Project Officer Application A1247
Food Standards Australia New Zealand
PO Box 10559
The Terrace
Wellington 6036

20 December 2023

Tēnā koe,

Application A1247 – D-allulose as a novel food

New Zealand Food Safety (NZFS) welcomes the opportunity to comment on the Call for Submissions for Application A1247 – D-allulose as a novel food.

Food technology assessment

NZFS agrees with FSANZ's conclusion that D-allulose is suitable for use in foods as a low energy substitute or partial substitute for conventional sugar ingredients, and that use of enzyme D-psicose 3-epimerase (EC 5.1.3.30) as a processing aid in the production of D-allulose is technologically justified and there are no safety concerns. Both D-allulose and enzyme D-psicose 3-epimerase meet the relevant identity and specifications of the Food Standards Code.

Hazard assessments of D-allulose and D-psicose-3-epimerase

NZFS notes that maximum levels for D-allulose are allocated by food category as a condition of use for the novel food to manage possible laxative effects. However, we note that there was no safety assessment specific to impaired kidney function. D-allulose may in theory pose a risk to individuals with low glomerular filtration rate or kidney disease, since approximately 80% of consumed D-allulose is excreted in the urine. We suggest that this potential risk could be monitored via FSANZ's routine horizon scanning programme.

NZFS agrees with FSANZ's safety assessment conclusion that, based on the available evidence, there are no public health and safety concerns identified from the proposed use of enzyme D-psicose 3-epimerase as a food processing aid at GMP levels in the production of D-allulose. We note the applicant provided analytic results confirming that the presence of D-psicose 3-epimerase in the final D-allulose products is expected to be negligible, and hence no dietary exposure for the enzyme was assessed.

Dietary intake assessment

The dietary intake assessment utilised food consumption data from three surveys, two of which provided New Zealand data (the 2002 NZ National Children's Nutrition Survey and the 2008/09 NZ Adult Nutrition Survey). Dietary intakes were estimated only for consumers of foods containing D-allulose. Two scenarios were assessed to estimate chronic dietary intakes of D-allulose: 'added D-allulose' and 'naturally occurring D-allulose'.

NZFS supports FSANZ's decision to lower the maximum percentage limit of D-allulose for the food categories identified as potentially causing a laxative effect at the proposed maximum use level suggested by the applicant. This minimises the risk of over-consumption.

[redacted]

NZFS notes that the dietary assessment was based on the consumption of each food category individually, without considering the possibility that two or more foods containing D-allulose may be eaten concurrently. FSANZ noted that it is unlikely for two or more foods eaten in combination at the highest level of intake (P97.5th). No sub-groups or at-risk groups were considered separately in the dietary intake assessment, since these were not identified from the toxicological assessment. However, 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. We suggest options in the *Labelling* section to help manage this risk.

NZFS notes that there is limited human research to inform the levels at which a laxative effect occurs. The tolerance 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 available for establishing a threshold for which laxative effects are minimised, NZFS suggests additional risk management via a mandatory advisory statement (see *Labelling* section).

We also note that 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.

Nutrition assessment

NZFS considers that future evidence could strengthen the accuracy of FSANZ's calculation of metabolisable energy from D-allulose. We note that 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.

Microbiology assessment

NZFS notes the potential risk that consumption of D-allulose may selectively favour growth of *K. pneumoniae* in the urinary tract, contributing to urinary tract infections. Data from the Dietary Intake Assessment was used to support the microbiological risk assessment. High intakes (P90) were double those assessed in the human trials, and participants in the human trials were "healthy" and without diseases such as diabetes, despite people with diabetes being potentially more likely to seek out low-energy and low-sugar foods. We consider that the maximum levels of use for each food category may help to mitigate the possible microbiological risk of high consumption.

NZFS recommends that FSANZ's routine horizon scanning programme should include monitoring for potential adverse effects of D-allulose for individuals with impaired kidney function or kidney disease.

Labelling

NZFS recommends requiring a mandatory advisory statement to the effect that "excess consumption may have a laxative effect" for products containing or comprised of D-allulose, similar to the mandatory advisory statements required for the low-energy sweeteners listed in Standard 1.2.3—

2(2). While the maximum limits do reduce the risk of laxative effects for most categories, these are determined on the assumption that only one D-allulose containing food is consumed at one time, and they are based on threshold studies that are limited only to healthy individuals. We consider that the threshold for which a mandatory advisory statement would apply should be based on conclusive evidence for all consumers and relevant population sub-groups. In the absence of evidence, a conservative approach is warranted.

NZFS suggests that 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 that 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 acknowledges the rationale for excluding D-allulose from the amount of total of sugars in the NIP. Instead, current drafting specifies that D-allulose would be listed in the NIP only if present at a concentration of 5 g/100g or more, to meet the requirements of Standard 1.2.8—6(9)(a). We note that many food categories will contain less than 5 g/100g of D-allulose (as per 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.

NZFS's position is to include D-allulose in the definition of 'added sugar' for the purpose of making claims. Permitting D-allulose containing foods to make 'no added sugar' claims may be considered inconsistent with fair trading legislation. As D-allulose is by definition a 'sugar' there is risk that permitting 'no added sugar' claims on products containing D-allulose may be considered 'liable to mislead the public'. We also note the limited available evidence demonstrates that the energy contribution from D-allulose varies according to the amount consumed and likely according to whether it is eaten concurrently with fructose, as previously discussed.

Finally, we question whether further consideration is needed for an energy cut-off at which a low-sugar sweetener can be considered an added sugar.

General concerns

While out-of-scope for this application, we note that there is a wider context of the numerous available sugar alcohols and low-energy sweeteners permitted in the Code. There may be an increasing need to consider cumulative risks of concurrent use of multiple sweeteners. It may be appropriate to take a consistent approach to the use of compositional limits and mandatory advisory statements as a risk mitigation strategy for all sugar alcohols and low-energy sweeteners.

Nāku noa, nā

[redacted]

[redacted]