

CONTEXT

Food is medicine – particularly low carb, effective sugar substitutes.

This is proven in this published medical audit showing how supporting those on low carb diets can battle the myriad of symptoms caused by obesity.

The application of carbohydrate-reduction in general practice: A medical audit

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Submitted: 03 July 2023 | Published: 08 December 2023

Journal of Metabolic Health | Vol 6, No 1 | a86 | DOI: <https://doi.org/10.4102/jmh.v6i1.86> | ©

Carb-reduction has been used successfully in the management of conditions arising from insulin resistance. 72 patients in primary care, given counseling using a low carbohydrate dietary approach.

DURATION: The mean duration of observation was 21.5 (\pm 10.4) months.

WEIGHT LOSS: On average patients lost 11kg (\pm 8.4)kg / 17% attained healthy body mass index (BMI)

DIABETES:

80% (Four out of five patients) reversed prediabetes over 20.8 (\pm 13.4) months.

25% per cent (28/113) of the practice population with type 2 diabetes (T2DM) participated, of which 64% reversed and 11% remitted T2DM over 20.7 (\pm 11.8) months.

Two patients stopped insulin and

10 reduced or stopped other diabetes medications.

BLOOD PRESSURE

Nearly 35% (25/72) of participants were initially hypertensive.

36% per cent (9/25) normalised systolic blood pressure (SBP),

28% (7/25) normalised diastolic blood pressure (DBP), and

16% (4/25) normalised both SBP & DBP.

64% reduced or stopped some or all antihypertensive medication. There was a mean reduction in SBP of 10.3 (\pm 17.7) mmHg and DBP of 4.8 (\pm 12.3) mmHg over 23.8 (\pm 9.0) months.

CHOLESTEROL

Lipid changes were generally favourable, with 52% normalising triglycerides, 61% increasing high density lipoprotein cholesterol (HDL-C) to greater than 1.0 mmol/L, and 39% reducing low density lipoprotein cholesterol (LDL-C).

So food choices are being proven to be like medicine and reverse the illnesses. How does that relate to the approval of allulose? The saddest thing I ever read was the comment in the application for submission that the introduction of allulose will result in “small, unquantified benefits to public health such as a reduction in obesity rates” (3)

And the only way that I can see the impact of being forced to be small, is if the incredibly low “based on worst case scenario” laxative effect allowable amounts pass through this exercise unchanged. To me the worst case scenario is the sheer number of people dying every year from preventable obesity related illnesses and industry unable to formulate reasonable alternatives, due to 10% of those who were already taking a whole lot of allulose.

INTRODUCTION

In this submission I see no issue with the approval of allulose as a novel food, nor any issue with the approval of the enzyme to manufacture it – it's long overdue because Australia and New Zealand's obesity rates are among the worst in the OECD (1).

The biggest contribution to calorific intake and blood sugar spikes is sugar. Taking that out of the equation by fully substituting with allulose and provide some education about better food choices, gets incredible results in a very short space of time, in ways that medicine alone could not.

It appears from reading that FSANZ have solely focused on laxation for the purposes of the application risks. I am inviting you to take a look into these alternative more significant numbers:

<https://www.worldlifeexpectancy.com/australia-coronary-heart-disease>

Click to change the cause, and on the right hand side, scroll and click to change country to New Zealand.

Here are the real substantial health risks that allulose has a role to play in remedying.

People are dying in their masses from Obesity, Diabetes, Hypertension, Heart attacks from elevated Cholesterol combined than any other cause in Australia and New Zealand. There are a myriad of preventable illnesses all linked back to Obesity. Whereas flatulence or diarrhea from Allulose is nowhere near as fatal in risks.

I have split my submission into a summary with various risk factors and additional benefits and costs. Then elaborated on each point in separate section, with references in order to make it easier to read.

I sincerely hope the FSANZ factors submissions into the decision making, and takes another look at the situation with Sanyang meeting the requirements for exclusivity. A lot of lives depend on it, as

Obesity is the root cause of the clear majority of deaths in Australia and New Zealand. And handled properly like in this medical audit above, the approval of Allulose can make significant inroads to solving the biggest and most significant health challenge of today.

It's so important to desired outcomes, that Australia have dedicated a National Obesity Strategy (12) to it along with key principles expected of those working in related fields. Approval of a sugar substitute would certainly apply as being impactful in this space. And there are a lot of costs measured in that document that apply equally to the costs you are seeking to be made aware of from submissions.

Section One

• **FSANZ has only focused on managing the lesser of the health risks when there's a duty of care to look at higher health risks.**

By FSANZ regulating products in order to manage low non-fatal health risks of laxation, it is failing to exercise their duty of care to use allulose to mitigate higher risks, that have fatal health consequences caused by obesity. The FSANZ regulations proposed also work against the four main pillars of food development strategies of the National Obesity Strategy 2022-2032 (12)

Section Two

• Lack of recent innovations for exclusivity consideration

Samyang's enzyme and the methods of making allulose date back before GRAS application to the USA based FDA. Both technologies have now been completely superseded by a more recent, more efficient, cheaper and sustainable innovation made by a separate business (21). FSANZ acquiring the right for Industry to purchase an obsolete enzyme and technology after suffering 15 months of overly inflated allulose ingredient prices for the privilege, will negate any industry benefit (20)

Section Three

• Scope of exclusivity requested extends beyond the applicant business's operational scope

Exclusivity requested covers both Nexweet Allulose sweetener manufactured by Samyang, and applies to 50 types of products across 15 food classifications that 'use' allulose yet none of these products are made by Samyang themselves (22). As an ingredient only manufacturer, this anti-competitive move prevents anyone else from selling existing products developed with a different brand of allulose in them. Preventing other businesses from selling products containing another brand of allulose is in breach of Trans-Tasman anti-trust legislation (23) and counter to making healthier food choices more accessible, particularly to indigenous peoples.

Section Four

• Difficult to understand scope of exclusivity therefore a lack of meaningful consultation

The exclusivity scope is poorly worded and not clear enough for sufficient consultation to be deemed to have happened on the matter of limiting products already developed that contain non-nexweet branded allulose (Part 1, 7d FSANZ Act).

Section Five

• The actual costs Samyang incurred to bring this application are questionable due to:

- ~ Samyang having already enjoyed 9 years of profitable selling allulose recovering costs
- ~ Multiple Allulose GRAS notes (24) have been approved over this time, giving benefits
- ~ No new unique technology has being developed specifically for the FSANZ approval process
- ~ Test results quoted in the applications were not funded by Samyang (26).
- ~ Similar wording across the USA, FSANZ, and European applications.
- ~ There is a risk that Samyang Corp is triple dipping on the cost recoveries across 3 continents and agencies (33) and not actually incurring many relevant costs to recover.

Section Six

• Samyang is a high risk, supplier with a poor reputation and history of illegal activities

2012 Samyang were fined by the Korean Fair Trade Commission for price fixing 2001 to 2010. (27)

2019, 2 class actions against in British Columbia for \$288,586.98 dollars in compensation.[30]

2019 - Samyang chairman Jeon In Jang was sentenced to prison for 3 years for embezzling USD \$4.43 million) of his company's funds. (31) His wife and CEO of Samyang, Kim Jung-soo, was given a 2-year prison term, albeit suspended for 3 years, on the same charges. Since Jeon's imprisonment, Kim has assumed her husband's leadership duties! (32)

2019 – Large shareholder Hyundai, wants suspension of board directors with criminal records.[29]

2018 – 1 billion USD, conflict deal settled between Korean based brother and USA based sister (28)

Section Six continued

Samyang are a overseas based Corporation (25) who made \$91.2 million AUD equivalent profit in the last financial year. They are a front for the Allulose Novel Food Consortium (ANFC) created to share costs, intel, information to fast track applications for Allulose food safety (21a). Having already been caught price fixing (27) it would be cautious to have the OIA look out for such risks that the global allulose consortium will undertake in price fixing and anti-competitive behaviours to ensure allulose supply remains at a premium price.

Section Seven

• OIA risk assessment would be recommended

Given the duty of care, legal risks, poor definitions of scope and anti-competitive actions, alignment of steps taken against National Obesity Strategy, and the poor reputation of the applicant. There is enough to these concerns to warrant taking another look at OIA involvement and assess some risks and put in mitigations.

Section 7

• The exclusivity terms

Are onerous given their duration, extended scope into so many food items that Samyang doesn't even manufacture, unnecessarily limiting healthy market competition, depriving consumers of choices of products in categories where none will be made by Samyang for 15 months, industry's ability to choose non-corrupt suppliers (27) and the acceptance of premium prices to be paid for D-allulose. These breach consumer protection laws (23) and will have an inequitable impact on all indigenous peoples both in Australia and New Zealand (National Obesity Strategy 1.3 and counter to partnership pledges made by FSANZ on the website.

Section Eight

• Supporting Innovation

The whole spirit of the supporting innovation through exclusivity was never intended to be used in an anti-competitive way that ultimately limits the access of healthy food to those who need it the most across a very broad range, stifles product innovation. It's a precedent to set when preventing product innovation as the nature of the applicant's business is just sweetener manufacturing, not 50 x products manufacturing. FSANZ risks accepting actions under one piece of legislation aimed to encourage innovation, and that action has the effect of being illegal under the Commerce Act 1986 (NZ) which prohibits a contract/arrangement that has the purpose, or to of substantially lessen competition in the market. Australia has also the Competition and Consumer Act 2010.

By over-regulation in food, and limiting the Allulose ingredient used to just one brand, innovation is stifled across all these food categories: Table A.1. Non-ingredient limitations are broad sweeping into categories of food that Samyang don't even manufacture.

Just look at all these foods from Table A that will be locked down to be exclusive use by Samyang Corp – and of all these items the only one that Samyang manufacture is the Sugar Substitutes.

Table 1. items pg 13-14

Specifically: Beverages water based flavoured drinks non-alcoholic Sweetened teas Instant coffees Gelatins Puddings Fillings Fruit fillings Breakfast cereals Cereal based bars reduced energy options reduced sugar options Processed cereal products Processed meal products Frozen dairy desserts ice cream soft serve sorbet Yogurt Frozen yogurt Edible ices Bakery bread rolls cakes cake-type rolls pastries doughnuts Biscuits cookies shortbread butter milk whole wheat biscuits crackers	Fat-based cream. used in modified fat/energy cookies, cakes, pastries, pies dairy based dessert products fat based dessert products Dips and snacks Icings and frostings Jams Fruit spreads Fruit jams Chutneys Vegetable spreads Vegetable jams chutneys Jellies Jelly products Dressings for salads Sweet sauces syrups Sauces and toppings mayonnaises salad dressings Hard candies confectionery Soft candies confectionery chocolate Sugar confectionery Chewing gum Bubble gum Chewing gum Sugar substitutes Tabletop sweeteners
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Section Nine • Proposed Alternative Solution

If FSANZ were to truly support innovation it would look like this. Secure the latest enzyme immediately that allows for continuous Allulose manufacture at a lower price point from here (<https://foodmatterslive.com/article/allulose-could-efficient-cheaper-technology-bring-healthier-sweetener-to-market/> 06 Jul 2023), then work with the sugar cane industry to convert their materials to Allulose immediately.

Section Nine • Proposed Alternative Solution, continued

Require product manufacturers to adequately label their products packaging with laxative information. Allow self-regulation because there's only so much Allulose that can be added for product performance and taste before it becomes cost prohibitive anyway.

Then meet the FSANZ legislation about applications. By setting 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 in Australia and New Zealand. Remembering that for every \$1 invested (or not charged Samyang) the payback in cost savings in the health system is \$6 (34)

Allow in all communications about approval for the brand reputation of Nexweet to be heroes and replace their poor reputation history of price setting, fraud and breaking contractual obligations. Provide a 4 month long exclusivity duration to only the ingredient supply & not covering the products that it's made in. Samyang already are ahead in that they will have notice of the approval. The most likely competitors are also Allulose consortium members, so I have little doubt that there will be price fixing discussions happening anyway. There's no way that Samyang is going to lose.

Section Ten Limitations • Risks of Limited uptake

The reasons why the uptake of Allulose is likely to be hindered is because FSANZ is over-reaching in 3 different ways through the approach to this application:

Over-reaching FSANZ introducing regulations where they aren't needed

FSANZ have over-reached introducing regulations which meddle in the affairs of industry preventing any Australian and New Zealand business from formulating their own food product by setting maximum allowable amounts of the Allulose ingredient that can be used. This is contrary to stating 2.4.1.1. FSANZ is currently unaware of any health or safety concerns to consumers, associated with permitting the use of D-allulose

What would be in the public's best health interest would be to get the lowest priced Allulose into the hands of as many businesses to convert into as many products as possible. To give food manufacturing businesses based in Australia and New Zealand a real shot at competing against ultra-low priced sugar, which causes well documented harm to peoples' health. To give consumers real choices when managing calorific intake and blood sugar responses when consuming their food.

The effects of added sugar intake — higher blood pressure, inflammation, weight gain, diabetes, and fatty liver disease — are all linked to an increased risk for heart attack and stroke (38) whereas allulose suppresses blood glucose elevation post-consumption (Hayashi et al., 2010; Iida et al., 2008) and reduces body fat accumulation (Matsuo et al., 2001). This sugar is minimally converted to energy in humans (Iida et al., 2010).

Looking at the statistics, it is NOT obesity which has the small unquantified benefits (3), laxation is 0.0037% of the deaths. How can FSANZ be looking at the wrong risks? How can a risk assessment not be undertaken when there are so many lives at risk? How many more people have to die unnecessarily or have their access to a viable sugar alternative restricted due to unnecessary regulation of company product formulations, and what we expect to be premium prices to fund a mega-rich overseas corporation and create a monopoly?

Section Ten Limitations • Risks of Limited uptake continued

Over-reaching & breaching consumer protection laws:

Accepting a situation where premium prices are charged for allulose for 15 months, due to the exclusivity clause, it will limit access to allulose to the rich and white populations.

In New Zealand, it is estimated that the number of people diagnosed with diabetes is over 300,000 people (predominantly type 2 diabetes) the effects of which can be managed with dietary food interventions (medical audit pg . Within the New Zealand population, the prevalence of diabetes in Māori and Pacific populations is around three times higher than among other New Zealanders. Prevalence is also high among South Asian populations (14). It's these same people in lower socio-economic areas that need it the most, yet can afford it the least.

Over-reaching & breaching consumer protection laws: continued

In Australia – 1.3 million people have Type 2 diabetes. If you need to imagine just how many people that is, it's the entire population of Adelaide. Around 58,600 people were newly diagnosed (incidence) with type 1 diabetes between 2000 and 2021 according to the National (insulin-treated) Diabetes Register (NDR). In 2021, there were 3,000 people newly diagnosed with type 1 diabetes in Australia, equating to 12 diagnoses per 100,000 population. (13)

Failing to give the lower socio-economic access to much needed allulose at an affordable pricing is the biggest opportunity cost. In 2020–21, an estimated \$3.4 billion of expenditure in the Australian health system was attributed to diabetes, representing 2.3% of total disease expenditure. The breakdown in expenditure by diabetes type included:

type 2 diabetes 68% (changeable by diet) refer to the medical audit results on page

type 1 diabetes 11%

gestational diabetes 2.1%

other and unspecified diabetes 20% (13).

Over reaching and breaching anti-trust laws

FSANZ have over-reached the scope of exclusivity way past the nature of the applicant's business. Exclusivity is being granted to an overseas based organisation, over products that the applicant doesn't even manufacture. This is a dangerous precedent that creates a monopoly and breaches anti-trust legislation.

The limits to the amount of allulose that can go into a range of foods limits the ability of industry to adopt Allulose as a sugar substitute. The short sightedness will cost everyone dearly in the long run.

By approving the exclusivity as requested in the application, FSANZ would be prioritising profits going to an overseas corporation and significantly inhibiting the ability to fight the obesity epidemic in both Australia and New Zealand right now, at a time when it's crucial to get better health outcomes. A 15 month long economic exclusivity prevents product manufacturers to function freely to achieve desired health outcomes.

Section Eleven • Direct costs

The personal and societal costs are significant. The financial and other costs of obesity are significant and continue to rise (35), with major impacts on individuals and on communities, society, the economy, and natural resources and ecosystems (36) If we don't act, obesity may cost an estimated \$87.7 billion in just 10 years (37) And to cover the costs of obesity, each Australian pays an additional \$678 in taxes each year (14)

Conclusion

The duration of exclusivity will prevent diabetics and anyone who has health issues connected with being obese from having access to more cost effective sources of Allulose as a sugar alternative. When statistics clearly show that it is the lower socio-economic disadvantaged that are overly represented by these diet related illnesses, restricting supply and overly inflating the cost of a solution to their health challenges for any length of time is not only suboptimum, it's a breach of the FSANZ duty of care. This creates the very same inequity that the government of Australia is trying to stamp out through the National Obesity Strategy 2022-2032

There is no issue with approving allulose. There is no issue approving the enzyme, although it's not the latest innovation. The meddling in industry wide product formulations will prevent obesity solutions from being formed and is unnecessary regulation because the consequences of laxation can be managed simply and cost effectively through product labelling (as is already done globally).

Approving the over-reaching by Samyang's exclusivity request into a huge broad range of products that they don't even manufacture breaches anti-trust laws. The approving of exclusivity for such a long length of time making consumers pay a premium for allulose breaches consumer protection laws. Also it breaches the duty of care and the statements of partnering with indigenous peoples, who are overly represented in obesity related statistics. The prize of the fight against obesity is 84,700 preventable deaths every year. I refute FSANZ's statements that is small, nor unmeasurable. So why over regulate the bowel movements of those who can self manage their allulose intake themselves?

While I have no doubt FSANZ have taken care in going through the paperwork requirements and in appreciation are taking the application for exclusivity at face value. They have simply failed to see Allulose for what it is. A game changer in fight against obesity epidemic. A food-based medicine that's got the potential to further the success already achieved in a medical study to reverse type 2 diabetes. And the latest innovations in Allulose enzymes and production methods, the risks of breaching FSANZ duty of care and other laws, understanding Samyang Corp's reputation, would have all been discovered had a proper risk assessment process been undertaken.

I appreciate the opportunity to play a part in this consultation process. To see statements that FSANZ are open to considering additional information is heartening to see. Particularly after reading that FSANZ has opted to see D-allulose as having a small role in tackling obesity (3) despite decades of scientific studies about D-allulose to the contrary. And while food based medicine is a concept not widely subscribed to, there have been hugely successful published medical trials with diabetics that prove otherwise (pg 1).

So now is the time. The tide needs to turn on the global sugar industry and while they have very deep pockets now, I would like to see them grab the readily available, more innovative enzyme and production methods (not Samyang's as that's obsolete already) and start to create D-allulose right here in Australia. After all 15 months is a long time during which another 108,750 people would have died from obesity related illnesses (17) and instead, a production solution could have been ready.

According to the National Obesity Strategy 2022, for every \$1 invested in obesity prevention, it has a return of up to \$6 (34) Both the personal and societal costs are significant. The financial and other costs of obesity are significant and continue to rise (35), with major impacts on individuals and on communities, society, the economy, and natural resources and ecosystems (36). If we don't act, obesity may cost an estimated \$87.7 billion in just 10 years in Australia alone (37). And to cover the costs of obesity, each Australian pays an additional \$678 in taxes each year (39).

None of these numbers are "small, nor unquantified benefits" (3) so with this submission I also hope to help the FSANZ make the obvious scientifically proven connection between D-allulose, a sugar substitute solving the obesity, that was caused by consumption of sugar. As that connection is woefully lacking the application seeking submissions, and the costs of not doing so, are just too important to pass by.

Section One - Supporting Information

- **FSANZ has only focused on managing the lesser of the health risks when there's a duty of care to look at higher health risks.**

By FSANZ regulating products in order to manage low non-fatal health risks of laxation, it is failing to exercise their duty of care to use allulose to mitigate higher risks, that have fatal health consequences caused by obesity. The FSANZ regulations proposed also work against the four main pillars of food development strategies of the National Obesity Strategy 2022-2032 (12)

Despite findings from the raft of scientific studies reviewed during this application process (2) FSANZ has significantly down played the role that allulose can play in tackling obesity in this application (3). FSANZ is proposing food formulation regulations be introduced with maximum permitted limits of allulose, across 50 different types of food (4) in order to minimize any risk of laxation (5) based on the tolerance of the top 10% of already high allulose consumers (6).

In doing so FSANZ's treatment of this application fails to focus on the highest fatal risks and costs to public health from obesity related illnesses (7) and breaches its legal duty of care (8). The approach FSANZ has taken by regulating low dosages of allulose in food, in the absence of any other risk D-allulose poses to health (9) fails to recognise that there are six variable individual factors that have a correlation to laxation outcomes (10) and also works directly against Strategies 1.1, 1.2, 1.3 and 1.4 from the National Obesity Strategy 2022-2032 (11) in Australia.

FSANZ cannot cherry pick the laxation aspect of public health it is choosing to protect at the expense of the far more pressing, extremely far more deadly and costly obesity aspects of public health. Allowing industry to self regulate inclusion of allulose as an ingredient, with products labelled as potentially causing laxation effects and limits and allowing consumers to self regulate their consumption will still all meet FSANZ's duty of care to safeguard public health. This is because the risk of death from laxation pales into insignificance compared with obesity related illnesses & costs.

According to the latest WHO data published in 2020 Diarrhoeal diseases Deaths in Australia reached 296 or 0.22% of total deaths. The age adjusted Death Rate is 0.51 per 100,000 of population. According to the latest WHO data published in 2020 Diarrhoeal diseases Deaths in New Zealand reached 19 or 0.01% of total deaths. Statistically insignificant when per 100,000 population.

Worked example using the FSANZ application

According to the National Obesity Strategy 2022-2032, unhealthy food and drinks make up 35% of daily intake for adults and children (12). So when you look at reformulating a drink and see how much a difference using allulose would be permitted by FSANZ. Also aiming for no blood sugar spike so that any of the 1.3 million diabetics in Australia (13) and the 300,000 diabetics in NZ (14), have the opportunity to drink it. A classic Bundaberg Ginger Beer has 10.8g sugar. It isn't the highest, that's Solo coming in at 11.5g, and perception wise you'd think a Coke was loaded higher but that comes in with 10.6g sugars per 100ml (15). Under the proposed FSANZ application as a water based flavoured drink, pg 13 submissions document, that would have a maximum limit and can only contain 1.5g allulose per 100ml (which is the equivalent sweetness to 1g of sugar).

Section One - Supporting Information continued

This is just one example of the constraints being enforced by the FSANZ regulated solution for allulose. With dose quantities determined to manage the risk of laxation of the top 10% of over consumers of allulose (6) this approach completely misses the opportunity to have a more practical & viable alternative to a major significant cause of obesity, by sugary, highly calorific drinks that have zero nutrients.

So should this FSANZ application go through unchanged, in the end the saddest words in the whole submissions document will come to fruition. Allulose would have “small, unquantified benefits to public health such as a reduction in obesity rates” (3). No laxation though. Just a whole heap of sugar related diseases would continue to kill Australians and New Zealanders by the 10,000’s based on numbers combined from the many obesity related illnesses (7) in our two countries every year (17).

And these continued poor health outcomes wouldn’t be due to the product performance of allulose, nor the allulose manufacturers, nor the product manufacturers looking to make substitutes. Those continued poor health outcomes would land squarely at the feet of FSANZ, as they are the source of the food regulations limiting how much allulose can be dosed as a substitute.

The opportunity is to change 35% of all food and drinks to be healthier and that size of the prize is not small, nor is it unquantified. The National Obesity Strategy document is loaded with quantified data (12) its woeful reading but there is hope. Allulose can make a bigger difference, if allowed to. If FSANZ were working aligned within the National Obesity Strategy we would see:

- Strategy 1.1 - build a healthier food system that favours the production, processing and distribution of healthy food and drinks.
- Strategy 1.2 - make sustainable healthy food and drinks more accessible with examples bearing in mind affordability for indigenous peoples
- Strategy 1.3 - explore and implement use of economic tools (pricing) to shift consumer purchases towards healthier food and drink options.
- Strategy 1.4 - make processed food and drinks healthier.

Nowhere is it aligned with the National Obesity Strategy for the FSANZ to limit the amount of a sugar substitute that can be included in the formulation of a healthy product, through costly methods of industry regulation (18).

Technical allulose performance in food means Industry will need to self-regulate their doses anyway

There are valid reasons why Industry will self-regulate when it comes to allulose. "The use of allulose in foods is considered to be self-limiting, for technological reasons such as product flavor profile, which could affect consumer acceptability" (19) Also in product performance there are natural performance limitations as allulose keeps texture in applications very soft. So there is no need for FSANZ to mandate allulose limits in products, as both food manufacturers and consumers will find those on their own accord, given the information with which to make their own decisions.

Section One - Supporting Information continued

The cost and need for regulation of the allulose content food has not been justified

In the application FSANZ has not established any significant, fatal health risk that warrants the regulation limiting allulose dosage limits. In the application, there is no mention of even having considered laxative product labeling 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 (4) will significantly hinder allulose from practically being enabled in product formulations, as a sugar substitute.

Duty of care

I would call so many people dying every year from what are totally preventable diet related health outcomes (18) my worst case scenario. Whereas FSANZ is calling laxation gas, flatulence or diarrhea in the top 10% of already highly dosed individuals, a worst case scenario underneath Table 5 in SD1. 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 Australia and New Zealand.

There is no justification for choosing a wide ranging, food dosing regulation regime, especially when taking a product labeling educative approach will effectively manage what is an individualistic, potential, variable and non-fatal laxation outcome. Regulation will not solve obesity. Whereas a free economic market containing many more food choices, all with lower calorific energy and lower carbohydrate foods featuring allulose as an ingredient, aligned with the National Obesity Strategy will make a real difference.

Proposed solution to manage the health risks – What will make inroads into tackling obesity and the related illnesses, would be to allow allulose as a substitute for the substantial amount of sugar and carbohydrate loads that are in our foods and drinks. Allulose is proven safe to consume after being done so for decades, in multiple countries around the world with populations far greater, all without introducing product dosage limits. Applying the current industry norm in place for other alternative sweeteners, to label products with information about potential laxative effects (10) would allow both Industry and consumers to self-regulate. So the doses of allulose would result in the best product performance and economics, and Consumers could self-regulate to establish their own individual limits of allulose consumption.

Section One Summary - It is a failure to exercise duty of care for the FSANZ to regulate food formulation limits that prioritise a non-lethal health inconvenience of flatulence / diarrhea, over fatal health issues linked to obesity. Especially considering the industry standard for every other sugar alternative sweetener is to cost effectively label the package with laxative warnings and doses. Both Industry and Consumers will likely succeed in self-regulation with allulose dosing and consumption, as it's in their best interests to do so.

Section One References

(1) Australia and New Zealand's obesity rates are among the worst in the OECD.

International comparisons of the prevalence of overweight and obesity can be made for member countries of the Organisation for European Co-operation and Development. Comparisons for measured body weight are based on data from 2021 or the latest available year (OECD 2022).

New Zealand is ranked 4th highest and Australia is ranked 8th highest for obesity in the OECD

The data set for Maori, Pacific Islanders, Aborigines, Torres Strait Islanders and those living in lower socio economic areas is even worse than that average.

Report produced by the Australian Institute of Health and Welfare.

<https://www.aihw.gov.au/reports/overweight-obesity/overweight-and-obesity/contents/overweight-and-obesity>

(2) Raft of scientific studies reviewed Scientific studies reviewed during this application process are too numerous to be included here but they are referenced across 8 pages from pg 59 – 67 (electronically pages 61 – 69) on the Technical and Risk assessment – Application A1247, Supporting Document SD1.

2.4.3 Subsection 18(2) considerations FSANZ has also had regard to • “the need for standards to be based on risk analysis using the best available scientific evidence. FSANZ has used the best available scientific evidence to conduct the risk analysis, which is summarised in SD1. The applicant submitted a dossier of scientific studies as part of the application. FSANZ had regard to this dossier, together with other technical information including scientific literature, in assessing the application”.

Call for submissions – Application A1247 document.

<https://consultations.foodstandards.gov.au>application-a1247-d-allulose-as-a-novel-food>

(3) FSANZ has significantly down played the role that D-allulose can play in tackling obesity in this application. “...if the use of D-allulose increases the choice and numbers of lower-energy products, eventually lead to small, unquantified benefits to public health such as a reduction in obesity rates” section 2.4.1. Section 29 2.4.1.1 consideration of costs and benefits – Government section in the Call for submissions – Application A1247 document.

<https://consultations.foodstandards.gov.au>application-a1247-d-allulose-as-a-novel-food>

(4) FSANZ is proposing food formulation regulations be introduced with maximum permitted limits of allulose, across 50 different types of food. Table 1 - Adjustments to food class names and maximum permitted levels of D-allulose from those requested in the application page 13 Call for submissions – Application A1247 document.

<https://consultations.foodstandards.gov.au>application-a1247-d-allulose-as-a-novel-food>

(5) Laxation levels

Pg ii – Supporting Document 1 - Technical and Risk assessment – Application A1247 D-allulose as a novel food. A short-term dietary intake assessment identified a number of food categories from which the intake of around 10% of high consumers exceeded the level of D-allulose that causes a laxative effect based on the maximum use levels provided in the application.

Section One References continued

(6) based on the tolerance of the top 10% of already high D-allulose consumers.

Pg ii – Supporting Document 1 - Technical and Risk assessment – Application A1247 D-allulose as a novel food. A further 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 amounts when consumed as one food containing D-allulose per eating occasion. This resulted in lower concentration levels compared to the maximum use levels proposed in the application for some foods.

(7) highest fatal risks to public health outcomes - Mayo clinic – list of obesity related illnesses:

<https://www.mayoclinic.org/diseases-conditions/obesity/symptoms-causes/syc-20375742#>:

People with obesity are more likely to develop a number of potentially serious health problems, including:

- Heart disease and strokes. Obesity makes you more likely to have high blood pressure and unhealthy cholesterol levels, which are risk factors for heart disease and strokes.
- Type 2 diabetes. Obesity can affect the way the body uses insulin to control blood sugar levels. This raises the risk of insulin resistance and diabetes.

Certain cancers. Obesity may increase the risk of

- cancer of the uterus
- cervical cancer
- endometrium cancer
- ovary cancer
- breast cancer
- colon cancer
- rectum cancer
- esophagus cancer
- liver cancer
- gallbladder cancer
- pancreas cancer
- kidney cancer and
- prostate cancer.

Digestive problems. Obesity increases the likelihood of developing

- heartburn
- gallbladder disease and
- liver problems.

- Sleep apnea. People with obesity are more likely to have sleep apnea, a potentially serious disorder in which breathing repeatedly stops and starts during sleep.
- Osteoarthritis. Obesity increases the stress placed on weight-bearing joints. It also promotes inflammation, swelling, pain and a feeling of heat within the body and complication: osteoarthritis.
- Fatty liver disease. Obesity increases the risk of fatty liver disease, a condition that happens due to excessive fat deposit in the liver. In some cases, serious liver damage, known as liver cirrhosis.
- Severe COVID-19 symptoms. Obesity increases the risk of severe cases needing intensive care units or even mechanical assistance to breathe.

Section One References continued

(8) Breach legal duty of care – lacking showing reasonable care, avoiding careless acts that could foreseeably harm others and lead to claims in negligence. Under the Food Standards Australia New Zealand Act 1991 - Part 1 section 3 - The objective is to ensure a high standard of public health protection throughout Australia and New Zealand.

(9) the absence of any other risk D-allulose poses to health (based on various test outcomes on pages i and ii Supporting document 1 - Technical and Risk assessment – Application A1247 D-allulose as a novel food:

- D-allulose is of very low acute and subchronic (90 day) toxicity in rats.
- Results of genotoxicity assays were negative
- D-allulose was not associated with carcinogenicity or with adverse reproductive or developmental effects in rats
- 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.
- Negligible likelihood of consumer exposure to the production organism, the intact enzyme, or residues from the enzyme. No significant homology was found with any known toxins or allergens.
- No evidence was identified to indicate that D-allulose consumption would affect the absorption of other nutrients.
- No toxicological risk to public health and safety from consumption of D-allulose in food, or from the use of D-psicose 3-epimerase in the production of D-allulose.
- An Acceptable Daily Intake (ADI) “not specified” is appropriate for both D-allulose and D-psicose 3-epimerase.
- No public health or safety concerns were identified in the microbiological safety assessment of D-allulose and healthy adults.

(10) The Scientific Committee for Food report concerning sweeteners (SCF 1985)

The amounts of the various sweeteners required to cause laxation depends upon the sweetener, whether the dose is spread over a number of meals or consumed all at once, whether the person or animal receiving the dose is fasting or not, and on individual differences in susceptibility to the laxative effect of these sweeteners.

(11) Strategies 1.1, 1.2, 1.3 and 1.4 from the National Obesity Strategy 2022-2032 in Australia.

(12) According to the National Obesity Strategy 2022-2032

https://www.health.gov.au/sites/default/files/documents/2022/03/national-obesity-strategy-2022-2032_0.pdf Addressing the causes of obesity pg 11 unhealthy food and drinks make up 35% of daily intake for adults and children.

(13) 1.3 million diabetics in Australia

<https://www.aihw.gov.au/reports/diabetes/diabetes/contents/summary>

(14) 300,000 diabetics in NZ

<https://www.tewhaturora.govt.nz/for-the-health-sector/health-sector-guidance/diseases-and-conditions/long-term-conditions/diabetes/about-diabetes/>

Section One References continued

(15) sugar levels in drinks <https://www.rethinksugarydrink.org.au/how-much-sugar>

(16) section 2.4.1. Section 29 2.4.1.1 consideration of costs and benefits - Industry
<https://consultations.foodstandards.gov.au>application-a1247-d-allulose-as-a-novel-food>
“Given the range of low-energy substitute for sugars as food and drink ingredients already in the market, permitting this voluntary D-allulose is not expected to significantly impact market dynamics”.

(17) <https://www.worldlifeexpectancy.com/australia-coronary-heart-disease>

(18) 2.4.1.1 Consideration of the costs and benefits - Government
Approving this application may result in a small cost to government in terms of an addition to the current range of ingredients and enzymes that are monitored for compliance
<https://consultations.foodstandards.gov.au>application-a1247-d-allulose-as-a-novel-food>

(19) The use of allulose in foods is considered to be self-limiting for technological reasons such as taste and product performance. Quote 170.240 part 4, self-limiting levels of use GRAS Notice No 893 - page 23 December 3, 2019.

Section Two

• Lack of recent innovations for exclusivity consideration

Samyang's enzyme and the methods of making allulose date back before GRAS application to the USA based FDA. Both technologies have now been completely superseded by a more recent, more efficient, cheaper and sustainable innovation made by a separate business (21). FSANZ acquiring the right for Industry to purchase an obsolete enzyme and technology after suffering 15 months of overly inflated allulose ingredient prices for the privilege, will negate any industry benefit (20)

Section Two supporting information

FSANZ has negotiated that Industry would also have the option to use the 'D-psicose 3-epimerase' enzyme to make the D-allulose in the longer-term and after the exclusivity period granted to the applicant finishes" (20). However Samyang Corp's 9 year old technology and enzyme approach only lasts for the reaction period, requires batch based manufacturing methods, with high input costs and results in low yields. It's at risk of being superseded by a far superior later innovation. Key features of the newest innovation are that a new enzyme allows for more prolonged use at higher temperatures, continuous manufacturing, more cost effective ingredients, provides a 90% yield, and requires fewer chemicals, water and energy to operate (21). This makes the FSANZ option for Industry to purchase Samyang's enzyme, after suffering 15 months of overly inflated allulose ingredient prices potentially of nil benefit.

Section Two references

(20) section 2.4.1.1. consideration of costs and benefits to Industry:

"Industry would also have the option to use the 'D-psicose 3-epimerase' enzyme to make the D-allulose in the longer-term and after the exclusivity period granted to the applicant finishes".

Samyang's enzyme only lasts for the reaction period, requires batch based manufacturing methods, and results in low yields.

(21) Both Samyang's enzyme and the methods of making allulose have already been superseded by a more recent, more efficient, cheaper and sustainable innovation.

<https://foodmatterslive.com/article/allulose-could-efficient-cheaper-technology-bring-healthier-sweetener-to-market/>

How new tech is striving to lower the price of allulose and bring it to a larger market

06-07-23 / 5 min read AUTHOR: FIONA HOLLAND

The global sweeteners market value is predicted to reach around \$158 billion by 2032, with high demand coming from consumers looking for healthier alternatives to sugar as well as those living with diabetes. Recent studies however have put the benefits of sweeteners into question, with some revealing alternatives like saccharin and sucralose increase blood sugar levels.

(21) Article: How new tech is striving to lower the price of allulose and bring it to a larger market, continued

Even naturally derived sweeteners like stevia have been found to upset the gut microbiome, while another study has shown that erythritol could raise the risk of a heart attack or stroke. With the WHO now planning to label aspartame as a possible carcinogen, the food industry is in need of other sugar alternatives.

Allulose is a natural sweetener emerging onto the market which is thought to have a better nutritional profile than other substitutes. Present in small quantities in foods like figs, molasses, maple syrup and raisins, it carries 70% of the sweetness of sucrose, and has been proven to improve blood glucose levels and help with weight loss in people with type 2 diabetes.

Allulose production

Allulose is already produced commercially by a number of global ingredient giants like Tate & Lyle and Ingredion, and it's mostly used for high end products like energy bars, condiments, ice creams, baked goods, and beverages. However it's produced in smaller quantities than other sweeteners due to its cost and difficulty to manufacture on a large scale. Now, Israeli biotech start-up Ambrosia Bio says it has developed a new proprietary enzyme-based technology which will help sugar refineries produce the ingredient more efficiently, cheaply, and sustainably.

Most companies develop allulose through a process of enzymatic conversion, taking fructose from sugar or corn starch and turning it into the ingredient using a natural enzyme called epimerase.

"In [the] industry sometimes they use the enzyme as a one shot, only using it for the reaction [period] and that's it", Ziv Zwighaft, CEO and co-founder of Ambrosia Bio tells Food Matters Live.

The company says its process differs from others as its proprietary enzyme has better stability and a longer shelf life. While epimerase survives for several days, Ambrosia's enzyme can be used for months, even functioning at an optimal level in high temperatures.

"In our process, we trap the enzyme in a column and bind it to a solid surface, allowing us to produce allulose for many months continuously," Zwighaft explains.

(21) Article: How new tech is striving to lower the price of allulose and bring it to a larger market, continued

During Ambrosia's production process, the enzymatic reaction generates a 70:30 ratio of fructose to allulose. The scientists then apply additional techniques such as chromatography (the separation of components in a mixture) to develop a fully allulose-based ingredient.

Having access to its unique proprietary enzyme allows the company to produce the ingredient cheaply, according to Zwighaft. Allulose is much more expensive to make than other sweeteners due to the high cost of starting materials and low yields. Ambrosia's technology however has allowed the team to achieve an allulose yield of 90%, and requires fewer chemicals, water, and energy to operate. With time, plus the right investments and partnerships, Zwighaft believes the technology could help allulose achieve price parity with fructose.

Scaling the allulose tech

In early July, the company announced its partnership with Ginkgo Bioworks, a US-based synthetic biology company. Ginkgo has developed a microbial expression strain which Ambrosia will use to scale the production of its proprietary enzymes that generate allulose. The collaboration could enable the start-up to scale its technology for commercial use, but it's not guaranteed. Ambrosia first must ensure its enzyme still works in the Ginkgo Bioworks expression strain. "It needs to be functional, and that's not just a question of time, but biology," says Zwighaft, adding that the company expects to make a final decision on whether Ginkgo's specific strain will be used for commercial production within the year.

Founded in 2020, Ambrosia Bio's goal is to partner with sugar refineries around the world, either through a joint venture (JV) agreement or royalty basis, and help them boost their sugar substitutes portfolio. As Zwighaft explains, "We don't have the skills to set up and run factories globally, but we can be part of them. So, once we have a partner in hand, we can start to work to revamp these facilities." The start-up is already in discussion with several companies about a possible JV agreement, including a factory in Central Europe. It also plans to commercialise in Southeast Asia and North America, where allulose is approved for human consumption in the United States and Singapore, as well as some countries in the MENA region.

Section Two references continued

(21a) A barrier preventing Ambrosia from commercialisation in Europe is the fact that allulose does not yet have regulatory approval in the EU. It's a significant "bottleneck", says Zwighaft, given the start-up's proximity to the region in comparison to other areas. The establishment of the **Allulose Novel Food Consortium in 2021** however could soon make it easier for the company to work with European sugar refineries. Made up of four global ingredients companies – Japanese Matsutani Chemical Industry, **South Korean Samyang Corporation**, US-based Ingredion, and Dutch sugar beet ingredients producer Cosun Beet Company – the consortium is working towards EU approval of allulose to be used in formulations where it could substitute standard sugar.

Ambrosia Bio is also in the early stages of developing additional sugars and dietary fibres. "We design [the technology] in a way that it can accommodate a few sugars or probiotic fibres. If there is a demand for new fibres, then [all we need to do is] tweak the system", Zwighaft explains. While the company is working mainly on improving allulose production for now, it intends to fully expand its portfolio of resources for the ingredients industry. As Zwighaft notes: "There isn't one solution that fits all, so we are still working on other sugars that can complement allulose."

Section Three

• **Scope of exclusivity requested extends beyond the applicant business's operational scope**

Exclusivity requested covers both Nexweet Allulose sweetener manufactured by Samyang, and applies to 50 types of products across 15 food classifications that 'use' allulose yet none of these products are made by Samyang themselves (22). As an ingredient only manufacturer, this anti-competitive move prevents anyone else from selling existing products developed with a different brand of allulose in them. Preventing other businesses from selling products containing another brand of allulose is in breach of Trans-Tasman anti-trust legislation (23) and counter to making healthier food choices more accessible, particularly to indigenous peoples.

Section Three supporting information meeting exclusivity criteria

Scope – The applicant is Samyang Corp, an ingredient manufacturer. The nature of their business is solely production of allulose ingredient. They do not manufacture 50 different foods that 'use' allulose in them as an ingredient. Should FSANZ approve exclusivity that over-reaches beyond the nature of the applicant's business operations, it will:

- sets a dangerous precedent, not in keeping with the spirit of the exclusivity clause.
- creates a monopoly, breaching anti-trust laws in both countries (22) preventing other trans-Tasman based businesses from selling over 50 types of products already developed that contain other brands of allulose as an ingredient, ultimately limiting consumer choice and health outcomes.
- the monopoly is likely to continue after the 15 month exclusivity duration requested by Samyang as changing product formulations can be a costly exercise, so there's a barrier to getting a healthy competitive market back in place
- means insufficient consultation occurred on this topic, because the application document didn't clearly outline the significant limitations being placed on Australian and New Zealand based businesses selling products already developed, that contain other brands of allulose.

Section Three references

(22) section 2.2.7 exclusivity scope

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

What '**use a novel food**' means isn't clear when it comes to preventing other businesses from selling products that have already been developed to contain a different brand of allulose as an ingredient. The applicant has requested an **exclusive use** permission for Samyang's D-allulose for a period of 15 months on the basis that they have invested significantly in the technology development and safety studies. It is not clear if the lack of clarity has resulted in a lack of effective consultation (Part 1, 7d FSANZ Act).

By over-regulation in food, and limiting the allulose ingredient used to just one brand, innovation is stifled across all these food categories: Table A.1. Non-ingredient limitations are broad sweeping into categories of food that Samyang don't even manufacture. Specifically: Bakery products Beverages (water based, non-alcoholic) Breakfast cereals and cereal based bars Chewing gum Icings and frostings Frozen dairy desserts Yogurt Dressings for salads Gelatins, pudding and fillings Hard and soft candies/confectionery Jams and jellies Sugar products Sugar substitutes Sweet sauces and syrups Fat-based cream.

Section Three references continued

(23) The Commerce Act 1986 in New Zealand prohibits collective restrictive trade practices that lessen competition. The Commerce Act 1986 prohibits a contract, arrangement or understanding that has the purpose, or has or is likely to have the effect, of substantially lessening competition in the market. Australia also has the Competition and Consumer Act 2010. It is the spirit of both these Acts that promote fair competition, prevent monopolies and protect consumers against anti-competitive practices. It would say that the FSANZ approving the expansion of the exclusive economic benefits that create a monopoly, however short lived, would run counter to such legislation.

Section Four

• Difficult to understand scope of exclusivity therefore a lack of meaningful consultation

The exclusivity scope is poorly worded and not clear enough for sufficient consultation to be deemed to have happened on the matter of limiting products already developed that contain non-nexweet branded allulose (Part 1, 7d FSANZ Act).

Section Five

• The actual costs Samyang incurred to bring this application are questionable due to:

- ~ Samyang having already enjoyed 9 years of profitable selling allulose recovering costs
- ~ Multiple Allulose GRAS notes (24) have been approved over this time, giving benefits
- ~ No new unique technology has being developed specifically for the FSANZ approval process
- ~ Test results quoted in the applications were not funded by Samyang (26).
- ~ Similar wording across the USA, FSANZ, and European applications.
- ~ There is a risk that Samyang Corp is triple dipping on the cost recoveries across 3 continents and agencies (33) and not actually incurring many relevant costs to recover.

Section Five References

(24) Cost Recovery - Samyang Corporation first applied for GRAS Notice 647 in 2016, then GRAS 693 in 2017, then GRAS828 in 2019 - all the while making money from the use of their technology they are now claiming more benefits for.

(26) Tests referenced but no costs contribution by Samyang Corp

Tate & Lyle, Tox Strategies applied to have GRAS over allulose in USA FDA dated 3/12/2019 for their <https://www.worldlifeexpectancy.com/australia-coronary-heart-disease> Allulose brand called Dolcia Prima. To support that application they also supplied an D-allulose content in foods based on a study done by others (Oshima et al., 2006) (Table 8 page 17) at this link <https://www.fda.gov/media/151854/download>

(26a) Tests referenced but no costs contribution by Samyang Corp

The date of the study non-randomized controlled trial on gastrointestinal tolerance of D-allulose in healthy and young adults (Han et al 2018b). Dec 19th and all All test materials were supplied by CheilJedang, Inc. (Seoul, Korea) ref 2.2 test materials Funding was provided by the Government

Section Five References continued

This study was supported by a grant from the National Research Foundation of Korea (NRF), funded by the Korean government (NRF-2016R1A2B4011329) and a Science Research Center Project (NRF-2015R1A5A6001906) from the Ministry of Science, ICT and Future Planning through the National Research Foundation. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6315886/> There was no financial or materials contributed or any involvement of the Samyang Corporation in the Allulose GI (Han et al 2018b) study that is being used as a reference and supporting material in the toxicology 2.1.2. section of their FSANZ application.

https://food.ec.europa.eu/system/files/2019-05/novel-food_sum_ongoing-app_2018-0544.pdf

This provides evidence testing costs have not been incurred by Samyang Corp.

There is no date provided on the 18 month chronic study in rats for genotoxicity to determine if that was the same study Yagi and Matsuo conducted in 2009. Certainly this information appears in both the abstract from the 2009 study and the FSANZ application.

The 90 day rate study was repeated following previously conducted methodologies.

<https://www.sciencedirect.com/science/article/abs/pii/S0273230019302491>

Section Six

• Samyang is a high risk, supplier with a poor reputation and history of illegal activities

2012 Samyang were fined by the Korean Fair Trade Commission for price fixing 2001 to 2010. (27)

2019, 2 class actions against in British Columbia for \$288,586.98 dollars in compensation.[30]

2019 - Samyang chairman Jeon In Jang was sentenced to prison for 3 years for embezzling USD \$4.43 million) of his company's funds. (31) His wife and CEO of Samyang, Kim Jung-soo, was given a 2-year prison term, albeit suspended for 3 years, on the same charges. Since Jeon's imprisonment, Kim has assumed her husband's leadership duties! (32)

2019 – Large shareholder Hyundai, wants suspension of board directors with criminal records.[29]

2018 – 1 billion USD, conflict deal settled between Korean based brother and USA based sister (28)

Samyang are a overseas based Corporation (25) who made \$91.2 million AUD equivalent profit in the last financial year. They are a front for the Allulose Novel Food Consortium (ANFC) created to share costs, intel, information to fast track applications for Allulose food safety (21a). Having already been caught price fixing (27) it would be cautious to have the OIA look out for such risks that the global allulose consortium will undertake in price fixing and anti-competitive behaviours to ensure allulose supply remains at a premium price.

Section Six Supporting information

Samyang Corp are not poor, nor do they need any exclusivity to fund their no longer innovative allulose manufacturing technology. In 2022, sales of Samyang Food (a smaller subsidiary to the overall group) amounted to about 909 billion South Korean won, increased from around 642 billion in the previous year. Samyang Food enjoyed its highest sales revenue in the past five years in 2022.

Section Six Supporting information continued

Samyang's Food Division 2022 Profits were 80.27 billion South Korean won – that's \$91.207,560.42 Australian Dollars. This is the financial performance of the company that FSANZ is providing extended amounts of exclusivity to and cost recovery at the expense of every Australian and New Zealand company wishing to make their food healthier by adding allulose into it.

Section Six References

(33) Even when you read the European application, it's copying and pasting from other's safety studies and no costs incurred by Samyang. "Since the specifications for the powder form of D-allulose in this submission are similar to those described for other sources of D-allulose, the metabolism, safety data and other pertinent information discussed for other sources of D-allulose (produced using various GMOs -CJ CheilJedang [US FDA, GRN 400], Matsutani Chemicals [US FDA, GRN 498], and Samyang Corp. [USFDA, GRN 693]) are applicable to the safety of Samyang's D-allulose in this novel food application. A subchronic toxicity study of D- allulose reported that the NOEL was 5,000 mg/kg bw/day, the highest dose tested. Other sources of D-allulose also did not show adverse effects. A chronic toxicity study in rats showed that D-allulose (manufacturer- Matsutani Chemicals) at a dose of 1,280 mg/kg bw/day, the maximum level tested, did not show adverse effects. Due to substantial equivalence between Matsutani Chemicals' and Samyang's D-allulose in specifications (i.e., purity), the results found in the chronic toxicity study of another source of D-allulose can be applied when evaluating the safety of Samyang's D-allulose".

While Samyang quote the results of this study - they had no involvement in it.

https://www.jstage.jst.go.jp/article/jcbrn/45/3/45_08-191/_article The 18 month long study was funded and supported by the Faculty of Agriculture, Kagawa University, Ikenobe, Miki-cho, Kita-gun, Kagawa 761-0795, Japan.

(27) In 2012, Samyang Foods along with several other companies in the Instant Noodles market, including Nongshim, Ottogi, and Korea Yakult, were fined by the Korean Fair Trade Commission for fixing instant noodles prices from 2001 to 2010.

https://www.pymnts.com/cpi_posts/nongshim-samyang-foods-ottogi-and-korea-yakult-fined-for-fixing-instant-noodle-prices/

(28) *"Samyang Foods settles legal battle with Samyang USA - Pulse by Maeil Business News Korea"*. pulsenews.co.kr (in Korean). Retrieved 2021-09-04.

(29) *"HDC seeks to remove Samyang Foods owner couple from board - Pulse by Maeil Business News Korea"*. pulsenews.co.kr (in Korean). Retrieved 2021-09-11.

(30) LLP, Klein Lawyers. *"Notice of approval of certification and settlement against Samyang Foods Co., Ltd"*. www.newswire.ca. Retrieved 2021-09-11.

(31) *"Samyang chief gets 3 years in jail for embezzlement"*. www.theinvestor.co.kr.

(32) *"HDC seeks to remove Samyang Foods owner couple from board - Pulse by Maeil Business News Korea"*. pulsenews.co.kr.

(34) According to the National Obesity Strategy 2022, for every \$1 invested in obesity prevention, it has a return of up to \$6. Ref Figure 6, return on investment of taking preventative action.

Section 7

• The exclusivity terms

Are onerous given their duration, extended scope into so many food items that Samyang doesn't even manufacture, unnecessarily limiting healthy market competition, depriving consumers of choices of products in categories where none will be made by Samyang for 15 months, industry's ability to choose non-corrupt suppliers (27) and the acceptance of premium prices to be paid for D-allulose. These breach consumer protection laws (23) and will have an inequitable impact on all indigenous peoples both in Australia and New Zealand (National Obesity Strategy 1.3 and counter to partnership pledges made by FSANZ on the website.

Section Eight

• Supporting Innovation

The whole spirit of the supporting innovation through exclusivity was never intended to be used in an anti-competitive way that ultimately limits the access of healthy food to those who need it the most across a very broad range, stifles product innovation. It's a precedent to set when preventing product innovation as the nature of the applicant's business is just sweetener manufacturing, not 50 x products manufacturing. FSANZ risks accepting actions under one piece of legislation aimed to encourage innovation, and that action has the effect of being illegal under the Commerce Act 1986 (NZ) which prohibits a contract/arrangement that has the purpose, or to of substantially lessen competition in the market. Australia has also the Competition and Consumer Act 2010.

By over-regulation in food, and limiting the Allulose ingredient used to just one brand, innovation is stifled across all these food categories: Table A.1. Non-ingredient limitations are broad sweeping into categories of food that Samyang don't even manufacture.

Just look at all these foods from Table A that will be locked down to be exclusive use by Samyang Corp – and of all these items the only one that Samyang manufacture is the Sugar Substitutes.

Table 1. items pg 13-14

Specifically: Beverages water based flavoured drinks non-alcoholic Sweetened teas Instant coffees Gelatins Puddings Fillings Fruit fillings Breakfast cereals Cereal based bars reduced energy options reduced sugar options Processed cereal products Processed meal products Frozen dairy desserts ice cream soft serve sorbet Yogurt Frozen yogurt Edible ices Bakery bread rolls cakes cake-type rolls pastries doughnuts Biscuits cookies shortbread butter milk whole wheat biscuits crackers	Fat-based cream. used in modified fat/energy cookies, cakes, pastries, pies dairy based dessert products fat based dessert products Dips and snacks Icings and frostings Jams Fruit spreads Fruit jams Chutneys Vegetable spreads Vegetable jams chutneys Jellies Jelly products Dressings for salads Sweet sauces syrups Sauces and toppings mayonnaises salad dressings Hard candies confectionery Soft candies confectionery chocolate Sugar confectionery Chewing gum Bubble gum Chewing gum Sugar substitutes Tabletop sweeteners
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Section Nine • Proposed Alternative Solution

If FSANZ were to truly support innovation it would look like this. Secure the latest enzyme immediately that allows for continuous Allulose manufacture at a lower price point from here (<https://foodmatterslive.com/article/allulose-could-efficient-cheaper-technology-bring-healthier-sweetener-to-market/> 06 Jul 2023), then work with the sugar cane industry to convert their materials to Allulose immediately.

Section Nine • Proposed Alternative Solution, continued

Require product manufacturers to adequately label their products packaging with laxative information. Allow self-regulation because there's only so much Allulose that can be added for product performance and taste before it becomes cost prohibitive anyway.

Then meet the FSANZ legislation about applications. By setting 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 in Australia and New Zealand. Remembering that for every \$1 invested (or not charged Samyang) the payback in cost savings in the health system is \$6 (34)

Allow in all communications about approval for the brand reputation of Nexweet to be heroes and replace their poor reputation history of price setting, fraud and breaking contractual obligations. Provide a 4 month long exclusivity duration to only the ingredient supply & not covering the products that it's made in. Samyang already are ahead in that they will have notice of the approval. The most likely competitors are also Allulose consortium members, so I have little doubt that there will be price fixing discussions happening anyway. There's no way that Samyang is going to lose.

Section Ten Limitations • Risks of Limited uptake

The reasons why the uptake of Allulose is likely to be hindered is because FSANZ is over-reaching in 3 different ways through the approach to this application:

Over-reaching FSANZ introducing regulations where they aren't needed

FSANZ have over-reached introducing regulations which meddle in the affairs of industry preventing any Australian and New Zealand business from formulating their own food product by setting maximum allowable amounts of the Allulose ingredient that can be used. This is contrary to stating 2.4.1.1. FSANZ is currently unaware of any health or safety concerns to consumers, associated with permitting the use of D-allulose

What would be in the public's best health interest would be to get the lowest priced Allulose into the hands of as many businesses to convert into as many products as possible. To give food manufacturing businesses based in Australia and New Zealand a real shot at competing against ultra-low priced sugar, which causes well documented harm to peoples' health. To give consumers real choices when managing calorific intake and blood sugar responses when consuming their food.

The effects of added sugar intake — higher blood pressure, inflammation, weight gain, diabetes, and fatty liver disease — are all linked to an increased risk for heart attack and stroke (38) whereas allulose suppresses blood glucose elevation post-consumption (Hayashi et al., 2010; Iida et al., 2008) and reduces body fat accumulation (Matsuo et al., 2001). This sugar is minimally converted to energy in humans (Iida et al., 2010).

Looking at the statistics, it is NOT obesity which has the small unquantified benefits (3), laxation is 0.0037% of the deaths. How can FSANZ be looking at the wrong risks? How can a risk assessment not be undertaken when there are so many lives at risk? How many more people have to die unnecessarily or have their access to a viable sugar alternative restricted due to unnecessary regulation of company product formulations, and what we expect to be premium prices to fund a mega-rich overseas corporation and create a monopoly?

Section Ten Limitations • Risks of Limited uptake continued

Over-reaching & breaching consumer protection laws:

Accepting a situation where premium prices are charged for allulose for 15 months, due to the exclusivity clause, it will limit access to allulose to the rich and white populations.

In New Zealand, it is estimated that the number of people diagnosed with diabetes is over 300,000 people (predominantly type 2 diabetes) the effects of which can be managed with dietary food interventions (medical audit pg . Within the New Zealand population, the prevalence of diabetes in Māori and Pacific populations is around three times higher than among other New Zealanders. Prevalence is also high among South Asian populations (14). It's these same people in lower socio-economic areas that need it the most, yet can afford it the least.

Over-reaching & breaching consumer protection laws: continued

In Australia – 1.3 million people have Type 2 diabetes. If you need to imagine just how many people that is, it's the entire population of Adelaide. Around 58,600 people were newly diagnosed (incidence) with type 1 diabetes between 2000 and 2021 according to the National (insulin-treated) Diabetes Register (NDR). In 2021, there were 3,000 people newly diagnosed with type 1 diabetes in Australia, equating to 12 diagnoses per 100,000 population. (13)

Failing to give the lower socio-economic access to much needed allulose at an affordable pricing is the biggest opportunity cost. In 2020–21, an estimated \$3.4 billion of expenditure in the Australian health system was attributed to diabetes, representing 2.3% of total disease expenditure. The breakdown in expenditure by diabetes type included:

type 2 diabetes 68% (changeable by diet) refer to the medical audit results on page

type 1 diabetes 11%

gestational diabetes 2.1%

other and unspecified diabetes 20% (13).

Over reaching and breaching anti-trust laws

FSANZ have over-reached the scope of exclusivity way past the nature of the applicant's business. Exclusivity is being granted to an overseas based organisation, over products that the applicant doesn't even manufacture. This is a dangerous precedent that creates a monopoly and breaches anti-trust legislation.

The limits to the amount of allulose that can go into a range of foods limits the ability of industry to adopt Allulose as a sugar substitute. The short sightedness will cost everyone dearly in the long run.

By approving the exclusivity as requested in the application, FSANZ would be prioritising profits going to an overseas corporation and significantly inhibiting the ability to fight the obesity epidemic in both Australia and New Zealand right now, at a time when it's crucial to get better health outcomes. A 15 month long economic exclusivity prevents product manufacturers to function freely to achieve desired health outcomes.

Section Eleven • Direct costs

The personal and societal costs are significant. The financial and other costs of obesity are significant and continue to rise (35), with major impacts on individuals and on communities, society, the economy, and natural resources and ecosystems (36) If we don't act, obesity may cost an estimated \$87.7 billion in just 10 years (37) And to cover the costs of obesity, each Australian pays an additional \$678 in taxes each year (14)

Section Eleven References

(35) The Obesity Collective. Weighing in: Australia's growing obesity epidemic. The Collective for Action on Obesity;2019.

(36) The NCD Alliance. NCD Alliance briefing paper: Tackling non-communicable diseases to enhance sustainable development. Geneva, Switzerland: NCD Alliance; 21 March 2012.

(37) Pricewaterhouse Coopers. Weighing the cost of obesity: a case for action. Sydney NSW: PwC;2015.

(38) <https://www.health.harvard.edu/heart-health/the-sweet-danger-of-sugar#:~:>

(39) Organisation for Economic Co-operation and Development. Heavy Burden of Disease Report. Country Highlights - Australia. Paris: OECD Publishing; 2019.

Response ID ANON-789J-4JGG-X

Submitted to Application A1247 D-allulose as a Novel Food
Submitted on 2023-12-20 17:57:45



Introduction

Name



Email address

Email:



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

Organisation:

n/a

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

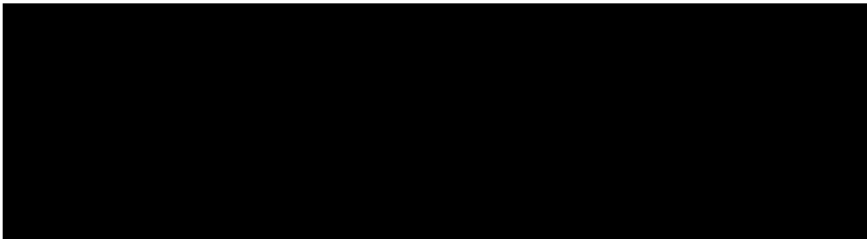
Groups to which you belong:

Public health group

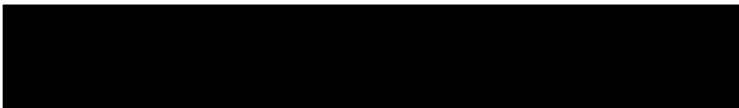
If other please specify:

Who is the contact person for this submission

Please include name, email address and phone number:



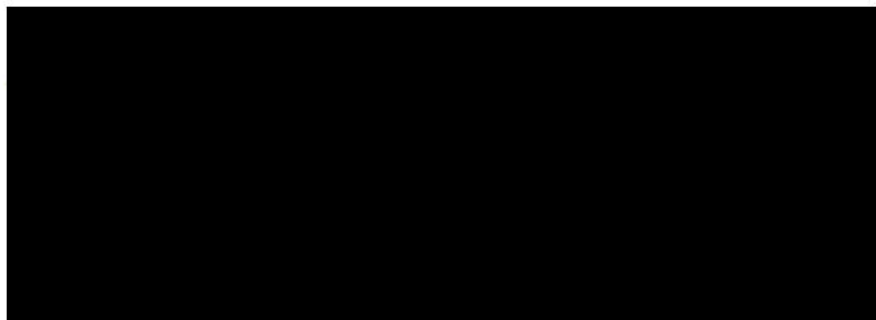
Submission



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Submission after review of D-allulose application A1247.pdf was uploaded



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