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

09/03
21 May 2003

FINAL ASSESSMENT REPORT

APPLICATION A453

TREHALOSE AS A NOVEL FOOD

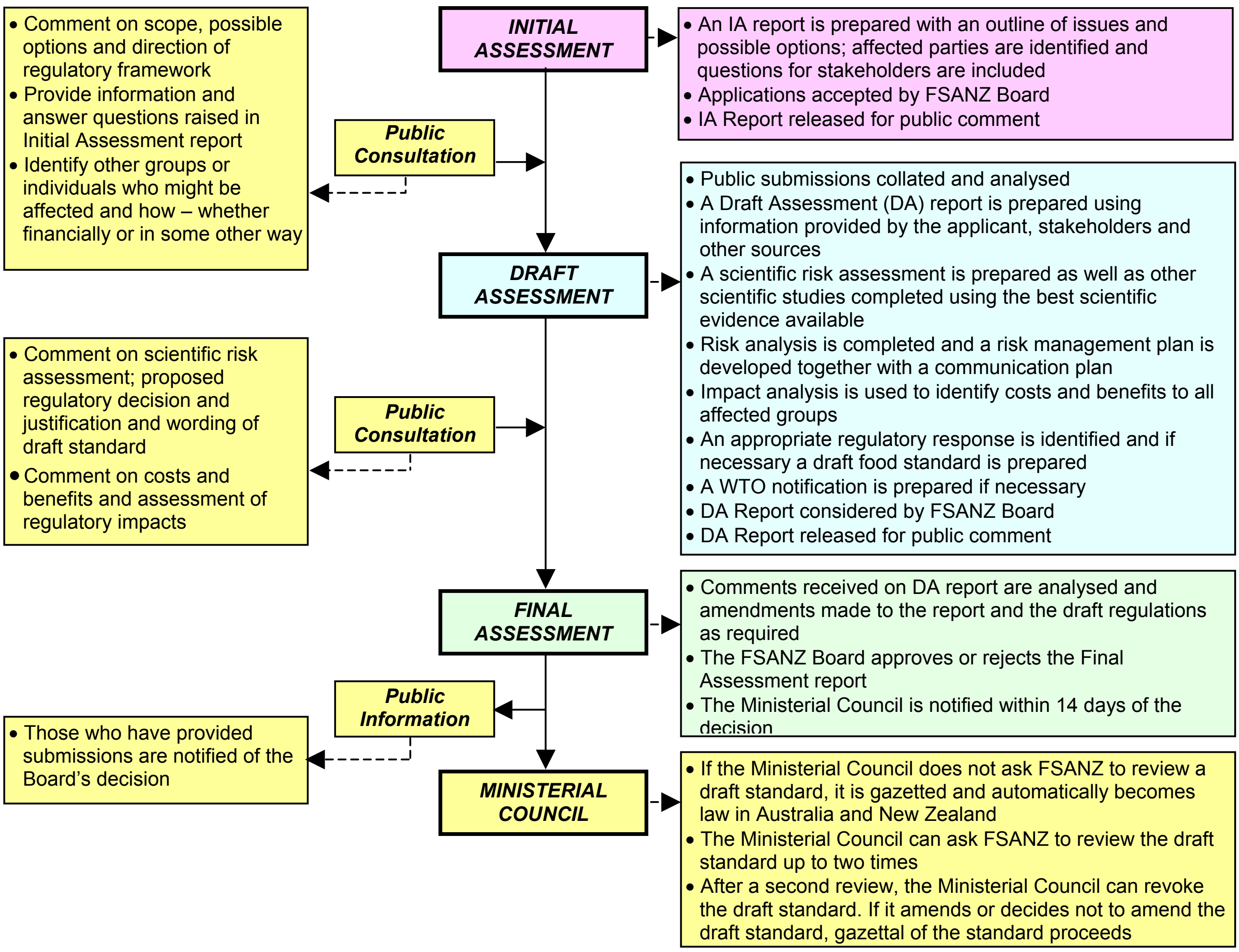
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the Commonwealth; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Commonwealth, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Commonwealth, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Australia New Zealand Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



Final Assessment Stage

The Authority has now completed two stages of the assessment process and held two rounds of public consultation as part of its assessment of this Application. This Final Assessment Report and its recommendations have been approved by the FSANZ Board and notified to the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council).

If the Ministerial Council does not request FSANZ to review the draft amendments to the *Australia New Zealand Food Standards Code*, an amendment to the Code is published in the *Commonwealth Gazette* and the *New Zealand Gazette* and adopted by reference and without amendment under Australian State and Territory food law.

In New Zealand, the New Zealand Minister for Health gazettes the food standard under the New Zealand Food Act. Following gazettal, the standard takes effect 28 days later.

FURTHER INFORMATION

Submissions

No submissions on this matter are sought as the Authority has completed its assessment and the matter is now with the Australia and New Zealand Food Regulation Ministerial Council for consideration.

Further Information

Further information on this Application and the assessment process should be addressed to the FSANZ Standards Liaison Officer at one of the following addresses:

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Assessment reports are available for viewing and downloading from the FSANZ website www.foodstandards.gov.au or alternatively paper copies of reports can be requested from the Authority's Information Officer at info@foodstandards.gov.au including other general enquiries and requests for information.

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EXECUTIVE SUMMARY

Food Standards Australia New Zealand (FSANZ) formerly known as the Australia New Zealand Food Authority (ANZFA) received an application from Hayashibara Company Ltd. on 4 October 2001 seeking to amend Standard A19[1] -Novel Foods of Volume 1 of the Australian *Food Standards Code* to permit the use of trehalose as a novel food ingredient.

Trehalose is a disaccharide consisting of 2 glucose units and is produced by a multi-step enzymatic process. Trehalose can be found at low levels in certain foods (brewers and bakers yeast, bread, beer and wine, honey and mushrooms). Trehalose exhibits the same technological properties as sucrose with a relative sweetness of 40-45% of that of sucrose.

Trehalose is used in a number of countries as a food (USA, South Korea and Taiwan) or food additive (Japan). Trehalose has approval as a novel food in the European Union.

Regulatory Problem

Under the current food regulations, novel foods and novel food ingredients are required to undergo a pre-market safety assessment, as per Standard 1.5.1 – Novel Foods. Trehalose is considered to be a novel food because the level of consumption in the proposed products is expected to be far greater than that normally consumed from current sources of trehalose in food. Therefore, under the proposed conditions of use, trehalose is considered to be a 'non-traditional' food and also a novel food because the safety of its use as proposed is unknown. A risk-based safety assessment must therefore be performed by FSANZ.

Objective

To determine whether the food regulations should be changed to permit the sale of trehalose as a novel food. Such an amendment needs to be consistent with the section 10 objectives of the FSANZ Act.

Technical properties of trehalose

Trehalose has a range of useful technological properties/functions (e.g. reduced sweetener, stabiliser, cryoprotectant etc) and approval may provide food processors with the opportunity to develop innovative new processed foods and to improve the quality and increase the shelf-life of existing processed foods. Therefore, there are benefits for both industry and consumers in the approval of trehalose.

Hazard assessment

There was no evidence of toxicity in a broad range of studies in both animals and humans. The main hazard from trehalose was gastro-intestinal symptoms. However, it was concluded that, provided consumers did not exceed a level of between 33-50g from a single exposure to trehalose in food, then no symptoms would be expected in the majority of the population. The level of 33g applies to the most sensitive individuals (Asian populations).

[1] Standard A19 Volume 1 of the *Australian Food Standards Code* was replicated in Standard 1.5.1 of Volume 2 of the *Australia New Zealand Food Standards Code*.

Dietary exposure

Predicted mean trehalose exposure from consumption of foods containing both added and naturally occurring trehalose is 5.7 g/day for Australians (2 years and above) and 4.5 g/day in NZ (15 years and above), rising to 22 and 18 g/day respectively at the 95th percentile of exposure. Exposure is higher, in total and on a bodyweight basis, among children and teenagers, reflecting the contribution of ice cream, toppings and confectionery in these age groups. 95th percentile exposure among teenagers, the group with the highest exposure, is 34 g/day in both Australia and New Zealand.

Risk assessment

The data supports the safety of trehalose at the level of intake that would be achieved by addition of trehalose to a range of foods at the maximum levels provided by the Applicant. Exposure for all ages for Australian and New Zealand populations is at or below the level (33-50g) at which minimal or no gastro-intestinal effects were observed in subjects, even at the 95th percentile (highest) exposure level.

Other issues raised in public submissions

No additional labelling statements for consumers were needed (other than general labelling requirements for ingredients of food) as it was considered that the potential to exceed a level in which gastro-intestinal effects had been reported was extremely unlikely.

Based on the dietary modelling, the level of consumption of trehalose is not expected to significantly alter the glycaemic load of the diet based on the reported carbohydrate intake in Australia and New Zealand.

Impact analysis of regulatory options

The only options identified were to permit or not permit the use of trehalose. The impact analysis shows that the first option (to permit trehalose as a novel food) satisfies the objectives based on the outcome of the scientific risk assessment and the Regulatory Impact Statement (RIS) taking into account matters raised following the public consultation period.

These matters included an assurance of the safety of trehalose, the provision of adequate labelling so as to give consumers informed choices for purchases of products containing trehalose, and the provision of benefits to industry and governments, in terms of enhanced market opportunities and trade.

Consultation

FSANZ has consulted on the advantages and disadvantages to specific stakeholders should permission be granted for trehalose as a novel food and evaluated the costs and benefits to consumers, the Government and industry.

Statement of Reasons

FSANZ recommends the approval of Application A453 for the following reasons:

- There are no public health and safety concerns associated with consumption of trehalose to food at the proposed levels.

- Trehalose provides a range of technological functions in a range of food products.

- The proposed changes to the *Australia New Zealand Food Standards Code* are consistent with the section 10 objectives of the *Food Standards Australia New Zealand Act 1991*.

- The Regulatory Impact Statement indicates that, for the preferred option, namely, to approve the use of trehalose as a novel food, the benefits of the proposed amendment outweigh the costs.

Recommendation

It is recommended that trehalose be approved as a novel food, without any conditions of use.

The proposed drafting to the *Australia New Zealand Food Standards Code* (the Code) is shown in Attachment 1.

1. INTRODUCTION

An Application has been received from Hayashibara Company Ltd. on 4 October 2001 seeking to amend Standard A19[2] -Novel Foods of Volume 1 of the *Australian Food Standards Code* to permit the use of trehalose as a novel food ingredient.

1.2 Transitional Requirements

This application reached full (draft) assessment stage under the operation of the *Australia New Zealand Food Authority Act 1991* (ANZFA Act), and will be finalised in accordance with the provisions of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act).

FSANZ has therefore been required to:

1. give the Applicant the opportunity to (by 29 July 2002) request deferral of consideration of the application in order to provide any additional information;

2. give notice under section 13A or 14 of the FSANZ Act; and

3. review the full (draft) assessment having regard to any new submissions received in response to the above notice as well as any written policy guidelines that have been notified by the Ministerial Council.

2. REGULATORY PROBLEM

The application is seeking approval of trehalose as a novel food ingredient. Under the current food regulations, novel foods and novel food ingredients are required to undergo a pre-market safety assessment, as per Standard 1.5.1 – Novel Foods. The purpose of Standard 1.5.1 is to ensure that non-traditional foods, which have features or characteristics that may raise safety concerns will undergo a risk-based safety assessment before they are offered for retail sale in Australia or New Zealand.

Novel Foods is defined in the Standard as:

> *A non-traditional food or food ingredient for which there is insufficient knowledge in the broad community to enable safe use in the form or context in which it is presented, taking into account -*
>
> *(a) the composition or structure of the product;*
> *(b) levels of undesirable substances in the product;*
> *(c) the potential for adverse effects in humans;*
> *(d) traditional preparation and cooking methods; or*
> *(d) patterns and levels of consumption of the product;*

A Non-traditional food means a food, which does not have a history of significant human consumption by the broad community in Australia or New Zealand.

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[2] Standard A19 Volume 1 of the *Australian Food Standards Code* was replicated in Standard 1.5.1 of Volume 2 of the *Australia New Zealand Food Standards Code*.

Trehalose is considered a novel food ingredient because it is a non-traditional food for which there is insufficient knowledge in the broad community to ensure safe use in the form in which it is presented. Thus, an assessment of its safety is required before it can be marketed.

3. OBJECTIVES

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives, which are set out in section 10 of the *Food Standards Australia New Zealand Act 1991.* These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying such measures, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry; and
- the promotion of fair trading in food.

The specific objectives in assessing this Application are:

- to protect the public health and safety of the community in their consumption of trehalose as an ingredient in a range of products; and

- to provide adequate information about the use of trehalose as an ingredient, where appropriate, to enable consumers to make informed choices.

4. BACKGROUND

4.1 Properties of trehalose

Trehalose is a disaccharide consisting of 2 glucose units linked by a 1,1 α-glucosidic bond produced by a multi-step enzymatic process. Trehalose occurs widely in nature with small amounts found in certain foods (brewers and bakers yeast, bread, beer and wine, honey and mushrooms).

The Applicant claims that trehalose exhibits the same technological properties as sucrose with a relative sweetness of 40-45% of that of sucrose. Therefore, it is useful in food applications where reduced sweetness is desired and has additional functions as a humectant, texturiser, stabiliser and formulation aid.

Trehalose does not undergo Malliard (browning) reactions and the applicant claims that trehalose has excellent thermal and hydrolytic stability over a broad pH range for use in food processing. Trehalose can also be used as a cryo-protectant and as a rehydration aid for dehydrated products.

The energy value factor for trehalose would be 17 kJ/g, which is the designated energy factor for carbohydrates as per Table 1 to subclause 2(2) of Standard 1.2.8-Nutrition Information Requirements.

4.2 Proposed uses

Trehalose is proposed to be used in the following foods for different applications (e.g. as a flavouring, stabiliser, cryoprotectant and for its rehydration abilities):

- Bakery Creams;
- Biscuits (reduced-fat)
- Cakes (sponge)
- Confectionery (Cream or fruit filled bars; chocolate covered bars);
- Confectionery (high-boils);
- Icings;
- Sugar Coatings;
- Ice-cream;
- Instant Noodles/Rice;
- Processed Fruit (jams, fillings, toppings);
- Restructured Sea Food

4.3 Approval in other countries

4.3.1 USA

A Generally Recognised As Safe (GRAS) notification was filed and accepted on 5 October 2000.

4.3.2 EU

An application was filed (25 May 2000) with the UK Food Standards Agency to seek approval under the EU Novel Food Regulations. Approval of trehalose as a novel food ingredient was granted (July 2001).

4.3.3 Japan

Trehalose is permitted as a food additive in Japan.

4.3.4 South Korea and Taiwan

Trehalose is considered as a food.

5. ISSUES RELEVANT TO THIS APPLICATION

5.1 Technical properties of trehalose

Trehalose is a food or food ingredient that has unique properties that make it very useful and versatile in food formulation and processing. Primarily it can be used to replace some of the sucrose where it is desirable to reduce the level of sweetness for a more balanced or improved taste profile. As trehalose is not a reducing sugar it does not undergo Maillard-type browning reactions. At elevated temperatures, it is more resistant to acid-catalysed hydrolysis, and it does not caramelise (**Attachment 3**).

It may be used in beverages, purees and fillings, nutrition bars, surimi, dehydrated fruits and vegetables, confectionery and white chocolate for cookies or chips. In instant noodles and pre-cooked rice, it accelerates rehydration. In baked goods it appears to inhibit starch retrogradation more effectively than other sugars and thus provides improved stability and delays the onset of staleness.

Trehalose appears more effective in stabilizing proteins against damage caused by drying or freezing than other sugars. Trehalose has also been shown to help maintain delicate protein structures after thawing and to stabilize disulfide bonds, thereby inhibiting the formation of odours and off-flavours.

Trehalose is currently being used in Japan to retard starch retrogradation in such products as Udon noodles (0.2% of flour), clam chowder (0.4% of product) and traditional Japanese confectioneries (10-50% of sugars).

Approval of trehalose will provide food processors with the opportunity to develop innovative new processed foods and to improve the quality and increase the shelf-life of existing processed foods.

5.2 Hazard assessment of trehalose

5.2.1 Joint Expert Committee on Food Additives review of the safety of trehalose

The Joint Expert Committee on Food Additives (JECFA) examined the safety of trehalose in June 2001 (**Attachment 2**). The animal and humans studies indicated that trehalose is rapidly converted to glucose by the enzyme trehalase. A range of toxicological studies undertaken in animals indicated that there was no evidence of toxicity in animals up to very high doses. The enzymes used in preparation of trehalose did not raise any safety concerns. Studies in humans indicate that trehalose is well tolerated. Increased frequencies of malabsorption and gastrointestinal symptoms were noted in individuals consuming single doses of 20g or more. In the limited data on individuals with known or suspected trehalase deficiency, the only effects seen were gastrointestinal effects expected of an undigested disaccharide. On the basis of the available information, JECFA considered that an acceptable daily intake (ADI) "not specified" was appropriate for trehalose[3].

[3] ADI "not specified" is used to refer to refer to a food substance of very low toxicity which, on the basis of the available data and the total dietary intake of the substance.

5.2.2 Food Standards Australia New Zealand Review of Trehalose

FSANZ has reviewed the data used by JECFA to assess the safety of trehalose in humans. FSANZ also considered new additional data submitted by the Applicant on tolerance levels for trehalose in humans (**Attachment 2**).

FSANZ has concluded from the review of the available human data that the 20g threshold level for gastrointestinal effects proposed by JECFA could not be supported by the available data.

FSANZ acknowledges that, from the available data, Japanese populations may be more intolerant of trehalose compared to western populations. However, the lack of detail in the methodology and inadequate reporting of time of onset and severity of gastro-intestinal symptoms experienced in Japanese subjects following dosing at 20g, limits the applicability of this threshold for the general consumer population. Furthermore, other studies at higher doses indicated that western populations could tolerate trehalose at doses as high as 50g.

Therefore, in conclusion, provided that consumers did not exceed a level of between 33-50g from a single exposure to trehalose in food, then there would be minimal gastro-intestinal symptoms expected in subjects. The level of 33g would apply to the most sensitive individuals (Asian populations) as identified in the current scientific literature.

5.3 Estimated dietary exposure

A dietary exposure assessment was conducted to predict exposure of Australians and New Zealanders to trehalose, as well as exposure through natural occurrence of trehalose in certain foods.

Predicted mean trehalose exposure from consumption of foods containing both added and naturally occurring trehalose is 5.7 g/day for Australians (2 years and above) and 4.5 g/day in NZ (15 years and above), rising to 23 and 18 g/day respectively at the 95th percentile of exposure. This is substantially higher than estimated exposure through natural occurrence of trehalose in mushrooms, honey, bread, wine, beer and prawns (mean and 95th percentile exposure is 0.3 and 0.9 g/day respectively in Australian and New Zealand adults).

Exposure is higher, in total and on a bodyweight basis, among children and teenagers, reflecting the contribution of ice cream, toppings and confectionery in these age groups. 95th percentile exposure among teenagers, the group with the highest exposure, is 34 g/day in both Australia and New Zealand.

Predicted exposures are considered to be overestimates of actual exposure if trehalose were to be approved for use as a novel food due to the conservative nature of the assumptions included in the modelling.

5.4 Risk assessment of trehalose

The data supports the safety of trehalose at the level of intake that would be achieved by addition of trehalose to a range of foods at the maximum levels provided by the Applicant. Exposure for all ages for Australian and New Zealand populations is at or below the level (33-50g) at which minimal or no gastro-intestinal effects were observed in subjects, even at the 95th percentile (highest) exposure level.

The highest potential exposure by age group (teenagers at the 95th percentile exposure level) was 34g/day for both Australia and New Zealand) consumers which is still within the level at which minimal or no gastro-intestinal effects were observed (**Attachment 2**).

The potential to exceed a level of 33-50g is considered most unlikely if trehalose is consumed over a 24-hour period due to the conservative nature of the assumptions used in the modelling; namely:

- trehalose would have to be added to all the foods proposed which is extremely unlikely;
- all the foods would have to contain trehalose at the maximum level proposed;
- the data used for modelling is a 24-hour record which overestimates food consumption for high consumers (the use of multiple day records tends to significantly reduce predicted high consumer exposure); and, that
- the modelling assumes that the individual foods eaten over 24 hours were in fact eaten at one time not over a period of two or more occasions during the day, which is more likely (eg confectionery).

The data reflecting a single eating occasion exposure, suggested that Australian and/or NZ teenagers consuming ice-cream at the 95th percentile exposure level could potentially approach a single consumption of 40g of trehalose from consumption of ice cream alone, on one eating occasion. Australian and New Zealand adults could approach a level of 50g (48g and 47g respectively) and NZ teenagers may exceed 50g (at 54g)[4] following consumption of toppings on one occasion.

In conclusion, high-consuming individuals of either ice-cream (teenagers) or toppings (adults) on one eating occasion are the only groups that have a potential to approach the level of between 33-50g where minimal gastro-intestinal symptoms were observed in some individuals. However, due to the conservative assumptions in the dietary exposure calculations and that trehalose is generally well tolerated in individuals (particularly individuals in western populations) up to a level of 50g, FSANZ concludes that there are minimal public health and safety concerns if trehalose is used in the manner proposed by the Applicant, which is consistent with Good Manufacturing Practice (GMP).

5.5 Other issues raised in public submissions

5.5.1 Trehalose as a novel food

The Australian Food and Grocery Council (AFGC) raised the issue that, since trehalose is found naturally in a range of foods, that trehalose is not a ‘non-traditional food’. It was also suggested in the submission that trehalose is currently defined as a food by the definition of ‘sugars’ in Standards K1 and 2.8.1 respectively, and therefore, the Application should be *rejected.*

[4] This figure is unreliable due to small sample numbers.

Evaluation at Draft Assessment

The dietary exposure assessment found that the amount of trehalose to which Australian and New Zealand populations could potentially be exposed to via addition in the proposed foods to be much greater than exposure that occurs through natural occurrence in foods (bread, beer, wine, honey and mushrooms) (**Attachment 3**).

Therefore, FSANZ considers that trehalose is a non-traditional food, as the level of consumption is far greater than that normally consumed from current sources of trehalose in food. It is also a novel food because under the proposed conditions of use, its safety is not known.

In addition, other regulatory bodies, namely the UK Advisory Committee on Novel Foods and Processes considered trehalose produced by a novel enzymatic process could be approved as a novel food ingredient (July 2001). Therefore, FSANZ is not inconsistent with other regulatory bodies determination with respect to the status of trehalose as a novel food.

5.5.2 Issues raised during Final Assessment

A further submission after Draft Assessment from the AFGC raised the following points in relation to trehalose and its status as a Novel Food:

- FSANZ has failed to address the issues raised at Draft Assessment;
- trehalose is already standardised as a food by the definitions of sugars in Standard 2.8.1
- FSANZ must address the strict definition of a "non-traditional food" which excludes trehalose from being classified as a novel food;
- by virtue of the outcome of the safety assessment which places no restrictions on the use of trehalose, FSANZ must acknowledge that there is sufficient knowledge in the community to enable safe use in the form or context in which it is presented and therefore should declare trehalose not to be a novel food.

Evaluation

Trehalose falls within the definition of a sugar in Standard 2.8.1 Sugars, Clause 1 (a) by virtue of its chemical structure (i.e., a disaccharide). However, this does not give automatic approval as a food, as foods must also meet the requirements of the *General Food Standards* in Chapter 1 of the Code. Trehalose is a non-traditional food and also a novel food (see below). Therefore, it is required to undergo a safety assessment performed under Standard 1.5.1. The purpose of Standard 2.8.1 is to provide a definition, not to give authorisation for use.

FSANZ considers trehalose to be a non-traditional food because the proposed food uses would lead to a significant increase in consumption by the broad community in Australia or New Zealand. FSANZ acknowledges that there has been some consumption of trehalose in foods such as bread, beer, wine, honey and mushrooms; however, trehalose is present at very low levels in these foods. FSANZ's evaluation therefore classifies it as a non-traditional food as there will be a significant increase in consumption in Australia and New Zealand if trehalose is permitted as a novel food in Standard 1.5.1.

The object of the Novel Food Standard is to assess the safety of non-traditional food for which there is 'there is insufficient knowledge to enable safe use' in the broader community. Prior to the application, trehalose had not undergone a safety assessment in the context of the Australian and New Zealand diets. There was therefore insufficient knowledge in the broad community to ensure safe use in the form in which it is presented. The safety of trehalose in the context of Australia and New Zealand has now been assessed by FSANZ as a consequence of trehalose being classified as a novel food. The safety assessment showed that trehalose is safe for human consumption, when used in the manner proposed by the Applicant, which is consistent with Good Manufacturing Practice (GMP).

Even though FSANZ's assessment has shown that trehalose can cause gastro-intestinal effects at high levels of exposure, the decision to not impose specific conditions of use on the use of trehalose does not mean that trehalose should no longer be considered as a novel food. Whether or not there are conditions of use is not a criterion for determining the novelty of the food under Standard 1.5.1, and the standard itself envisages approvals of novel foods without any restrictions on use.

5.5.3 Labelling of trehalose as a novel food

The New Zealand Food Safety Authority submission suggested that Trehalose does not meet the generic name sugar contained in Standard 1.2.4[5] and therefore requested that FSANZ comment on whether trehalose should be more clearly described in the ingredient list.

Evaluation

FSANZ considers that the current labelling requirements should be adequate for consumers to make an informed choice. Trehalose would be labelled according to current labelling requirements of any ingredient in food as described in Standard 1.2.4 Labelling of Ingredients, in particular, Clause 4 (b) which pertains to a requirement of a description of the true nature of the ingredient. By virtue of the limitations on the generic name 'sugar' under Standard 1.2.4, the name trehalose would be used with the addition of other information to qualify or clarify the name, provided it was not false and misleading to consumers.

In addition, any information required in or on a food label needs to comply with the legibility requirements in Standard 1.2.9 of the Code, which requires that all food labels present information so that it is:

- legible, and
- prominent (such as to afford a distinct contrast to the background) and
- in English.

5.5.3 Requirement for a warning statement

Public submissions raised the following issues:

[5] Sugar may be used to describe; white sugar, white refined sugar, caster sugar, castor sugar, loaf sugar, or cube sugar, icing sugar, coffee sugar, coffee crystals, raw sugar. The word 'sugars' must not be used in a statement of ingredients.

- Due to a hereditary form of trehalose intolerance, the possibility of an advisory statement on the label to alert these specific consumers should be considered.

- There are some individuals that are intolerant to trehalose and have gastro-intestinal effects following consumption. Therefore, a mandatory advisory statement should be considered.

Evaluation

It is correct that there is a hereditary form of trehalose intolerance in some individuals due to a deficiency in the enzyme trehalase, which metabolises trehalose to glucose in humans. In trehalase deficient individuals gastro-intestinal symptoms may possibly occur at lower doses of trehalose, however, the incidence of trehalase deficient individuals (particularly in the western population) appears to be very low and the dose at which trehalose is tolerated in these populations are unclear from the available data.

There are also some individuals that cannot tolerate high dose levels of trehalose. The threshold for effects was reported as a level of 20g by JECFA (2001). At or above that dose malabsorption and gastrointestinal effects were reported (e.g. malabsorption, laxation, abdominal dysphoria and crepitus). However FSANZ's assessment was that the study used to support a 20g threshold level proposed by JECFA could not support this threshold level.

Therefore, FSANZ consider that a mandatory advisory statement is considered unnecessary to alert consumers to the possibility of gastro-intestinal effects following consumption of trehalose-containing products. The risk to consumers has been addressed in section (5.4) above).

5.5.4 Consideration of the glycaemic index

Public submissions raised the following issues:

- The glycaemic index of trehalose and its potential impact on glycaemic load of the diet should be taken into account in dietary modelling.

FSANZ approached the submitter in order to clarify the concerns raised with respect to glycaemic index (GI) and the following information was supplied to FSANZ:

- Glycaemic load (GL) reflects the impact foods have on blood glucose levels and insulin production, taking into account both their GI and amount of carbohydrate.

- High glycaemic load causes greater blood glucose responses post prandially (post-meal) and are undesirable, as high glycaemic load diets are associated with increased risk of type 2 diabetes, cardiovascular disease and some cancers.

- The glycaemic load of a food is GI times carbohydrate content (divided by 100). The GL of the diet is found by summing the GL's of all the carbohydrate containing foods in the diet - the proportional contribution of any one food can then be determined.

The difficulty is in interpreting the individual contributions. As the overall aim is to lower the GI of the average, Western diet for better health, then novel foods that disproportionately increase the GL of the diet would be disadvantageous - especially if they become used in a range of different foods and/or there are a number of new, high GL sweeteners being used.

Evaluation

Trehalose is broken down (metabolised) to glucose by the enzyme trehalase in the small intestine and then readily absorbed. The metabolism of trehalose resembles maltose or starch in that both products are absorbed in the form of glucose and very little is absorbed as the parent trehalose. Since trehalose is similar to maltose or starch it may be considered nutritionally equivalent.

From the Dietary Modelling Report (**Attachment 3**) the predicted mean exposure from the consumption of foods containing both added and naturally occurring trehalose is 5.7 g/day for Australians (2 years and above) and 4.5 g/day for New Zealanders aged 15 years and above.

The estimated mean dietary exposures are higher, in total and on a bodyweight basis, for children and teenagers: 6.3 g/day (Australian children aged 2 –12 years); 8.7 g/day (Australians aged 13 –1 8 years); and 7.5 g/day (New Zealanders aged 15 –1 8 years). These are likely to be overestimates as the dietary modelling assumes individual consumption of all food items containing trehalose at the proposed levels.

The 1995 Australian National Nutrition Survey (NNS) and the 1997 New Zealand NNS report mean daily intakes of total carbohydrate of 255 g/day (19 years and over) and 267 g/day (15 years and over) respectively. Therefore it can be assumed that the quantity of trehalose expected to be consumed would not be significant when compared to the expected overall daily carbohydrate intake.

Hence it can be concluded that the proposed use of trehalose as a novel food will have minimal impact on nutrition when considered in the context of the overall diet.

Overall conclusion: Based on the dietary modelling, the level of consumption of trehalose from the proposed foodstuff (estimated 4.5 - 5.7 g/day) is not expected to significantly alter the glycaemic load of the diet based on the reported carbohydrate intake in Australia and New Zealand (average daily intake of approx. 250g/day). In addition, there is no provision to date in the *Australia New Zealand Food Standards Code* to regulate the glycaemic index of foodstuff.

5.5.5 Changes to the drafting at Final Assessment

The AFGC suggested that the reference to Standard 1.3.4 Identity and Purity in the current drafting should be amended to *Must comply with the requirements of Standard 1.3.4* rather than the present words *May only be added to food according to Standard 1.3.4* as Standard 1.3.4 does not set conditions under which substances can be added to food.

Evaluation

Following advice from the Office of Legal Counsel, FSANZ accepts that it is not necessary to make reference to Standard 1.3.4 as a condition of use, as that Standard is of general application in any event. As a result, the suggestion by the AFGC is redundant.

6. REGULATORY OPTIONS

Options available are:

Option 1. Not permit the use of trehalose.

Option 2. Permit the use of trehalose.

Other alternatives to regulation (e.g. a Code of Practice) are not considered appropriate with regard to the use of trehalose as a novel food.

7. IMPACT ANALYSIS

Parties likely to be affected by the possible options as listed above are:

- Manufacturers of food products in Australia and New Zealand that are intending to or could use trehalose as an ingredient.
- Consumers, who may wish to purchase products containing trehalose.
- Governments of the States, Territories, Commonwealth and New Zealand.

7.1 Option 1

Maintain the *status quo* and not permit the use of trehalose as a novel food.

AFFECTED PARTY	BENEFITS	COSTS
Government	No perceived benefits	No perceived costs. Although there is no perceived cost for the government, lack of approval in Australia or New Zealand may be construed as a non-tariff barrier to trade.
Industry	No perceived benefits	No perceived costs.
Consumers	No perceived benefits	Foods with reduced sweetness or other qualities provided by trehalose may be seen as desirable to have available to some consumers. Therefore, this option may deny consumers products with possibly improved flavour profiles and a range of other functions that may be advantageous to consumers.

7.2 Option 2

Amend Standard 1.5.3 to permit the use of trehalose.

AFFECTED PARTY	BENEFITS	COSTS
Government	No perceived benefit	No perceived cost other than the cost of amending the Food Standards Code.
Industry	Permitting the use of trehalose would provide food manufacturers with an ingredient with a range of useful functions.	No perceived costs..
Consumers	Approval of trehalose may assist in improving food variety and possibly improved flavour profiles, which may be of benefit to some consumers.	No perceived costs.

7.3 Evaluation

Maintaining the *status quo* (Option 1) appears to provide no benefit to the government, industry and consumers. Option 1 denies industry access to a new novel food ingredient, which has been demonstrated to be safe and achieve a number of beneficial functions in food.

Option 2, which proposes to amend the *Australia New Zealand Food Standards Code* to permit the use of trehalose as a novel food appears to impose no significant costs on government, industry or consumers and may be of benefit to industry and consumers. Assessment of the costs and benefits of Options 1 and 2 indicates that there would be a net benefit in permitting the use of trehalose. Therefore, option 2 is the preferred option.

8. CONSULTATION

8.1 Public consultation

FSANZ conducted an initial assessment (Preliminary Assessment under section 13 of FSANZ Act 1991) on A453. Public comment was called for on the Application from 8 May 2002 to 19 June 2002.

A total of five submissions were received and are summarised in **Attachment 4**.

No additional submissions were received in response to the section 13A or 14 notice required under the ANZFA to FSANZ transitional provisions.

8.2 Notification to the World Trade Organization

Australia and New Zealand are members of the World Trade Organization (WTO) and are signatories to the agreements on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and on Technical Barriers to Trade (TBT Agreement). In some circumstances, Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comments.

Amending the Code to permit the use of trehalose as a novel food is unlikely to have a significant negative effect on trade. Therefore, notification will not be made to the WTO as a TBT in accordance with the WTO Technical Barrier to Trade (TBT) agreements.

9. Transitional Issues

In accordance with the transitional requirements for an application which has reached Full (Draft) Assessment prior to the commencement of the FSANZ Act, the Full (Draft) Assessment has been reviewed.

No relevant policy guidelines have been notified by the Ministerial Council and no additional submissions were received in response to the notice given under section 13A or 14.

10. CONCLUSIONS

The conclusions from the final assessment are as follows:

- There are no public health and safety concerns associated with consumption of trehalose to food at the proposed levels.
- Trehalose provides a range of technological functions in a range of food products.
- The proposed changes to Code are consistent with the section 10 objectives of the FSANZ Act.
- The Regulatory Impact Statement indicates that, for the preferred option, namely, to approve the use of trehalose as a novel food, the benefits of the proposed amendment outweigh the costs.

11. RECOMMENDATION

It is recommended that trehalose (Attachment 1) be approved as a novel food, without any conditions of use.

ATTACHMENTS

1. Draft variation to the *Australia New Zealand Food Standards Code*
2. Safety Assessment Report
3. Food Technology Report
4. Dietary Modelling report
5. Summary of public submissions

ATTACHMENT 1

DRAFT VARIATION TO THE *AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE*

To commence: on gazettal

[1] ***Standard 1.5.1*** *of the Australia New Zealand Food Standards Code is varied by inserting in the* Table to clause 2 –

Trehalose	

ATTACHMENT 2

SAFETY ASSESSMENT REPORT

FSANZ has reviewed the data used by the Joint Expert Committee on Food Additives (JECFA) to assess the safety of trehalose in humans. FSANZ has also considered new additional information submitted by the Applicant on tolerance levels for trehalose in humans.

FSANZ undertook this review of the human studies to investigate more recent studies in order to re-consider the threshold for gastrointestinal effects in humans following single bolus oral doses of trehalose, from the new data submitted.

A summary of the JECFA conclusions and a review of the additional human studies is provided below.

Joint Expert Committee's Review of Trehalose

JECFA considered the safety of trehalose in June 2001. The following is a summary of the key properties and toxicological profile of trehalose as concluded by JECFA.

Trehalose is a disaccharide consisting of 2 glucose units linked by a 1,1 α-glucosidic bond. Trehalose occurs widely in nature with small amounts found in certain foods (brewers and bakers yeast, bread, beer and wine, honey and mushrooms). The product used commercially (the dihydrate) is produced from liquefied starch by a multi-enzymatic process and is 40-45% less sweet than sucrose.

Trehalose is rapidly hydrolysed to glucose by the enzyme trehalase in the intestinal mucosa, and the small amount of intact trehalose that may be absorbed is hydrolysed in the plasma, liver or kidney. Trehalase deficiency has been identified in some individuals but its prevalence appears to be very low in most populations, with the possible exception of Greenland, where an 8% prevalence has been recorded.

In acute toxicity studies performed in rats, mice and dogs by either the oral or intravenous route of administration up to doses of 16g/kg bw (in rats), there were no treatment related signs of toxicity, or changes in bodyweight during the observation period.

Acute, short-term repeat dose and subchronic studies in mice, rats and dogs did not indicate any evidence of toxicity up to doses of 7.3g/kg bw/day in male mice (subchronic) and 5g/kg bw/day in dogs (14-day study), other than some sporadic changes in clinical chemistry at the highest dose in male mice and in individual dogs. There were no clinical or histopathological changes of significance in the animal studies.

There were no effects on reproduction in rats and no teratogenicity observed in rats and rabbits. Genotoxicity tests were negative. The enzymes used in preparation of trehalose did not raise any safety concerns.

Studies in humans indicate that trehalose is well tolerated. Increased frequencies of malabsorption and gastrointestinal symptoms were noted in individuals consuming single doses of 20g or more. In the limited data on individuals with known or suspected trehalase deficiency, the only effects seen were gastrointestinal effects expected of an undigested disaccharide.

On the basis of the available information, JECFA considered that an acceptable daily intake (ADI) "not specified" was appropriate for trehalose[6].

Review of additional human studies

A study in humans (Ushijima et al, 1995) suggested increased frequencies of malabsorption and gastrointestinal symptoms in individuals consuming single doses of trehalose of 20g or greater.

In this study 30 healthy adults (10 Mongoloid Japanese, 10 Caucasian, 8 African-American and 2 others (nationality not stated) were orally administered trehalose at 10g, 20g, 30g and 40g (volume of water or other vehicle used to dissolve trehalose was not stated) and then hydrogen gas concentration and blood glucose were measured before and every 30 minutes after administration for 3 hours. An increase of 20 ppm from the standard value of hydrogen gas was considered to be a sign of malabsorption. Malabsorption rates were 0, 40, 43 and 75% at 10g, 20g, 30g and 40g respectively, whilst the rates of gastrointestinal symptoms (malabsorption, abdominalgia, laxation, abdominal dysphoria and crepitus) were 0, 40%, 43% and 50%. More than half the subjects had malabsorption at 40g.

In the second part of the study, subjects were orally administered trehalose at a dose of 0.6g/kg bw to determine whether there was any racial difference in the ability to absorb trehalose under the expiratory method. Differences in malabsorption rates were not significant between groups (Japanese 50%, Caucasian 67% and African-American 63%). However, the Japanese subjects showed a significantly higher rate of gastrointestinal symptoms (90%) compared to Caucasian (11%) and African-Americans (0%) and significantly lower blood glucose levels compared to the other subjects.

However, there were some limitations in this study due to the following:

- There was a limited number of subjects studied;
- Volunteers were fasted overnight and administered a single bolus of trehalose on an empty stomach, which may have enhanced gastro-intestinal symptoms in individuals more intolerant of trehalose. Previous studies have suggested that when disaccharides such as trehalose are used in food they are digested over a longer period of time, thus allowing more complete hydrolysis to glucose and increasing the ability of subjects to digest disaccharides (Elias et al, 1968);
- The time of onset, number and severity of the gastro-intestinal symptoms, concentration of trehalose and the vehicle used to dissolve trehalose before oral administration were not provided in the study;

[6] ADI "not specified" is used to refer to refer to a food substance of very low toxicity which, on the basis of the available data and the total dietary intake of the substance.

- When equal amounts of trehalose were given on a bodyweight basis, as per the second part of the study, Caucasians and African-Americans appear to absorb glucose at a significantly higher rate than Japanese subjects. This data is inconsistent with the results showing similar absorption rates using measurements of hydrogen gas concentration (Richards et al, 2002).

A second study in the Japanese population has been undertaken in which 20 healthy Japanese women were orally administered single daily doses of trehalose at 30 g, 40 g, 50 g and 60 g in 200 mL water after eating (Oku and Okazaki, 1998). The time of onset and type of abdominal symptoms and stool frequency and consistency was measured. No subjects reported diarrhoea at 30g although there were reports of other gastro-intestinal symptoms at this dose (nausea, discomfort, flatus, distension and lower abdominal pain). At 60g half the subjects reported diarrhoea. Although there was variation between individuals for transitory laxation, a threshold dose for laxation was estimated at 0.65 g/kg bw (33 g for a person weighing 50 kg or more).

A third study in a Japanese population where 20 healthy Japanese women were orally administered single daily doses of trehalose at 30 g, 40 g, 50 g and 60 g in 100-150 mL of water after eating has been performed (Oku and Nakamura, 2000). Diarrhoea was reported in 5/20 subjects at 40g, 2/15 remaining subjects at 50g and 3/13 remaining subjects at 60g. No diarrhoea was reported at 30 g, although abdominal symptoms (flatus, distension and borborygmus) were reported in 30% of subjects at the 30 g level.

Other studies in humans have suggested that individuals in western populations are also capable of consuming greater than 20g of trehalose as a single bolus without experiencing adverse abdominal effects. A single dose of 25g trehalose in 200 ml water 1 hour following breakfast did not provoke diarrhoea or other abdominal symptoms in 10 subjects (Heine et al, 1996), and when 34 subjects consumed 25 g trehalose in 400 mL water no signs of intolerance were reported (Arola et al, 1999).

Sixteen subjects showed no intolerance to trehalose after a 50 g single dose in 400 mL of water (Bergoz, 1971) and similarly, in 60 subjects orally administered trehalose at a dose of 50 g in 400 mL of water following an overnight fast, no abdominal symptoms were reported (Bolte et al, 1973).

Although the study by Ushijima et al (1995) did not indicate the volume in which trehalose was administered, in a second study in the Japanese population, it was noted that trehalose (≥30g) was dissolved in 200 mL of water (Oku and Okazaki, 1998) or ≥30g in 100-150 mL water (Oku and Nakamura, 2000). However, in the other studies in Western populations lower concentrations were used; 25 g dissolved in 200 mL (Heine et al, 1996) or 400 mL (Arola et al, 1999) or 50 g in 400 mL (Bergoz, 1971; Bolte et al, 1973). Therefore, it is possible that the gastro-intestinal effects noted in the study in Japanese women at the lower dose levels (Oku and Ozaki, 1998; Oku and Nakamura, 2000) were increased by the use of higher concentrations of trehalose.

At higher doses of trehalose (>50g) gastro-intestinal symptoms become more severe with symptoms of flatulence, distension, watery stools being reported (Oku and Okazaki, 1998).

Various studies have also reported trehalase deficiency in individuals, which leads to subjects experiencing intestinal discomfort such as laxation after ingestion of excessive amounts of trehalose (reviewed by JECFA 2001; Richards et al, 2002). However, the prevalence in the western population has been reported as low (Murray et al, 2000).

In summary, studies performed to determine tolerance of trehalose in humans suggest that in populations that have been reported as quite sensitive to trehalose (i.e., Eastern populations) single doses of trehalose (33g) can be tolerated (with some differences in individual sensitivity) with minimal abdominal symptoms. Doses of up to 50g have also been reported in traditional western population subjects as being tolerated without accompanying gastrointestinal symptoms. The data on Japanese subjects suggest that as a population they may have a lower capacity to tolerate trehalose and exhibit increased gastro-intestinal symptoms at lower doses of trehalose in comparison to subjects from a Western population. In trehalase deficient individuals gastro-intestinal symptoms may possibly occur at lower doses, although the incidence of trehalase deficient individuals (particularly in the western population) appears to be low and the dose at which trehalose is tolerated in these populations are unclear from the data available.

Conclusions from the Human Studies

- There was limited information available in a study where 10 Japanese subjects experienced significantly higher rates of gastro-intestinal symptoms at 20g single bolus doses of trehalose.

- Factors such as the lack of reporting of the time of onset and severity of gastro-intestinal symptoms, specific concentration of trehalose, the vehicle used to dissolve trehalose, and the inconsistency in correlation between the malabsorption assay, gastro-intestinal symptoms and blood glucose uptake suggest that the study was not complete enough to support the threshold level of 20g proposed by JECFA (WHO, 2001).

- Data on the second and third studies undertaken on adult Japanese women subjects suggests that a level of trehalose of up to 33g could be tolerated without appreciable gastro-intestinal symptoms. This study was more detailed in its methodology, although it was noted that the severity of gastro-intestinal symptoms were still not reported.

- Four other studies in western populations suggest that trehalose can be tolerated up to a level of 50 g as a single bolus without appreciable gastro-intestinal symptoms.

- The above studies suggest that eastern populations may be more intolerant of trehalose, compared to western populations, particularly at lower doses of trehalose.

- The differences in tolerance to trehalose between these population groups may possibly be due to the higher concentrations of trehalose administered to Japanese subjects; and/or a lower general tolerance to trehalose in that population.

Overall conclusion

FSANZ has concluded from the review of the available human data that the study used to support a 20 g threshold level proposed by JECFA could not support this threshold level.

FSANZ acknowledges that from the available data, Japanese populations may be more intolerant of trehalose compared to western populations. However, the lack of detail in the methodology and inadequate reporting of time of onset and severity of gastro-intestinal symptoms experienced in Japanese subjects following dosing at 20 g, limits any definitive conclusions indicating that a threshold level as low as 20 g could apply for the general population. Furthermore, other studies at higher doses indicated that western populations could tolerate trehalose at doses as high as 50 g.

Therefore, in conclusion, provided that consumers did not exceed a level of between 33-50 g from a single exposure to trehalose in food, then there would be minimal gastro-intestinal symptoms expected in subjects. The level of 33 g would apply to the most sensitive individuals (Asian populations) as identified in the current scientific literature.

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ATTACHMENT 3

FOOD TECHNOLOGY REPORT

Trehalose is a food or ingredient found naturally in honey, mushrooms, lobster, prawns and food produced using baker's and brewer's yeast. It is commercially made from starch by an enzymatic process. Trehalose's chemical name is α-D-glucopyranosyl-α–D-glucopyranoside, with other synonyms being mycose and mushroom sugar. Its CAS number is 6138-23-4.

Physico-chemical properties

Trehalose (α,α–trehalose) is a disaccharide formed by a 1,1 linkage of two D-glucose molecules. It is a non-reducing sugar that is not easily hydrolysed by acid, and the glycosidic bond is not cleaved by the enzyme α–glucosidase. The molecular formula and weight are $C_{12}H_{22}O_{11}$ and 342.31, respectively. When purified it is usually found in a dihydrate form, which is the typical commercial product.

Trehalose can impart some beneficial properties to food products. Compared to most sugars, trehalose is more stable to wide ranges of pH and heat and it does not easily interact with proteinaceous molecules.

Trehalose has a low hygroscopic profile which is a main advantage compared to other sugars. It appears that trehalose could be of benefit compared with other sugars in dry blending operations in which low hygroscopicity is desired. The water content of trehalose dihydrate remains stable (9.54%) up to a relative humidity of approximately 92%.

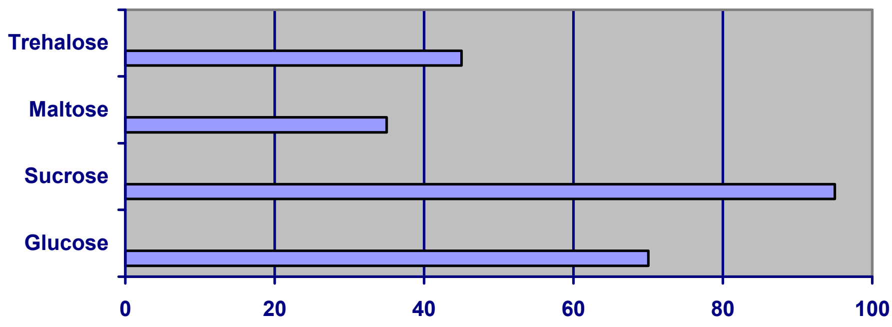
Physical properties that make trehalose unique are its high degree of optical rotation ($[\alpha]^2{}_D$ + 178°) and its melting behaviour. Trehalose first melts at 97 ° C. Additional heat drives off the water of crystallization until the material re-solidifies at 130 ° C, and then the anhydrous trehalose melts at 203 ° C. The combination of the molecular structure and the physico-chemical properties of trehalose results in a very stable disaccharide. Trehalose has a solubility and osmotic profile similar to maltose. Above 80 ° C trehalose becomes more soluble in water relative to other sugars.

Taste

Trehalose, a non-reducing disaccharide, is similar to reducing disaccharides in that it does not produce as great a sensation of sweetness as does sucrose. Trehalose is believed to have only one glucose molecule occupying the binding site on the sweet taste receptor.

Trehalose in aqueous solution (at concentrations from about 10-34% anhydrous trehalose) has a sweetness of about 40-45% relative to that of sucrose (Figure 1). The concentration at which a solution of trehalose is perceived as sweet, is about two-times higher than that of sucrose and the sweetness persists longer than sucrose.

Figure 1. The relative sweetness of various sugar solutions compared with a 22.2% (w/w) solution of trehalose.



Relative sweetness (%)

Natural Occurrence

Trehalose is found in over 80 species of organisms representing plants, algae, fungi, yeasts, bacteria, insects and invertebrates.

In brewer's yeast, the biosynthesis of trehalose is catalysed by enzymes that facilitate the reaction of uridine diphosphate-D-glucose with D-glucose 6-phosphate, resulting in uridine diphosphate and α,α–trehalose 6-phosphate. The phosphate is enzymatically removed leaving a trehalose molecule. Several other organisms produce trehalose by similar mechanisms. Degradation of trehalose is accomplished by a highly specific enzyme, trehalase. Trehalase has been identified in many organisms shown to contain trehalose but is not found in mammals.

History of human consumption

Modern food sources may contain substantial quantities of trehalose. Some of these include honey (0.1 – 1.9%), mirin (1.3 - 2.2%), sherries (< 10 – 391 mg/l), brewer's yeast (0.01 – 5.0%) and baker's yeast (15 – 20%), and therefore most items made using yeast.

Commercially grown mushrooms may contain 8 –17 % (w/w) trehalose. It also occurs in lobsters (2.5 mg/100 ml blood), crab (1.5 mg/100 ml blood) and prawns (0.5% dry weight). Trehalose is not presently a significant part of the modern diet but has been a consistent part of the human diet for thousands of years.

Technical application in food formulation and processing

The unique properties of trehalose make it a useful and versatile ingredient in food formulation and processing (Table 1). Primarily it can be used to replace some of the sucrose where it is desirable to reduce the level of sweetness for a more balanced or improved taste profile. As trehalose is not a reducing sugar it does not undergo Maillard-type browning reactions. At elevated temperatures, it is more resistant to acid-catalysed hydrolysis, and it does not caramelise.

It may be used in beverages, purees and fillings, nutrition bars, surimi, dehydrated fruits and vegetables, confectionery and white chocolate for cookies or chips. In instant noodles and pre-cooked rice, it accelerates rehydration.

In baked goods it appears to inhibit starch retrogradation more effectively than other sugars and thus provides improved stability and delays the onset of staleness.

Trehalose appears more effective in stabilizing proteins against damage caused by drying or freezing than other sugars. Trehalose has also been shown to help maintain delicate protein structures after thawing and to stabilize disulfide bonds, thereby inhibiting the formation of odours and off-flavours.

Trehalose is currently being used in Japan to retard starch retrogradation in such products as Udon noodles (0.2% of flour), clam chowder (0.4% of product) and traditional Japanese confectioneries (10-50% of sugars).

Table 1 Technical effects of Trehalose

Food category	Technical effect	Approximate trehalose addition
Bakery products	Moisture retention Shelf-life extension Crumb softener Reduced sweetness Reduced hygroscopicity	2% flour
Frozen bakery products	Protein preservation freeze-thaw stabilization Shelf-life extension Crumb softener	13-18%
Frozen desserts	Freeze-thaw stabilization Texture stabilization	13-18%
Dairy-based foods and toppings	Texture stabilization Flavour profile improved	2-12.5%
Dried, frozen, or processed fruits and vegetables	Colour stabilization Flavour profile improved Mask bitterness	5% of carrier solution
Beverages	Colour stabilization Flavour profile improved Reduced sweetness pH stabilization	0.4% of product to 50% of sugars
Jellies and gelatin	Moisture retention Reduced sweetness Reduced hygroscopicity Colour stabilization Flavour profile improved	15-30% of sugars
Confectionery	Moisture retention Reduced sweetness Reduced hygroscopicity Shelf-life extension Texture improvement Flavour profile improved	5-40% of product 5-80% of sugars
Meat/fish/eggs	Protein preservation Moisture retention Texture improvement Masks cooking odours	2-10%

Manufacture

Trehalose is produced commercially by the Hayashibara enzymatic process. The enzymes utilised are derived from the non-pathogenic soil microbe *Arthrobacter ramosus*.

The first step in the process is the suspension of starch to produce a slurry. The starch slurry is heated and liquefied by the addition of an α-amylase. After liquefaction the enzyme is inactivated by increasing the temperature, and the slurry is cooled further for processing.

Other enzymes (isoamylase, cyclodextrin glucanotransferase, α-amylase and glucoamylase) are added to the solution. The purposes of these enzymes are to debranch amylopectin, shorten the chain length and/or to recycle unused portions of amylose and amylopectin. The resulting oligosaccharides are substrates for the two trehalose producing enzymes, maltooligosyl-trehalose synthase and maltooligosyl-trehalose trehalohydrolase. The process is controlled for temperature, pH and concentration of products.

The solution is then decolourised with activated carbon, and the carbon and other insoluble substances are removed by filtration. Salts and proteins are removed in a two step procedure using ion exchange. The suspension is concentrated by evaporation and the solution further evaporated under vacuum. Crystallization of trehalose occurs at this stage and the crystals are removed from the solution by centrifugation, washed, dried and granulated. This process produces dihydrate trehalose crystals that are at least 98% pure and the process is substantially less expensive than other methods heretofore used. The reduction in process cost makes trehalose now possible to be available for food applications. The trade name for trehalose is Trehaose™.

Since becoming commercially available in Japan in November 1995 until the end of 1998, a cumulative total of more than 15,000 metric tons has been sold. There has not been a recall of trehalose because of degradation of the product, since trehalose is chemically, thermally and pH stable.

Regulatory Status

In 1995 trehalose, produced by the Hayashibara method, was first sold in Japan under a food additive approval. Since then it has been incorporated into hundreds of Japanese food products. There are no limits for the use of trehalose under this approval. The general product categories are: Japanese confectioneries, sugar confectioneries, beverages, retort foods, processed vegetables and fruits, bakery goods, processed seafoods, frozen foods and refrigerated items.

Trehalose was approved as a food ingredient in Korea and Taiwan in 1998 with no use limits. Trehalose was previously approved as a novel food n 1991 in the UK for use as a cryoprotectant for freeze-dried foods at concentrations up to 5%.

Trehalose was affirmed in the US as generally recognised as safe (GRAS) May 2000. In October 2000, the US FDA gave a letter of no objection to GRAS Notice (GRN 000045). The use of trehalose in the US is limited only by current Good Manufacturing Practices.

JECFA reviewed and approved trehalose in June of 2000. The Acceptable Daily Intake was not specified. Regulatory approval as a novel food or food ingredient was granted in Europe, September 2001.

Conclusions:

- Trehalose is a food or food ingredient that has unique properties that make it very useful and versatile in food formulation and processing. Its stability and reduced sweetness make it a valuable alternative to other sugars in food processing.

- Approval of trehalose will provide food processors with the opportunity to develop innovative new processed foods and to improve the quality and increase the shelf-life of existing processed foods.

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ATTACHMENT 4

DIETARY MODELLING REPORT

Summary

An application was received by FSANZ in October 2001 requesting approval of the disaccharide trehalose for use as a novel food in ice creams, baked goods, confectionery, jams, instant noodles and rice, processed seafoods and toppings.

A dietary exposure assessment was conducted to predict exposure of Australians and New Zealanders to trehalose when used in accordance with the application, as well as exposure through natural occurrence of trehalose in certain foods.

Predicted mean trehalose exposure from consumption of foods containing both added and naturally occurring trehalose is 5.7 g/day for Australians (2 years and above) and 4.5 g/day in NZ (15 years and above), rising to 22.7 and 18.2 g/day respectively at the 95th percentile of exposure. This is substantially higher than estimated exposure through natural occurrence of trehalose in mushrooms, honey, bread, wine, beer and prawns (mean and 95th percentile exposure is 0.3 and 0.9 g/day respectively in Australian and New Zealand adults). Exposure is higher, in total and on a bodyweight basis, among children and teenagers, reflecting the contribution of ice cream, toppings and confectionery in these age groups. 95th percentile exposure among teenagers, the group with the highest exposure, is 33.8 and 33.7 g/day in Australia and New Zealand respectively. Predicted exposures are considered to be overestimates of actual exposure if trehalose were to be approved for use as a novel food due to the conservative nature of the assumptions included in the modelling.

Background

Trehalose (α-D-glucopyranosyl-(1$\rightarrow$1)-α-D-glucopyranose) is a disaccharide consisting of two glucose molecules linked by a 1,1 α-glycosidic bond.

Trehalose is produced commercially by enzymatic hydrolysis of starch but is also found in nature in mushrooms (2-12 g trehalose/100 g dry basis) and in some fungi-containing foods such as yeast (0.1-200 g/kg), bread (1.2-1.5 g/kg dry basis), mirin (13-22 g/kg), beer (45-240 mg/L), honey (0.1-2.3 g/100 g), wine (44-129 mg/L) and sherry (<10-391 mg/L) (UK Advisory Committee on Novel Foods & Processes, 2000; Richards et al 2002). Trehalose is also found in insect shells, in crustacea (0.5% dry basis in prawns) and in some plants (Richards et al 2002).

The Joint Expert Committee on Food Additives (JECFA) have allocated a 'not-specified' Acceptable Daily Intake (ADI) to trehalose.

Proposed use of trehalose

The applicant provided information on the foods likely to have trehalose added to them, if the application were to be approved, and the maximum level of use in these foods (see Table 1). Trehalose is intended for use in products where the physical properties of sucrose are required, but with reduced sweetness.

Table 1: Proposed range of foods and levels of use of trehalose

Food	Use level (maximum)
Bakery creams	5-6%
Biscuits (reduced fat)	10%
Cakes (sponge)	8-10%
Confectionery (cream or fruit filled bars, chocolate covered bars)	7%
Confectionery (high boils)	20%
Icings	25% in food component 5% (presumably refers level in iced foods)
Sugar coatings	50% in food component 10% (presumably refers to level in coated foods)
Ice cream (premium)	10%
Instant noodles/rice	2%
Processed fruit (jams, fillings, toppings)	10-20%
Restructured seafood	10%

Dietary Exposure Assessment provided by the applicant

The applicant provided a detailed dietary exposure assessment for trehalose, based on the same food groups and levels of use as are being proposed for Australia. However this assessment was not considered to be sufficient for assessing the safety of potential exposure to trehalose in Australia and New Zealand as the assessment, although detailed, was based on United States food consumption data (US Department of Agriculture Continuing Survey of Food Intakes by Individuals, 1994-96).

The exposure assessment submitted by the applicant indicated that mean daily exposure to trehalose for consumers of foods containing added trehalose was 5.2 g for children aged 2-12 years (male and female), 7.5 g for teenagers (13-19 years) and 7.2 g for adults. 90th percentile exposure was 10.9 g, 15.2 g and 16.4 g/day respectively. US food consumption data are based on two days of food records, in contrast to the Australian and New Zealand data, which is only one-day data. Use of multiple day records tends to significantly reduce the predicted high consumer exposure (Rutishauser, 2000).

The exposure assessment submitted by the applicant based on US data, also estimated exposure to trehalose per single eating occasion (eg. per meal or per snack). The mean amount of trehalose consumed at a single occasion was 3.9 g, 5.6 g and 5.6 g for children, teenagers and adults respectively. However consumption of ice cream containing 10% trehalose could lead to trehalose exposure on a single occasion of up to 24 g among teenagers consuming large quantities of ice cream. The ice cream category provided the largest exposure to trehalose per eating occasion within each population group.

This Applicant's data did not take into account any background exposure to trehalose through its natural occurrence in certain foods.

Dietary Modelling conducted by FSANZ

The dietary exposure assessment was conducted using dietary modelling techniques that combine food consumption data with food chemical concentration data to predict exposure to the food chemical from the diet. The dietary exposure assessment was conducted using FSANZ's dietary modelling computer program, DIAMOND.

Exposure to trehalose was predicted by combining usual patterns of food consumption, as derived from 1995 national nutrition survey (NNS) data, with proposed levels of use of trehalose in foods and with naturally occurring levels of trehalose where this information was available.

Dietary exposure = food chemical concentration x food consumption

Dietary Survey Data

DIAMOND contains dietary survey data for both Australia and New Zealand; the 1995 NNS from Australia that surveyed 13 858 people aged 2 years and above, and the 1997 New Zealand NNS that surveyed 4 636 people aged 15 years and above. Both of these surveys used a 24-hour food recall methodology to develop food consumption data.

The dietary exposure assessment was conducted for both Australian and New Zealand populations. Modelling was conducted for the whole population, as well as for children aged 2-12 years (Australia only), teenagers aged 13-18 years (15-18 years in NZ) and adults aged 19 years and above. An exposure assessment was conducted on these age groups in order to determine the pattern of exposure to trehalose with age. Children and teenagers generally have higher exposures on a body weight basis due to their smaller body weight and their higher consumption of food per kilogram of body weight compared to adults. In particular, ice cream, one of the foods proposed to include trehalose and which was identified as a major contributor to potential trehalose exposure in the US, is consumed in larger amounts by children and teenagers than by adults (see Table 2 for a summary of the food consumption data used).

Trehalose Concentration levels

The levels of added trehalose used in the models were obtained from the application. Where the applicant indicated that foods would contain a range of levels of added trehalose, the upper limit of this range was used for modelling purposes.

Table 2: Food consumption amounts# for foods proposed to contain added trehalose - Australia

Food group	Children 2-12 years, Consumers only (g/day)		Teenagers (13-18 years Aust, 15-18 years NZ) Consumers only (g/day)		Adults (19+ years) Consumers only (g/day)	
	Mean	95th percentile	Mean	95th percentile	Mean	95th percentile
Ice creams, stick and tub (excl low fat ice cream)	103	252	159	426	96	248
Fruit spreads inc jam, chutney	19	27	15	51	16	54
Filled chocolate confectionery	36	90	46	113	43	118
Hard sugar confectionery	21	58	33	134	21	61
Instant noodles & flavoured rice	68	173	94	387	81	326
Cream filled/coated biscuits, cakes, buns, pastries	43	107	69	219	59	192
Jam or fruit filled biscuits, cakes, buns, pastries	84	223	135	354	112	270
Sponge cakes	78	270	88	190	75	222
Iced biscuits, cakes, buns, pastries	68	231	114	533	90	254
Reduced fat biscuits	21	51	27	61	25	60
Icings and frostings not already included	20	*40	23	*27	27	82
Processed fish products	45	83	87	133	46	131
Toppings	35	90	51	111	41	120

Food consumption amounts derived through DIAMOND from the 1995 Australian and 1997 NZ NNSs.
*Figures may be unreliable due to insufficient consumer numbers (<21 consumers)

Table 2 (continued): Food consumption amounts# for foods proposed to contain added trehalose – New Zealand

Food group	Children 2-12 years, Consumers only (g/day)		Teenagers (13-18 years Aust, 15-18 years NZ) Consumers only (g/day)		Adults (19+ years) Consumers only (g/day)	
	Mean	95th percentile	Mean	95th percentile	Mean	95th percentile
Ice creams, stick and tub (excl low fat ice cream)	-	-	134	372	91	248
Fruit spreads inc jam, chutney	-	-	23	*79	14	46
Filled chocolate confectionery	-	-	58	147	46	125
Hard sugar confectionery	-	-	39	*184	34	122
Instant noodles & flavoured rice	-	-	273	*878	210	557
Cream filled/coated biscuits, cakes, buns, pastries	-	-	117	485	69	228
Jam or fruit filled biscuits, cakes, buns, pastries	-	-	155	*247	60	166
Sponge cakes	-	-	149	*217	74	237
Iced biscuits, cakes, buns, pastries	-	-	101	*428	71	227
Reduced fat biscuits	-	-	54	*200	26	71
Icings and frostings not already included	-	-	10	*10	10	*24
Processed fish products	-	-	36	*36	41	*164
Toppings	-	-	100	*269	41	109

Food consumption amounts derived through DIAMOND from the 1995 Australian and 1997 NZ NNSs.
*Figures may be unreliable due to insufficient consumer numbers (<21 consumers)

In the case of ice cream, where the applicant had indicated trehalose would only be added to 'premium' ice creams, all ice cream identified as low fat or reduced fat was excluded from modelling. For chocolate-based confectionery, plain milk, dark or white chocolate were excluded as the application indicated trehalose would be added to coated and filled products.

Hard boil confectionery included toffees, caramels (including filled caramels), honeycomb, hard lollies, cough lollies and lollies not further specified; jellies, fudges and soft lollies were excluded.

Sweet biscuits, cakes, pastries, pies, buns and doughnuts were included in modelling where the description of the food indicated that it could contain jam, bakery cream, fruit filling, icing or sugar coating, or was sponge-based. Reduced fat biscuits were considered, for modelling purposes, to include all sweet and savoury biscuits recorded as being of 'low' or 'moderate' fat content or containing polyunsaturated fat.

Although the application indicated that trehalose would be added to bakery creams and sugar coatings, these foods were not modelled as separate groups, as neither food group is consumed on its own but as components of cakes, biscuits, pastries, doughnuts and confectionery.

Homemade baked products were excluded from modelling as it was considered these foods would not be likely to contain added trehalose.

Where information was provided in the application or in available published literature about naturally occurring levels of trehalose, these levels have also been included in the modelling. Where a range of values was reported, the upper limit of the range was used for modelling purposes. Trehalose concentration levels reported on a dry weight basis were converted to a wet weight (as consumed) basis using estimates of water content[7] contained in Australian food composition tables. The information provided on naturally occurring trehalose levels was not comprehensive and there are some foods that may contain trehalose (e.g. yeast-based spreads such as vegemite) for which no data were available.

The foods included in the dietary modelling and the concentrations of trehalose used (whether added or naturally occurring) are shown in Table 3.

How were the dietary exposures calculated?

The DIAMOND program allows trehalose concentrations to be assigned to food groups, as outlined in Table 3 above. DIAMOND multiplies the specified concentration of trehalose by the amount of food that an individual consumed from that group in order to estimate the exposure to each food. Once this has been completed for all of the foods specified to contain trehalose, the total amount of trehalose consumed from all foods is summed for each individual. Population statistics (mean and high percentile exposures) are then derived from the individuals' ranked exposures.

Exposure to trehalose was predicted for naturally occurring trehalose only ('baseline') and then for a scenario where trehalose was added to foods in the levels proposed in the application ('scenario'); this scenario also took into account baseline exposure to trehalose.

[7] Mushrooms common, raw, approximately 90% water; school prawns approximately 80% water (English & Lewis 1991)

Table 3: Levels of added and naturally occurring trehalose used in dietary modelling

Food Name	Concentration Level (g/kg)
Added trehalose	
Ice cream (excludes low fat ice creams and ice confections)	100
Fruit & vegetable spreads including jams & chutneys	200
Filled chocolate confectionery	70
Hard sugar confectionery (excludes chewing gum)	200
Icings and frostings (where not already included in other categories)	50
Instant noodles and flavoured rice products	20
Cream filled/coated biscuits, cakes, pies, buns & pastries	60
Jam & fruit filled biscuits, cakes, pies, buns & pastries	100 (assumes products contain 50% jam/fruit)
Iced biscuits, cakes, pies, buns & pastries	50
Sponge cakes	100
Reduced fat biscuits	100
Processed fish and fish products (excluding cooked crustacea)	100
Toppings	200
Naturally occurring trehalose	
Processed and unprocessed fruits and vegetables – mushrooms only (raw, canned, cooked)	12
Breads and related products	0.9
Honey and related products	23
Beer and related products	0.24
Prawns/shrimps	1.0
Wine, wine based drinks, fruit wine	0.129

Estimating Risk

As part of a dietary exposure assessment, exposure estimates are normally compared to a reference health standard, such as an Acceptable Daily Intake (ADI) where available. However as the ADI for trehalose is not specified, only a determination of predicted dietary exposure (g/day) to trehalose in Australia and New Zealand can be made.

Assumptions in the dietary modelling

Assumptions made in the dietary modelling include:

- all the foods within the specified group contain trehalose at the specified/proposed levels (see Table 3 for food groups and levels);
- food and beverage consumption patterns measured in the 1995 and 1997 NNSs reflect current patterns; and
- that there are no intrinsic dietary sources of trehalose other than those included in the model (bread, wine, beer, honey, prawns and mushrooms).

The first of these assumptions is likely to lead to a conservative prediction of trehalose dietary exposure. This is because is it unlikely that all foods permitted to contain trehalose would in fact contain it, and if they did contain trehalose it is unlikely to always be added at the maximum amounts outlined in the application. However the application did not contain information on the likely market share of trehalose-containing foods.

The third assumption ignores the contribution of some foods such as yeast spreads to trehalose exposure but this is unlikely to significantly underestimate total trehalose exposure.

Limitations of the dietary modelling

A limitation of estimating dietary exposure over a period of time associated with the dietary modelling is that only 24-hour dietary survey data were available, and these tend to over-estimate habitual food consumption amounts for high consumers. Therefore, predicted high percentile exposures are likely to be higher than actual high percentile exposures over a lifetime.

In addition, the NNS data used in DIAMOND do not distinguish between eating occasion so it is not possible to report the amount of trehalose eaten in one meal/snack. For example, the 426 g of ice cream reportedly eaten by Australian teenage high consumers (95th percentile, see Table 2 above) could have been eaten at one time or over two or more occasions during the day (lunch and dinner, for example). For the purpose of this report it is assumed that this amount is eaten at one meal, which is the worst case scenario.

Results

Estimated dietary exposures to trehalose

The estimated baseline dietary exposures for trehalose are shown in Table 4, and scenario + baseline trehalose exposures in Table 5. As trehalose is proposed for use, or occurs naturally, in a range of popular foods, more than 95% of NNS respondents (i.e. all those who participated in the Surveys) are also consumers of trehalose under scenario conditions. Therefore only consumer exposure to trehalose will be discussed in detail; respondent and consumer exposure estimates are, however, very similar.

The amount of trehalose to which Australians and New Zealanders would potentially be exposed through addition as outlined in this application, is much greater than exposure that occurs through natural occurrence of trehalose. The estimated 'baseline' exposure was less than 1 g per day at the 95th percentile for all population groups for which modelling was conducted. For the consumer population as a whole, mean baseline exposure to trehalose represented 5% or less of the potential exposure when sources of added trehalose were considered.

Under the scenario outlined in Table 3 above, mean predicted exposure to trehalose for all ages surveyed is 5.7 g/day in Australia and 4.5 g/day in NZ, rising to 22.7 and 18.2 g/day respectively at the 95th percentile. Exposure to trehalose is potentially greatest in teenagers when trehalose is intentionally added to foods. Compared to adults, both mean and 95th percentile teenage exposure to trehalose is at least 50% higher.

This reflects not only teenagers' higher overall food consumption than adults, but also the larger amounts of ice cream, topping and confectionery eaten in this age group.

Younger children also had a higher exposure to trehalose than adults for the scenario modelled, although this was not as pronounced as for teenagers. Australian children aged 2-12 years had predicted exposure of 6.3 and 23.4 g trehalose per day (mean and 95th percentile respectively), equivalent to 0.23 and 0.83 g/kg bodyweight per day respectively. Exposure for children on a bodyweight basis is approximately three times the adult Australian mean and 95th percentile exposure to trehalose of 0.07 and 0.30 g/kg bw/day.

Mean trehalose exposure predicted in this report is similar to that reported in the US dietary exposure assessment that was submitted by the applicant. US predicted intakes for children 2-12 years, teenagers 13-19 years and adults aged 20 years and above were 5.2, 7.5 and 7.2 g/day compared to 6.3, 8.7/7.5 and 5.3/4.4 g/day respectively in Australia/NZ for very similar age groups. In contrast, predicted exposure among high consumers of trehalose is substantially higher in Australia/NZ. This reflects the US use of the 90th percentile compared to the 95th percentile in Australia/NZ, as well as differences in the methodology used to collect food consumption data, with the US estimates based on two days of records compared to only one day in Australia/NZ. The differences also reflect differences in eating patterns between the countries. The US assessment did not take into account the small 'baseline' trehalose exposure from fungi-based foods.

All predicted exposures are considered to be overestimates due to the conservative nature of the assumptions used in the modelling.

Table 4: Estimated dietary exposures to trehalose through naturally occurring trehalose ('baseline' exposure)

Country	Age group	Number of consumers of trehalose	Consumers as a % of total respondents#	Mean all respondents g/day	Mean consumers g/day	95th percentile consumers g/day
Australia	Whole population (2 years+)	12907	93.1	0.2	0.2	0.8
	2-12 years	1930	92.9	0.1	0.1	0.4
	13-18 years	843	90.8	0.2	0.2	0.7
	19+ years	10134	93.3	0.2	0.3	0.9
New Zealand	Whole population (15 years+)	4293	92.6	0.2	0.3	0.9
	15-18 years	221	89.8	0.2	0.2	0.7
	19+ years	4072	92.8	0.2	0.3	0.9

Total number of respondents for Australia: whole population = 13 858, 2-12 years = 2079, 13-18 years = 928, 19+ years = 10851; New Zealand: whole population = 4 636, 15-18 years = 246, 19+ years = 4390.

Table 5: Estimated dietary exposures to trehalose through added and naturally occurring trehalose ('scenario + baseline' exposure)

Country	Age group	Number of consumers of trehalose	Consumers as a % of total respondents#	Mean all respondents g/day	Mean consumers g/day	95th percentile consumers g/day
Australia	Whole population (2 years+)	13468	97.2	5.5	5.7	22.7
	2-12 years	2040	98.1	6.2	6.3	23.4
	13-18 years	903	97.3	8.5	8.7	33.8
	19+ years	10525	97.0	5.1	5.3	21.5
New Zealand	Whole population (15 years+)	4457	96.1	4.4	4.5	18.2
	15-18 years	234	95.1	7.2	7.5	33.7
	19+ years	4223	96.2	4.2	4.4	17.1

Total number of respondents for Australia: whole population = 13 858, 2-4 years = 583, 5-12 years = 1 496, 13-18 years = 928; New Zealand: whole population = 4 636, 15-18 years = 246, 19+ years = 4390.

Major contributing foods

Foods contributing to the total estimated exposure of trehalose, under the scenario outlined above, are displayed in Table 6 for the total population as well as for the different age groups.

Table 6: Major contributors (≥10%) to total trehalose dietary exposure for Australia and New Zealand, and for different age groups, under scenario conditions

Country	**Age group**	**Major contributing foods and percent of total trehalose exposures**
Australia	Whole population (2+ years)	Filled, coated biscuits, cakes & pastries (32%) Ice cream (28%) Jams etc (13%)
	2-12 years	Ice cream (38%) Filled, coated biscuits, cakes & pastries (23%) Chocolate & hard confectionery (12%) Topping (10%)

	13-18 years	Ice cream (38%) Filled, coated biscuits, cakes & pastries (27%) Topping (11%) Chocolate & hard confectionery (11%)
	19+ years	Biscuits, cakes & pastries (34%) Ice cream (24%) Jams etc (15%)
New Zealand	Whole population (15+ years)	Biscuits, cakes & pastries (33%) Ice cream (30%) Chocolate & hard confectionery (13%)
	15-18 years	Ice cream (36%) Filled, coated biscuits, cakes & pastries (30%) Chocolate & hard confectionery (18%)
	19 + years	Biscuits, cakes & pastries (33%) Ice cream (30%) Chocolate & hard confectionery (13%)

The major contributors to potential trehalose exposure in adults were coated, filled and iced sweet biscuits, cakes, buns and pastries, followed by ice cream; together these foods contributed two-thirds of predicted trehalose exposure. For Australian children and Australian/NZ teenagers, ice cream was the major source of trehalose exposure; coated, filled and iced sweet biscuits, cakes, buns and pastries, and chocolate/hard sugar confectionery were also significant contributors to trehalose exposure, as was topping in Australia.

Single eating occasion exposure

DIAMOND uses food consumption data derived over a full 24 hour period only, not broken down by eating occasion (e.g. a single meal or snack). However, if it is assumed that the estimated consumption amounts of trehalose-containing foods reported in Table 2 are consumed at a single eating occasion, it is possible to estimate potential single eating occasion exposure to trehalose. Table 7 shows the potential exposure to trehalose from individual food groups if they were to be consumed on a single occasion at the 95th percentile consumption level. Figures for icings are not included due to inadequate consumer numbers leading to an unreliable estimate of 95th percentile consumption.

Ice creams, hard boil confectionery, sponges and toppings, when consumed in large amounts, can lead to predicted exposure of between 24 to 54g on a single eating occasion in the majority of age groups surveyed. In addition, consumption of large serves of iced cakes, biscuits and pastries can lead to exposure from 20 to 28g per occasion among teenagers but not among other age groups surveyed. Although there appears to be a potential for high trehalose exposure for NZ teenagers eating cream-filled cakes, biscuits and pastries, consumer numbers in this age group and for this food group were insufficient to enable reliable estimation of the 95th percentile consumption amount.

Conclusion

Predicted trehalose exposure, based on 24 hour food consumption data, from both added and naturally occurring trehalose is 5.7 g/day in Australia and 4.5 g/day in NZ, rising to 22.7 and 18.2 g/day respectively at the 95th percentile (consumers only). This is higher than estimated exposure through intrinsic trehalose occurrence in mushrooms, honey, bread, wine and beer, which was less than 1 g/day even among high consumers (95th percentile). Exposure is higher, in total and on a bodyweight basis, among children and teenagers. Predicted exposures are considered to be overestimates of actual exposure if trehalose were to be approved for use as a novel food due to the conservative nature of the assumptions included in the modelling.

Table 7: Single occasion exposure# to trehalose from food groups consumed at the level equivalent to the 95th percentile of consumption identified in the NNS.

Food group	Trehalose level (g/kg)	Australian children (g)	Australian teenagers (g)	NZ teenagers (g)	Australian adults (g)	NZ adults (g)
Ice creams, stick and tub (excl low fat ice cream)	100	25.2	42.6	37.2	24.8	24.8
Fruit spreads inc jam, chutney	200	5.4	10.2	*10.2	10.8	9.2
Filled chocolate confectionery	70	6.3	7.9	10.3	8.3	8.8
Hard sugar confectionery	200	11.6	26.8	*36.8	12.2	24.4
Instant noodles & flavoured rice	20	3.5	7.7	*17.5	6.5	11.1
Cream filled/coated biscuits, cakes, buns, pastries	60	6.4	13.1	29.1	11.5	13.7
Jam or fruit filled biscuits, cakes, buns, pastries	50	11.2	17.7	*12.4	13.5	8.3
Sponge cakes	100	27.0	19.0	21.7	22.2	23.7
Iced biscuits, cakes, buns, pastries	50	11.6	27.7	*21.4	12.7	11.4
Reduced fat biscuits	100	5.1	6.1	*10.0	6.0	7.1
Processed fish products	100	5.1	6.1	*10.0	6.0	*7.1

Toppings	200	18.0	22.2	*53.8	48.8	46.6

Exposure (g) = 95th percentile consumption amount (kg) multiplied by trehalose level (g/kg)
*Figures may be unreliable due to insufficient consumer numbers (<21 consumers)

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ATTACHMENT 5

SUMMARY OF PUBLIC SUBMISSIONS FIRST ROUND

Australian Food and Grocery Council (AFGC)

Since trehalose is found naturally in a range of foods (brewers and bakers yeast, bread, beer, wine, honey and mushrooms) it has already been consumed widely by the Community in Australia and New Zealand. As such, it cannot fit the definition of a novel food.

Trehalose is already defined as a food by the definition of "sugars" in Standards K1 and 2.8.1 respectively. As it is not novel, the application should be rejected.

Food Technology Association of Victoria Inc

Supports the Application.

Dietitians Association of Australia

The application is supported in principle subject to a safety assessment by FSANZ. Due to a hereditary form of trehalose intolerance, the possibility of an advisory statement on the label to alert these specific consumers should be considered.

The DAA recommends that the glycaemic index of trehalose and its potential impact on glycaemic load of the diet be taken into account in dietary modelling.

National Council of Women of Australia (Elaine Attwood)

Unable to provide a comprehensive view due to the limited information supplied in the Application.

Since some sugars can exert a laxative effect FSANZ should consider an advisory statement on the label if considered necessary. Considered that there are no direct benefits to consumers as there are already other alternatives available and the costs of products containing trehalose is not likely to be less than the others.

Consumers Association of South Australia Inc.

Supports the comments of Elaine Attwood from the National Council of Women.

SUMMARY OF PUBLIC SUBMISSIONS SECOND ROUND

Australian Food and Grocery Council (AFGC)

Restated that trehalose is already defined as a food by the definition of "sugars" in Standard 2.8.1-Sugars. As it is not novel, the application should be rejected.

Considered that FSANZ has failed to address the issues raised by the AFGC

FSANZ must address the strict definition of a “non-traditional food” which the AFGC considers excludes trehalose from being classified as a novel food.

By virtue of the safety assessment and that there are no restrictions on use of trehalose, FSANZ must acknowledge that there is sufficient knowledge in the community to enable safe use in the form or context in which it is presented and declare that trehalose is not a novel food.

FSANZ must re-examine the drafting in the Table to Clause 2 of Standard 1.5.1-Novel Foods.

Food Technology Association of Victoria Inc

Supports the Application.

New Zealand Food Safety Authority

Support the recommendation that trehalose should be regulated as a novel food. Trehalose does not meet the definition of a sugar contained in Standard 1.2.4 and suggest that trehalose should be more clearly described in the ingredient list.

CSIRO Health Sciences and Nutrition

Supports the recommendation that trehalose should be regulated as a novel food.