Application to amend the Australia New Zealand Food Standards Code to permit D-Allulose as a novel food

EXECUTIVE SUMMARY

Samyang Corporation Korea

November 2021

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Samyang Corporation (Samyang) is a food ingredient manufacturer based in Korea and is seeking to amend Schedule 25 of 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, also known as D-psicose, is a monosaccharide sugar that is an epimer of D-fructose and occurs naturally at very low levels in foods such as cakes, brown sugar, fruits and maple syrup (1.5 - 130 milligrams per 100 grams). D-allulose provides only a fraction of the metabolisable energy of conventional sugars such as sucrose, meaning that D-allulose is well suited as a low-energy sugar substitute ingredient.

Samyang is seeking approval to add D-allulose to foods such as bakery products, cereals, chewing gum, yoghurt, jams, non-alcoholic beverages and as a table sugar substitute at levels ranging from 2 – 100%. These intended use levels of D-allulose will result in significantly higher dietary intake compared to intake from natural D-allulose levels in foods, meaning that Samyang's D-allulose meets the definition of novel food in the Code. Novel foods require assessment and approval by FSANZ before they can be sold as food or added to food. Samyang is requesting exclusive permission for its 'Allulosa' brand of D-allulose in the classes of food listed in Table A.1 of the application.

D-allulose is approximately 70% as sweet as sucrose. In order to provide a similar sweetness profile to sucrose, D-allulose may need to be added at to foods at slightly greater amounts than the sucrose it replaces or can be added at lower levels when combined with other non-sugar sweeteners (such as intense sweeteners or sugar alcohols). Despite the lower metabolisable energy content of D-allulose, the ingredient fulfils or exceeds properties that make conventional sugars and intense sweeteners popular ingredients in foods, including bulking and sensory properties, browning, foaming properties in aerated foods, and antioxidant and gelling qualities. These properties of D-allulose, combined with the low-energy content, make D-allulose an attractive ingredient for food manufacturers to incorporate into a variety food matrices.

Samyang's D-allulose is produced by conversion of fructose by the enzyme D-allulose-3epimerase (also known as D-psicose-3-epimerase), which is naturally present in a nongenetically modified organism, *Microbacterium foliorum* (SYG27B-MF). The enzyme is not currently permitted to be used as a processing aid in Australia and New Zealand. Samyang is therefore also seeking to amend Schedule 18 of the Code to permit the use of D-allulose-3epimerase, harboured in *M. foliorum* (SYG27B-MF), as a processing aid. The safety of the enzyme and *M. foliorum* for use food production is demonstrated in this application. The enzyme and *M. foliorum* is totally removed from commercially available D-allulose and will not be present in food.

D-allulose is not metabolised in the body like sugars such as sucrose, meaning it has a lower available energy content compared to sucrose and other conventional sugars typically used to sweeten foods. Most ingested D-allulose is absorbed in the small intestine but is not broken down and is subsequently excreted in urine. The small amount of D-allulose that passes to the large intestine is poorly fermented by intestinal microflora and is mostly excreted in faeces. D-allulose provides only 1 kJ/g of metabolisable energy compared to 17 kJ/g for traditional simple carbohydrates. Samyang is requesting an energy factor of 1 kJ/g for D-allulose be included in Schedule 11 of the Code for nutrition information labelling purposes. Inclusion of this energy factor for D-allulose in Schedule 11 will ensure that the appropriate energy value for D-allulose can be reflected on the labels of foods containing D-allulose as an ingredient.

Given the unique low-energy properties of D-allulose, this application also requests that D-allulose be treated differently to conventional sugars in the context of making sugar nutrition content claims, including claims relating to 'low', 'reduced' and 'no added' sugars. Unlike conventional sugar ingredients, D-allulose provides negligible metabolisable energy and Samyang considers this unique property distinguishes D-allulose from the types of sugars that are subject to the conditions for sugar nutrition content claims in section S4—3 of the Code. This application therefore requests that FSANZ investigate an appropriate mechanism to exclude D-allulose from the conditions for sugar nutrition content claims.

D-allulose has been extensively studied in animal and human trials and has been demonstrated to be very well tolerated at doses above the intended use levels included in this application. Very high doses of D-allulose can produce similar intestinal reactions to other commonly consumed non-digestible carbohydrates, including bloating and diarrhea. A tolerable intake level in humans of up to 0.55 grams per kilogram of body weight per day is considered protective of these adverse effects, with some people being able to consume much higher amounts without experiencing adverse effects. The intended uses of D-allulose will result in dietary exposures well below this tolerable intake level. Estimated dietary intakes using United States food consumption data suggest that all consumers of D-allulose containing foods have an estimated dietary intake below the tolerable level (including 90th percentile consumers). Actual dietary intakes are expected to be much lower because of the conservative assumptions made in calculating the estimated dietary intakes.

In summary, D-allulose is demonstrated to be safe at the intended levels of use outlined in this application and provides an attractive very low energy alternative to conventional sugar ingredients that are commonly used in foods.