordance with Standard 1.2.1 if the food for sale: is a food listed in subparagraphs 1.2.3—2(2)(d)(i) – (x); and contains added D-allulose as an ingredient.

Item [3]

Item [3] amends the definition of "sugars" in Note 1 of section 1.2.7—2 by repealing the paragraph and substituting it with the following new paragraph:

"***sugars***, in Standard 1.2.7, Standard 1.2.8 and Schedule 4—means monosaccharides (other than D-allulose) and disaccharides. (Elsewhere in the Code it has a different definition)."

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

Item [4]

Item [4] amends the definition of "sugars" in Note 1 of section 1.2.8—4 by repealing the paragraph and substituting it with the following new paragraph:

"***sugars***, in Standard 1.2.7, Standard 1.2.8 and Schedule 4—means monosaccharides (other than D-allulose) and disaccharides. (Elsewhere in the Code it has a different definition)."

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

Item [5]

Item [5] amends 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—means monosaccharides (other than D-allulose) and disaccharides; and"

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

Item [6]

Item [6] amends Schedule 2 of the Code. It inserts 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 needed as the amendment in item [11] below refers to "w/w". Schedule 2 does not currently contain a meaning for that symbol.

Weight per weight (w/w) is a reference to the weight of each component being used to calculate levels of addition, irrespective of whether either is a solid or a liquid. In the case of a liquid, the volume is ignored. Instead, the weight of that liquid is used in the calculation.

Item [7]

Item [7] amends 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—means monosaccharides (other than D-allulose) and disaccharides; and"

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

Item [8]

Item [8] amends Schedule 4 of the Code. It amends the conditions listed in column 4 of the table to section S4—3 for making "no added sugars" nutrition content claims. The amendment replaces the words ("hexose monosaccharides and disaccharides") in condition (f)(i) with "hexose monosaccharides (other than D-allulose) and disaccharides".

The amendment's effect is provides that conditions (a) and (b) listed in the table to section S4—3 for making a "no added sugars" nutrition content claim do not apply to D-allulose, which is a hexose monosaccharide.

Item [9]

Item [9] amends 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"

The effect of this amendment is to assign D-allulose an energy factor of 2 kJ/g to be used in the calculation of "average energy content" for the purposes of Standard 1.2.8 and Schedule 11.

Item [10]

Item [10] amends the table to subsection S18—9(3) in Schedule 18 of the Code. The table lists substances permitted by the Code to be used as a processing aid for a specific technological purpose. The amendment inserts, in alphabetical order, a new entry into the table.

The new entry lists in column 1 of the table the permission to use the following enzyme as a processing aid: "D-psicose 3-epimerase (EC 5.1.3.30) contained in *Microbacterium foliorum*".

The new entry lists in column 2 of the table the specific permitted technological purpose for which this enzyme may be used as a processing aid: "For use in the manufacture of D-allulose".

The permission is subject to the condition, as prescribed in column 3 of the table, that the maximum permitted level or amount of this enzyme that may be present in a final food must be consistent with *GMP* or *Good Manufacturing Practice* (as defined in section 1.1.2—2 of the Code).

The effect of the amendment is to permit the proposed use of the above-mentioned enzyme as a processing aid in accordance with the Code.

Item [11]

Item [11] amends the table to section S25—2 of Schedule 25 of the Code

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 the express permission required by those paragraphs. The section provides that a food offered for retail sale may consist of, or have as an ingredient, a novel food if:

(a) the novel food is listed in the table to section S25—2;

(b) 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.

Item [11] inserts a new entry into the table. The new entry:

- permits D-allulose as a novel food to be a food for retail sale or to be present as an ingredient in a food for retail sale; and

- specifies seven conditions of use for D-allulose as a permitted novel food.

The conditions specified are as follows.

Condition 1 provides that D-allulose may only be a food for retail sale if that food is a tabletop sweetener. That is, D-allulose itself may be sold at retail sale only as a tabletop sweetener.

Condition 2 provides that D-allulose may only be added to a food listed in condition 4. That is, D-allulose must not be added to any food which is not listed in condition 4.

Condition 3 provides that food listed in condition 4 must not contain added D-allulose in an amount or at a level greater than the limit, if any, specified in that condition for that food.

Condition 4 lists the foods to which D-allulose may be added and the maximum permitted amount for D-allulose in each food. As explained above, condition 3 requires that the amount of D-allulose present in the relevant food not exceed that specified limit.

A Note is provided following condition 4 which directs the reader to the advisory statement required by subsection 1.2.3—2(2). The Note states that an advisory statement to the effect that excess consumption may have a laxative effect is required for certain foods for sale containing D-allulose.

Condition 5 clarifies, for the purposes of the permission to add D-allulose to non-alcoholic water based flavoured drinks, as per the condition at 4(n), that the meaning of a non-alcoholic water based flavoured drink**:**

(a) includes: a brewed soft drink; a non-brewed soft drink; a cola type drink; a formulated caffeinated beverage; a fruit drink; a tea beverage; a coffee beverage; a powdered drink concentrate; and a liquid drink concentrate; and

(b) does not include: a food standardised in Part 2.9 of the Code; a dairy analogue; a fruit juice; a vegetable juice; a formulated beverage; an electrolyte drink; and an electrolyte drink base.

Condition 6 provides that, during the exclusive use period as defined by condition 7, only D-allulose sold under the brand *Nexweet* may be:

- a food for retail sale in accordance with condition 1 above; or
- added to food in accordance with conditions 2 to 5 above.

Condition 7 defines the term “exclusive use period” for the purposes of condition 6 as 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 6 will automatically cease to have effect. At that point, the D-allulose novel food permission provided by the new entry will apply to - and permit - any and all brands of D-allulose that comply with the Code.

Attachment C – Draft variation to the Australia New Zealand Food Standards Code (call for submissions)

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

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	4.	May only be added to a food listed in condition 3.
	5.	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.