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

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FINAL ASSESSMENT REPORT

APPLICATION A578

ISOMALTULOSE AS A NOVEL FOOD

For information on matters relating to this Assessment Report or the assessment process generally, please refer to http://www.foodstandards.gov.au/standardsdevelopment/

Executive Summary

FSANZ received an application from PALATINIT GmbH on 27 April 2006 to amend Standard 1.5.1 – Novel Foods, of the *Australia New Zealand Food Standards Code* (the Code) to approve the use of isomaltulose as a novel food.

Isomaltulose is a disaccharide comprised of glucose and fructose joined by an α-1,6 glycosidic bond. Isomaltulose is naturally present at very low levels in sugar cane juice and honey.

Under the current food standards, novel foods are required to undergo a pre-market safety assessment, as per Standard 1.5.1 - Novel Foods. Isomaltulose is considered to be a non-traditional food because there is no history of significant human consumption in Australia or New Zealand. Based on the potential for increased consumption patterns if isomaltulose were used as a food ingredient, and the fact that the safety of isomaltulose had not yet been determined, isomaltulose is considered to be a novel food and is accordingly considered under Standard 1.5.1.

The objective of this assessment is to determine whether it is appropriate to amend the Code to permit the use of isomaltulose as a novel food. Such an amendment would need to be consistent with the section 10 objectives of the FSANZ Act.

The safety assessment and dietary exposure assessment indicate that isomaltulose poses no public health and safety concern to the vast majority of consumers.

Concerns around the potential for effects in a small group of consumers with sucrase/isomaltase deficiency or hereditary fructose intolerance will be managed through extensive communication with this community. FSANZ will prepare a fact sheet, to be available on the website, and a media release targeted at the mainstream and medical press containing information on isomaltulose for these consumers. We will correspond with medical practitioners and metabolic disorder support groups in both Australia and New Zealand in order to disseminate the information in a targeted manner. FSANZ will also take this opportunity to remind these consumers of other sugars that they need to avoid such as D-tagatose and sorbitol.

The only regulatory options identified were to approve or not approve the use of isomaltulose as a novel food. On balance, there is likely to be a benefit to consumers and public health professionals (by offering additional choice) and industry (potential to market new products) from the approval of this Application. There is unlikely to be a significant impact on government enforcement agencies as a result of approval for the use of isomaltulose as a novel food.

Purpose

The Applicant seeks amendment to Standard 1.5.1 – Novel Foods, to include isomaltulose in the Table to clause 2.

Decision

Amend Standard 1.5.1 – Novel Foods, to include isomaltulose in the Table to clause 2. The specification for isomaltulose will be added to the Schedule to Standard 1.3.4 – Identity and Purity.

Reasons for Decision

This draft variation is proposed for the following reasons.

- The proposed draft variation to the Code is consistent with the section 10 objectives of the FSANZ Act. In particular, it does not raise any public health and safety concerns for the general population and an appropriate risk management strategy has been put in place to ensure the protection of consumers who may need to avoid isomaltulose. The safety assessment of isomaltulose is based on the best available scientific evidence, and approval of isomaltulose will help promote an efficient and internationally competitive food industry.

- Isomaltulose has desirable qualities that are of interest to the food manufacturing industry.

- The regulation impact assessment concluded that the benefits of permitting use of the enzyme outweigh any costs associated with its use.

- To achieve what the Application seeks, there are no alternatives that are more cost-effective than a variation to Standards 1.5.1 and 1.3.4.

Consultation

The Initial Assessment was advertised for public comment between 9 August 2006 and 20 September 2006. Thirteen submissions were received during this period. The Draft Assessment Report was advertised for public comment between 13 December 2006 and 7 February 2007. Ten submissions were received during this period. FSANZ has taken the submitters' comments into account in preparing the Final Assessment of this Application. A summary of submissions is attached to this report.

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INTRODUCTION

1. Background

FSANZ received an application from PALATINIT GmbH on 27 April 2006 to amend Standard 1.5.1 – Novel Foods, of the *Australia New Zealand Food Standards Code* (the Code) to approve the use of isomaltulose as a novel food.

Final Assessment of the Application has been completed, including a comprehensive safety assessment, dietary exposure assessment and food technology report.

1.1 Current Standard

Under Standard 1.5.1, novel foods are required to undergo a pre-market safety assessment. The purpose of this Standard is to ensure that non-traditional foods that 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 Food is defined in clause 1 of Standard 1.5.1 as:

> *a non-traditional food 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*
> *(e) patterns and levels of consumption of the product.*

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.*

1.2 Properties of isomaltulose

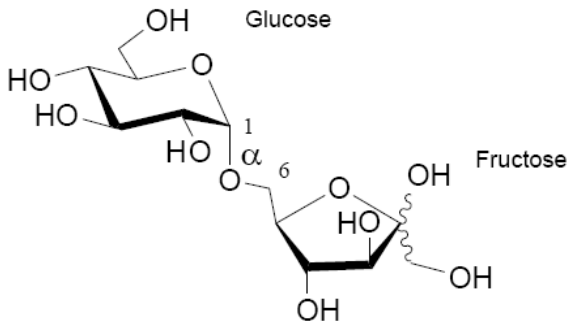
Isomaltulose (also known as Palatinose™ or 6-O-α-D-glucopyranosyl-D-fructofuranose) is a nutritive sweetener. Like sucrose, isomaltulose is a disaccharide made up of glucose and fructose (Figure 1). However, in contrast to sucrose, these saccharides are joined by an α-1,6 glycosidic bond in isomaltulose compared to a α-1,2 glycosidic link in sucrose.

Commercial isomaltulose is produced from food grade sucrose through enzymatic isomerisation with sucrose-6-glucosylmutase (EC 5.4.99.11). It is approximately half as sweet as sucrose. It is found naturally in very small quantities in honey (0.1 – 0.7%) and sugar cane juice. Therefore exposure to isomaltulose from natural sources is very low.

Isomaltulose is digested more slowly than sucrose due to the α-1,6 glycosidic bond, accounting for lower and slower increases in blood glucose compared to sucrose. It is also more resistant to oral fermentation.

According to the Applicant, the lower glycemic index of isomaltulose compared to sucrose, and its non-cariogenic properties make isomaltulose desirable to food manufacturers as a total or partial replacement for sucrose in certain products.

Figure 1: Structural Formula of Isomaltulose



1.3 Proposed uses

The Applicant wishes to use isomaltulose as a slow release carbohydrate in a variety of foods. Example of the types of food in which it potentially could be used include:

Examples of food categories	**Specific type of food within the given food category**	**Approximate use levels in food (%)**
Beverages	Soft-drinks	1-10
	Instant drink preparations	
	Teas	
	Beer and related beverages	
	Fruit or vegetable juices/drinks	
Baked goods/ baking mixes		10-25
Cereals and cereal products	Breakfast cereals,	20-35
	Cereal bars	5-20
Soups, toppings, desserts		15-30
Milk-based products		3-20
Fruit and water ices		15
Confectionery/bakery	Hard candies	99
	Soft candies, toffees	30-50
	Chewing gum	5-35
	Chocolate and related products	25-50
	Compressed goods, tablets	98-99
	Ice creams	30
	Fondants, fillings, crèmes	90
Snack foods		10-25
Others	Jams, marmalades	25-40
	Energy-reduced foods	5-40
	Meal replacement/slimming food	5-20

1.4 Approval in other countries

According to the Applicant, isomaltulose is marketed as a sugar in Japan, South Korea and Taiwan. It is an approved food additive in China. In Europe, isomaltulose is an approved novel food or novel food ingredient. Notification has been made to the US FDA that isomaltulose is Generally Recognized As Safe (GRAS) (GRN No. 184).

No approval has been rejected or withdrawn by any regulatory body.

2. The Issue / Problem

Novel foods are required to undergo a pre-market safety assessment under Standard 1.5.1 – Novel Foods, to ensure that non-traditional foods that 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.

Isomaltulose falls within the scope of the definition of 'sugars' as defined in Standard 2.8.1 - Sugars in the Code and hence is regarded as a food. At Initial Assessment FSANZ considered that isomaltulose meets the definition of a 'non-traditional food' in Standard 1.5.1 as it does not have a history of significant human consumption by the broad community in Australia or New Zealand. FSANZ also considered that isomaltulose meets the definition of a 'novel food' based on its composition and structure, and potential patterns and levels of consumption.

Therefore isomaltulose has been assessed as a novel food, which allowed FSANZ to assess and appropriately manage any risk to public health and safety posed by its use. Dietary exposure assessment was also conducted to determine potential levels of consumption.

Isomaltulose must be added to the Table to clause 2 of Standard 1.5.1 before it may be sold in Australia or New Zealand.

3. Objectives

The objective of this assessment is to determine whether or not it is appropriate to amend the Code to permit the use of isomaltulose as a novel food. Such an amendment would need to be consistent with the section 10 objectives of the FSANZ Act.

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 FSANZ Act. 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 standards, 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;

- the promotion of fair trading in food; and

- any written policy guidelines formulated by the Ministerial Council.

4. Key Assessment Questions

These are the questions FSANZ has considered at Draft Assessment:

- What would be the potential dietary intake of isomaltulose for mean and high consumers if it were approved?

- Considering the information provided by the Applicant, other available information, and FSANZ's dietary exposure assessment, would the approval of isomaltulose as a novel food ingredient pose any risk to public health and safety?

- What are the food technology implications of this Application?

RISK ASSESSMENT

5. Risk Assessment Summary

5.1 Safety assessment

From the safety assessment of isomaltulose (**Attachment 2**) it has been concluded that:

- Isomaltulose is broken down into glucose and fructose by isomaltase in the digestive tract. The resulting glucose and fructose are then absorbed and metabolised in the same way as glucose and fructose derived from other sources such as sucrose;

- therefore, no adverse effects were expected in animals from the consumption of isomaltulose. This was shown to be the case in a number of studies:

    - there was no evidence of toxicity in the repeat dose toxicity studies in rats. The highest dose tested, in an 8-week rat study, 30% isomaltulose in the diet, was considered the No Observed Effect Level (NOEL). This is equivalent to approximately 15g isomaltulose/kg body weight/day;
    - an embryotoxicity/developmental toxicity study showed no isomaltulose-related adverse effects on reproductive parameters at 10% isomaltulose in the diet (6.9g/kg bw per day, the highest dose tested);
    - Isomaltulose produced no evidence of genotoxic potential in *in vitro* assays; and

- There is no evidence of adverse effects in healthy or diabetic humans from the consumption of isomaltulose at doses up to 50 g or 1 g/kg body weight. However, it is anticipated that gastrointestinal effects may occur in individuals who lack the enzyme isomaltase and are unable to digest isomaltulose. Individuals with Hereditary Fructose Intolerance may also experience severe adverse effects if they consume isomaltulose. Risk management strategies will need to be developed to manage the risk to these individuals.

5.2 Dietary exposure assessment

A dietary exposure assessment was undertaken by FSANZ to estimate dietary exposure to isomaltulose should it be approved as a novel food (Dietary Exposure Assessment Report at **Attachment 3**).

The Applicant estimated that isomaltulose will replace the use of sucrose in the market at levels of approximately 5-10%. Based on this the exposure assessment was conducted in two different ways; firstly using a sugar replacement model using total dietary sugar intakes and secondly using individual dietary records from nutrition surveys to derive exposures for individuals from which summary statistics for the population were derived. For the individual dietary records approach, two scenarios were examined:

1. 'Brand-loyal consumer' scenario; and
2. 'Market share' scenario.

Scenario 1 – Brand-loyal consumer, represents the situation where individual people always remove sugared or intensely sweetened foods and beverages from the diet and include isomaltulose-containing foods and beverages in their place. It therefore represents an extreme case and is therefore not representative of the population as a whole, tending to overestimate potential mean consumption. *Scenario 2 – Market share* assumes that the sugar in foods is replaced with isomaltulose 10% of the time and represents the potential impact on isomaltulose dietary exposures over the long term and across the population.

The population groups assessed with the total sugar replacement model were the Australian population (2-3 years, 4-7 years, 8-11 years, 12-15 years, 16-18 years, 19-24 years, 25-44 years, 45-64 years, 65 years & over and 19 years & over) and New Zealand population (5-6 years, 7-10 years, 11-14 years, 15-18 years, 19-24 years, 25-44 years, 45-64 years, 65 years & above and 15 years & above). Individual dietary records were assessed for the Australian population (2 years and above), the New Zealand population (15 years and above) and Australian children (2-6 years).

Based on the total sugar replacement model assuming 10% of total sugar intakes are replaced with isomaltulose, Australians two years and above would have an exposure of between 10-17 g/day depending on age. For Australian children 2-6 years, exposure would be between 11-13 g/day. For New Zealanders, potential intakes would be 10-15 g/day and 11g/day for ages 5 and above, and 5-6 years respectively.

Of the population groups assessed for the individual dietary records assessment, Australians aged 2 years and above had the highest mean and 95th percentile dietary exposures to isomaltulose (in g/day) for both *Scenario 1 – Brand-loyal consumer* (39 g/day and 105 g/day) and *Scenario 2 – Market share* (3.9 g/day and 11 g/day).

When estimated dietary exposures were considered in g/kg bw/day, Australian children aged 2-6 years had the highest mean and 95th percentile dietary exposures to isomaltulose for both *Scenario 1 – Brand-loyal consumer* (1.8 g/kg bw/day and 4.0 g/kg bw/day) and *Scenario 2 – Market share* (0.18 g/kg bw/day and 0.4 g/kg bw/day).

As expected, the estimated dietary exposures to isomaltulose were much higher for 'brand loyal' model than either market share or population estimates based on sugar replacement. These high estimates represent the top end of the expected range of possible exposures and not a population estimate. Although the results for market share and sugar replacement models were similar, the former estimates are considered more accurate.

Major contributors to the estimated dietary exposure to isomaltulose, depending on the population groups assessed, were processed cereal & meal products (contributing to 13-22% of total exposure), confectionery (12-18%), beer & related products (13-16%) and ice cream & edible ices (7-14%).

5.3 Risk characterisation

In animal studies, the highest dose of isomaltulose tested was 30% of the total diet of rats. This is approximately 15 g /kg body weight/day. No adverse effects were noted at this level of consumption. Studies in human volunteers with doses up to 50 g/day or 1 g/kg body weight found no adverse effects.

Dietary exposure assessment conducted by FSANZ indicated that the highest consumption estimated for isomaltulose was for Australians aged 2-6 years (4.0 g/kg bw per day or 0.4 g/kg bw per day at the 95th percentile for *'Scenario 1 – Brand-loyal consumer'* and *'Scenario 2 – Market share'* respectively). Mean exposure (1.8 g/kg bw/day and 0.18 g/kg bw/day for Australian children) is a better representation of potential exposure over a longer period of time.

Human exposure levels are anticipated to be much lower than the highest levels used in animal experiments, which were found to cause no adverse effects. Dietary exposure suggests that some individuals may exceed the highest dose used in human trials, around 50 - 70 g /day, however, this is assuming they always select the isomaltulose version of each product type, which is very unlikely. Furthermore, no effects were observed at this dose level, and intakes are still below the level causing no adverse effects in animals. Given the available data on isomaltulose (chemical, biochemical and toxicological) and the intended level of use, its use in a wide variety of products does not raise any safety concerns for the vast majority of the population.

The exception to this is for individuals with a sucrase-isomaltase deficiency, and for individuals with Hereditary Fructose Intolerance who may not recognise that isomaltulose is metabolised to fructose. The risk to these individuals needs to be managed.

RISK MANAGEMENT

6. Risk Management Considerations

The Novel Foods Standard allows for conditions of use to be specified where there is evidence of a potential public health and safety risk to the general population or an identified population sub-group in Australia or New Zealand. In relation to this Application, the risk assessment indicates that there is no identified public health and safety concern related to the use of isomaltulose as a novel food for the vast majority of the population.

However, the risk assessment identified that isomaltulose is likely to be unsuitable for individuals with HFI or sucrase-isomaltase deficiency. Consideration was given to how best to inform affected individuals to avoid foods containing isomaltulose. These people will be unfamiliar with isomaltulose and may not recognise it as a product they need to avoid. One such mechanism might be through the imposition of conditions of use or labelling requirements, however consideration was also given to other means such as targeted education and information dissemination.

It was concluded that the use of additional labelling requirements was not warranted in this case, for a number of reasons. These are:

- HFI and sucrase/isomaltase deficiency are rare conditions;
- the acute effects of inadvertent consumption of isomaltulose are easily recognisable and reversible
- affected individuals typically display a natural aversion to sweet foods;
- diagnosed individuals are typically receiving dietary counselling;
- that there are well established networks for disseminating information regarding metabolic disorders; and
- the foods to which isomaltulose is intended to be added are foods that individuals with this condition are likely to already be avoiding.

Instead of a mandatory advisory statement, FSANZ proposes to prepare appropriate notifications regarding isomaltulose for the relevant health professionals and organisations, as well as the medical press and will circulate these prior to foods containing isomaltulose being placed on the market. This is discussed further under Section 9 – Communication.

7. Options

FSANZ is required to consider the impact of various regulatory (and non-regulatory) options on all sectors of the community, which includes consumers, the food industry, governments in both Australia and New Zealand and often public health professionals. The benefits and costs associated with any proposed amendment to the Code will be analysed in a Regulatory Impact Assessment.

Novel foods or novel food ingredients used in Australia and New Zealand are required to be listed in Standard 1.5.1 – Novel Foods. As isomaltulose is a novel food and requires pre-market approval under Standard 1.5.1, it is not appropriate to consider non-regulatory options to address this Application.

Two regulatory options are identified for this Application:

Option 1 – Not permit the use of isomaltulose as a novel food.

Option 2 – Permit the use of isomaltulose as a novel food.

8. Impact Analysis

8.1 Affected Parties

Parties possibly affected by the regulatory options outlined above include:

1. Consumers who may be affected, either positively or negatively, by new products containing isomaltulose.

2. Public health professionals because of the role of slow release carbohydrates in human nutrition.

3. Those sectors of the food industry wishing to market foods containing isomaltulose, including potential importers, manufacturers of isomaltulose and manufacturers of foods that may potentially contain isomaltulose.

4. Government agencies enforcing the food regulations.

8.2 Benefit Cost Analysis

8.2.1 Option 1 – Not permit the use of isomaltulose as a novel food

Under Option 1, the affected parties and potential impacts are:

- Manufacturers of isomaltulose, manufacturers wishing to produce foods containing isomaltulose and importers of foods containing isomaltulose, would be disadvantaged as they would be unable to innovate and take advantage of market opportunities for the development and sale of isomaltulose-containing products.

- Consumers may be disadvantaged as they would be unable to take advantage of any potential health benefits from the consumption of isomaltulose-containing foods.

- Public health professionals may be disadvantaged as they would be unable to promote any potential health benefits of foods containing isomaltulose.

- There is no perceived impact on government agencies, although lack of approval may be regarded as unnecessarily trade restrictive.

8.2.2 Option 2 – Permit the use of isomaltulose as a novel food

Under Option 2, the affected parties and potential impacts are:

- Manufacturers of isomaltulose, manufacturers wishing to produce foods containing isomaltulose and importers of foods containing isomaltulose, would benefit. There would be greater opportunities to innovate and take advantage of market opportunities, both domestically and overseas, for the development and sale of isomaltulose-containing products.

- Consumers may benefit from foods containing isomaltulose as they would be able to take advantage of any potential health benefits that may arise from consumption of these foods. Additionally, some consumers may benefit from the reduced sweetness or other sensory qualities of isomaltulose that may be seen as desirable. However, there is a small risk to those individuals who lack the enzyme required to digest isomaltulose and to those individuals who are fructose intolerant. As discussed in section 8, a risk management strategy has been proposed to manage the risk to these individuals.

- Public health professionals may benefit as they would be able to promote any potential health benefits of foods containing isomaltulose.

- There is no perceived impact on government agencies.

8.3 Comparison of Options

Option 1 appears to provide no benefits to industry, consumers, public health professionals or government. Option 1 denies industry access to a new novel food ingredient which has been demonstrated to be safe. It also denies consumers access to foods containing isomaltulose, and any associated benefits.

Option 2 does not appear to impose any significant costs on industry, consumers, public health professionals or government. Option 2 provides benefits to industry in terms of product innovation and development and potential sales of foods containing isomaltulose, while consumers may benefit from possible improved flavour/taste profiles and the potential for positive health effects.

An assessment of the costs and benefits of Options 1 and 2 indicates that there would be a net benefit in permitting the use of isomaltulose. Therefore, Option 2 is the preferred option.

COMMUNICATION

9. Communication

For the general population, FSANZ has applied a limited communication strategy. FSANZ will advertise the availability of assessment reports for public comment in the national press, and make the reports available on the FSANZ website. The Applicant and individuals and organisations that have made submissions on this Application will be notified at each stage of the Application.

If the FSANZ Board approves the Final Assessment Report, we will notify the Ministerial Council. The Applicant and Stakeholders, including the public, will be notified of any changes to the Code in the national press and on the website.

FSANZ provides an advisory service to the jurisdictions on changes to the Code.

In addition, FSANZ has identified the need for extensive distribution of information relating to isomaltulose for those individuals with hereditary fructose intolerance or sucrase-isomaltase deficiency.

FSANZ considers the most appropriate risk management strategy for isomaltulose involves general and targeted distribution of information regarding the unsuitability of isomaltulose for individuals with HFI and sucrase-isomaltase deficiency.

In Australia and New Zealand, metabolic disorders are managed through a network of clinics, with essentially one clinic in operation per state and New Zealand. In addition, researchers and health professionals working in this field are generally also members of the Australasian Society for Inborn Errors of Metabolism (ASIEM), a special interest group within the Human Genetics Society of Australasia (www.hgsa.com.au/asiem/). Although there is no formal register of individuals with HFI or sucrase-isomaltase deficiency FSANZ believes that most treating physicians would be members of the ASIEM. Individuals with enzyme deficiencies are also assisted directly through the Metabolic Dietary Disorders Association (MDDA) (www.mdda-australia.org), a self-help and support group for sufferers of metabolic disorders and their families.

FSANZ will write formally to the ASIEM and advise them of concerns regarding the suitability of isomaltulose for individuals with HFI and sucrase-isomaltase deficiency and request they advise patients. To ensure that the greatest number of patients are reached, FSANZ will also provide similar advice to the respective Paediatric and Gastroenterology societies in both countries. To assist in the provision of advice to patients, FSANZ will develop a Fact Sheet for distribution to relevant patients and also make this available on the FSANZ website. A Media Release will also be prepared.

The Media Release will be timed to coincide with gazettal of the changes to the code, and will be distributed to the mainstream and medical press. A similar media release on D-tagatose was made at the time of its approval, and received significant coverage across Australia and New Zealand.

FSANZ will use this opportunity to remind affected consumers about other carbohydrates they may need to avoid, such as sorbitol and D-tagatose. Information on these products will be included in the Fact Sheet and Media Release prepared by FSANZ.

10. Consultation

10.1 Public Consultation

The Initial Assessment was advertised for public comment between 9 August 2006 and 20 September 2006. Thirteen submissions were received during this period. The Draft Assessment was advertised for public comment between 13 December 2006 and 7 February 2007. Ten submissions were received during this period. Seven of these supported the application, three expressed no preference and no submitters opposed the approval of isomaltulose. A summary of all submissions received is included in **Attachment 3** to this Report.

FSANZ has taken the submitters' comments into account in preparing the draft assessment of this application. The major issues raised at Draft Assessment are discussed here.

10.1.1 Inclusion of isomaltulose in Standard 2.8.1 - Sugars

A number of submitters suggested that as isomaltulose is a sugar, it ought to be specifically listed in Standard 2.8.1 – *Sugars*.

10.1.1.1 FSANZ Response

Isomaltulose is a hexose disaccharide and as such meets the definition of a sugar in Standard 2.8.1 which states that –

> ***sugars*** *means –*
>
> *(a) hexose monosaccharides and disaccharides, including dextrose, fructose, sucrose and lactose; or*
> *(b) starch hydrolysate; or*
> *(c) glucose syrups, maltodextrin and similar products; or*
> *(d) products derived at a sugar refinery, including brown sugar and molasses; or*
> *(e) icing sugar; or*
> *(f) invert sugar; or*
> *(g) fruit sugar syrup;*
>
> *derived from any source, but does not include -*
>
> *(h) malt or malt extracts; or*
> *(i) sorbitol, mannitol, glycerol, xylitol, polydextrose, isomalt, maltitol, maltitol syrup or lactitol.*

Standard 2.8.1 does not specifically name all carbohydrates that meet this definition, and it is unnecessary to expressly name isomaltulose.

10.1.2 Sugar free claims

A number of submitters were concerned that manufacturers should not be permitted to make 'sugar free' or 'no added sugar' claims on products containing isomaltulose.

10.1.2.1 FSANZ Response

As isomaltulose meets the definition of a sugar under Standard 2.8.1, products containing isomaltulose cannot be said to be 'sugar free'. If such a claim were made, laws pertaining to false, misleading and deceptive conduct (e.g. *Trade Practices Act 1974,* New Zealand *Fair Trading Act 1986*) may apply.

10.1.3 Potential for misleading claims to be made

It was identified that manufacturers may wish to make claims around isomaltulose relating to its low GI compared to sucrose. Concern was expressed that consumers may confuse low GI claims with low-joule claims, and that isomaltulose is not a low-joule product. The potential for claims to be made around the non-cariogenic properties of isomaltulose was also of concern, as was the association of isomaltulose with weight loss.

10.1.3.1 FSANZ Response

Glycemic index and other claims are being considered as part of the health claims work currently being conducted by FSANZ (Proposal P293 – Nutrition, Health and Related Claims). It is intended that consumer and industry confidence in the framework behind such claims be assured by building in a number of safeguards to ensure that all claims are true, scientifically substantiated and not misleading. More information about Proposal P293 – Nutrition, Health and Related Claims, is available on the FSANZ website[1].

GI is calculated on whole foods, not individual ingredients, and there is an Australian Standard in place for determining the GI of foods (*Australian Standard Glycemic index of foods* AS 4694 – 2007). Any GI claim would have to meet the requirement of this Standard, and in the future, the new food Standard for nutrition, health and related claims.

The energy content of a food must be listed in the Nutrition Information Panel (NIP) on a food label. This allows consumers to compare the energy values of different foods and make decisions around which products to purchase. Isomaltulose will also be included in the NIP as part of the carbohydrate content.

10.1.4 Labelling isomaltulose to advise hereditary fructose intolerance sufferers and sucrase-isomaltase deficient individuals that it is a source of fructose and glucose

A number of submitters suggested that a mandatory advisory statement be required on products containing isomaltulose, to inform HFI and sucrase-isomaltase deficient people to avoid these products. Although, in the past similar products have not been required to carry an advisory statement, it was queried whether the previous approach to information dissemination had been effective.

10.1.4.1 FSANZ Response

FSANZ considered different options to provide information to HFI and sucrase-isomaltase deficient consumers, including additional labelling requirements such as a mandatory advisory statement, as well as other methods of communicating this information. Mandatory advisory statements may be used in some circumstances, particularly where the effects of consumption of a particular ingredient may be serious and irreversible (e.g. aspartame and phenylketonuria).

[1] http://www.foodstandards.gov.au/foodmatters/healthnutritionandrelatedclaims/index.cfm

However, in the case of HFI and sucrase-isomaltase deficiency, given the rarity of the conditions, the fact that the acute effects of inadvertent consumption of isomaltulose are easily recognisable and reversible, the fact that affected individuals typically display a natural aversion to sweet foods, that diagnosed individuals are typically receiving dietary counselling, and that there are well established networks for disseminating information regarding metabolic disorders, the use of a mandatory advisory statement was not considered warranted. Furthermore, the foods to which isomaltulose is intended to be added are foods that individuals with this condition are likely to already be avoiding.

Instead of a mandatory advisory statement, FSANZ proposes to prepare appropriate notifications regarding isomaltulose for the relevant health professionals and organisations, as well as the mainstream and medical press and will circulate these prior to foods containing isomaltulose being placed on the market. The fact sheet and media release will target not only isomaltulose, but will use this opportunity to remind affected consumers about other sugars they need to avoid, such as D-tagatose.

The effectiveness of this approach in relation to previous similar circumstances (e.g. in the approval of D-tagatose) has not been specifically evaluated, however, nor has FSANZ received any reports of adverse outcomes. The small number of sufferers and the lack of a comprehensive register make evaluation of this approach difficult. However, FSANZ is considering how this approach might be evaluated in the future, for example, by considering the effectiveness and reach of other media releases and fact sheets in different population groups to determine if similar conclusions may be drawn.

Standard 2.8.1 requires that sugars be listed by name in the ingredient list (i.e. the term 'sugar' cannot be used in place of the specific type of sugar), therefore isomaltulose will be required to be included in the ingredient list.

10.1.5 Limiting the range of foods permitted to contain isomaltulose

The New Zealand Food Safety Authority (NZFSA) suggest that FSANZ limit the range of foods to which isomaltulose be permitted to be added. They express concern that if the replacement of sucrose with isomaltulose exceeds the Applicant's estimated 5-10%, that dietary exposure may exceed 1g/kg body weight per day. As many of the foods to which isomaltulose could be added are consumed by children, this is a particular concern for children.

10.1.5.1 FSANZ Response

Isomaltulose is broken down into fructose and glucose in the digestive system and therefore has the same systemic effect as the consumption of an equivalent amount of sucrose. Although the highest dose tested in human tolerance studies was approximately 1g/kg body weight per day, an amount that can be consumed easily in a single dose, this does not represent a level above which there may be unexpected consequences. There is no limit on the range of foods allowed to contain sucrose, glucose and fructose, and FSANZ has not considered limiting the range of food permitted to contain isomaltulose.

10.1.6 Use of isomaltulose in food exempt from labelling requirements

The NZFSA also suggest that isomaltulose should not be permitted to be used in foods that are exempt from ingredient labelling, such as beer and other alcoholic beverages.

10.1.6.1 FSANZ Response

Foods which are exempt from ingredient labelling pose a problem for individuals who must avoid particular ingredients. As a consequence, these individuals must take a cautious approach to the consumption of unlabelled foods.

It should be recognised that many foods contain sucrose and/or fructose, and that affected individuals will already be avoiding these products. Isomaltulose is generally intended to replace sucrose in foods, rather than be added to foods which previously contained neither sucrose nor fructose. In addition, there are other ways of obtaining information about unlabelled products, e.g. from the salesperson at the point of sale or by enquiring with the food manufacturer.

10.1.7 Use of isomaltulose in electrolyte drinks

The Victorian Department of Human Services has raised the issue that if isomaltulose is intended to be used in electrolyte drinks, evidence should be presented to show that it enhances gastrointestinal water absorption in a similar manner to glucose and sucrose.

10.1.7.1 FSANZ Response

Electrolyte drinks are covered in the compositional standards of the Code under Standard 2.6.2 – Non-alcoholic beverages and brewed soft drinks. The definition of an electrolyte drink is *a drink formulated and represented as suitable for the rapid replacement of fluid, carbohydrates, electrolytes and minerals*. The types and levels of carbohydrate required in an electrolyte drink is specified as –

(a) no less than 50 g/L and no more than 100 g/L total –

(i) dextrose; and
(ii) fructose; and
(iii) glucose syrup; and
(iv) maltodextrin; and
(v) sucrose; and

(b) no more than 50 g/L fructose.

For Standard 2.6.2 to be amended to include isomaltulose, evidence would need to be presented to indicate that it serves a similar function to these other sugars. This has not been considered as part of this Application.

However, it is permitted to use other foods as ingredients in electrolyte drinks, in addition to those sugars listed above which must be present. Therefore as an approved novel food, isomaltulose may be used as an ingredient in electrolyte drinks as long as it is in addition to, not substituted for, the required sugars listed above.

10.1. Use of isomaltulose at levels greater than the traditional use of sucrose

The NZFSA and Victorian Department of Human Services reiterated the concern of the Dietitians Association of Australia (DAA) from the Draft Assessment Report that as isomaltulose is only half as sweet as sucrose it may be used in greater quantities to achieve the same level of sweetness, which would lead to higher energy content in these foods. Furthermore, consumers may be misled by low GI claims on these types of foods.

10.1.8.1 FSANZ Response

As discussed at Draft Assessment, the Applicant states that it is not their intention to use isomaltulose at twice the volume at which sucrose would traditionally be used. It is not feasible to double the quantity of isomaltulose to increase the sweetness of a product.

Sugars provide qualities in mixed foods such as moisture retention, in addition to sweetness. Doubling the amount of a sugar in a mixed food recipe (e.g. a cake or breakfast bar), would negatively affect the final product as the ratios of other ingredients would be incorrect. In addition, the final product would not necessarily be twice as sweet.

Products containing isomaltulose may be less sweet and allow for greater flavour. For some products, e.g. sports drinks, sweetness may not be so important, and isomaltulose would be used mainly as a source of slow release carbohydrate.

If the same sweetness as sucrose is needed in a particular product, isomaltulose can be combined with other sugars or intense sweeteners. The energy supplied by a particular product is required to be on the nutrition information panel so consumers can make an informed choice when they purchase food products.

Glycemic index and glycemic load claims are being considered as part of the health claims work currently being conducted by FSANZ (Proposal P293 – Nutrition, Health and Related Claims) and cannot be considered separately as part of this Application. It is anticipated that disqualifying criteria may prevent certain foods from making low GI claims.

10.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

Although approval of isomaltulose may have a liberalising effect on international trade, the potential food applications for isomaltulose are limited in terms of market size. Therefore, amending the Code to permit the use of isomaltulose as a novel food was not notified to the WTO under either the Technical Barrier to Trade or Sanitary and Phytosanitary Measure agreements as the permission was unlikely to significantly affect trade.

CONCLUSION

11. Conclusion and Decision

Approval is agreed for isomaltulose as a novel food. Permission will be provided by adding isomaltulose into the Table to clause 2 of Standard 1.5.1. – Novel Foods. A specification for isomaltulose will be added to the Schedule to Standards 1.3.4 – Identity and Purity.

Decision

Amend Standard 1.5.1 – Novel Foods, to include isomaltulose in the Table to clause 2. The specification for isomaltulose will be added to the Schedule to Standard 1.3.4 – Identity and Purity.

10.1 Reasons for Decision

This draft variation is agreed for the following reasons.

- The proposed draft variation to the Code is consistent with the section 10 objectives of the FSANZ Act. In particular, it does not raise any public health and safety concerns for the general population and an appropriate risk management strategy has been put in place to ensure the protection of consumers who may need to avoid isomaltulose. The safety assessment of isomaltulose is based on the best available scientific evidence, and approval of isomaltulose will help promote an efficient and internationally competitive food industry.

- Isomaltulose has desirable qualities that are of interest to the food manufacturing industry.

- The regulation impact assessment concluded that the benefits of permitting use of the enzyme outweigh any costs associated with its use.

- To achieve what the Application seeks, there are no alternatives that are more cost-effective than a variation to Standards 1.5.1 and 1.3.4.

11. Implementation and Review

It is proposed that the draft variation come into effect on the date of gazettal.

ATTACHMENTS

1. Draft variation or standard to the *Australia New Zealand Food Standards Code*
2. Risk Assessment Report
3. Dietary Exposure Assessment Report
4. Food Technology Report
5. Summary of issues raised in public submissions in the first and second rounds

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 –*

Isomaltulose	

.

[2] ***Standard 1.3.4*** *of the Australia New Zealand Food Standards Code is varied by inserting in the Schedule –*

Specification for isomaltulose

Chemical name	6-O-α-D-glucopyranosyl-D-fructofuranose
Description	White or colourless, crystalline, sweet substance, faint isomaltulose specific odour
Isomaltulose (%)	Not less than 98% on a dry weight basis
Water	Max. 6%
Other saccharides	Max. 2% on a dry weight basis
Ash	Max. 0.01% on a dry weight basis
Lead	Max. 0.1 ppm on a dry weight basis

Attachment 2

Safety Assessment Report

Summary

Introduction

The safety of isomaltulose as a novel food is based on: (i) its composition; (ii) its metabolism including human tolerance studies; and (iii) in vivo and in vitro toxicological studies.

Composition

Isomaltulose is a disaccharide composed of glucose and fructose. In this regard, it is similar to sucrose, where glucose and fructose are joined by an α-1,2 glycosidic link, however in isomaltulose these saccharides are joined by an α-1,6 glycosidic bond. Specification and batch analysis indicate that isomaltulose is greater than 98% pure and does not contain chemical or microbiological contaminants above relevant limits.

Metabolism

Isomaltulose is fully hydrolysed in the small intestine into fructose and sucrose by the enzyme isomaltase. This occurs more slowly than the hydrolysis of sucrose, thus isomaltulose has a lower glycemic index than sucrose. Fructose and glucose from isomaltulose are absorbed and metabolised as from any other source. Isomaltulose was well tolerated by healthy and diabetic volunteers, however is likely to cause severe gastrointestinal effects in individuals with Hereditary Fructose Intolerance or sucrase-isomaltase deficiency.

Toxicological studies on isomaltulose

Although the metabolism of isomaltulose indicates that it is very unlikely to produce adverse effects, a number of toxicity studies have been conducted with isomaltulose, including a several repeat-dose studies and an embryotoxicity/developmental study in rats. No significant isomaltulose-related adverse effects were reported in any study and the No Observed Effect Level was determined to be 30% in the diet of rats (approximately 15g/kg bw per day, the highest dose studied).

Isomaltulose was not mutagenic in *Salmonella* test strains in presence or absence of activation.

Overall Conclusion

The available toxicology studies conducted in animals and gastrointestinal tolerance studies conducted in humans do not raise any safety concerns. For the vast majority of the population, the use of isomaltulose in foods at the levels proposed by the Applicant is not expected to lead to any adverse health effects. The exception to this is for individuals lacking the sucrase-isomaltase enzyme complex, and for the small number of people who are intolerant to fructose and may not recognise that isomaltulose is metabolised to fructose. The risk to these individuals needs to be managed, for example, through education, provision of information or labelling.

ISOMALTULOSE AS A NOVEL FOOD

1. Introduction

The purpose of this assessment is to determine the safety of isomaltulose as a novel food. Although it is found naturally at low levels in honey (0.1 – 0.7%) and sugar cane juice, isomaltulose does not have a history of significant human consumption by the broad community in Australia or New Zealand and therefore is regarded as a 'non-traditional food' for the purposes of Standard 1.5.1. FSANZ regards isomaltulose as a novel food based on its composition and structure, and potential patterns and levels of consumption.

Isomaltulose (also known as Palatinose™ or 6-O-α-D-glucopyranosyl-D-fructofuranose) is a nutritive sweetener produced commercially from food grade sucrose. Isomaltulose is digested more slowly than sucrose due to the α-1,6 glycosidic bond, accounting for lower and slower increases in blood glucose compared to sucrose. It is also more resistant to oral fermentation. According to the Applicant, these properties make isomaltulose desirable to food manufacturers as a total or partial replacement for sucrose in certain products.

1.1 Specifications for isomaltulose

The following specifications for isomaltulose were provided by the Applicant.

Specification for isomaltulose (Palatinose™)

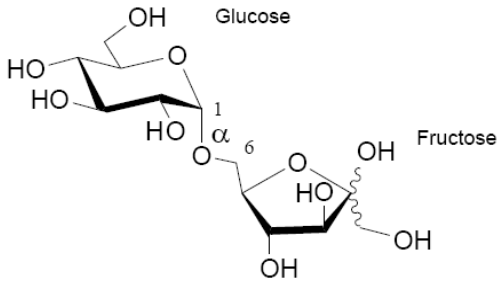
Full chemical name of isomaltulose	6-O-α-D-glucopyranosyl-D-fructofuranose
Description	White or colourless crystalline sweet substance. Faint isomaltulose specific odour
Isomaltulose (%)	Not less than 98% on a dry weight basis
Water	Maximum 6%
Other saccharides	Maximum 2%
Lead (ppm)	max. 0.1
Ash (%)	max. 0.01

Batch analysis was conducted on five samples, all of which complied with the above specification.

1.2 Chemistry of isomaltulose

Isomaltulose is a disaccharide made up of glucose and fructose (Figure 1). On a physical and chemical level it is similar to sucrose, which is also a glucose-fructose disaccharide. However in contrast to sucrose, where glucose and fructose are joined by an α-1,2 glycosidic link, in isomaltulose these saccharides are joined by an α-1,6 glycosidic bond. Isomaltulose is approximately half as sweet as sucrose, and has a similar sweetness quality.

Figure 1: Structural Formula of Isomaltulose



1.3 Natural occurrence and dietary intake of isomaltulose

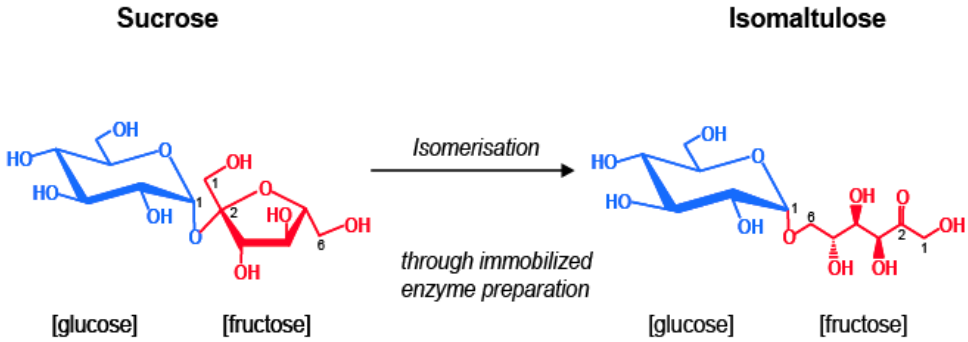
Isomaltulose is present at low levels in honey (0.1-0.7%) and sugar cane juice. Therefore exposure to isomaltulose from natural sources is very low, particularly when compared to the potential dietary intake of isomaltulose if it were approved as a novel food and added to a wide range of food products.

A dietary exposure assessment has been conducted for this application and is at Attachment 3.

2. Production of Isomaltulose

Commercial isomaltulose is produced from food grade sucrose through enzymatic isomerisation with sucrose-6-glucosylmutase (EC 5.4.99.11) (Figure 2). In solution, the α-1,2-linkage in sucrose is converted into the α-1,6-linkage in isomaltulose. The resulting solution is dried and crystallised, following filtration and ion exchange purification steps.

Figure 2: Enzymatic conversion of sucrose to isomaltulose



The enzyme, sucrose-6-glucosylmutase, is produced in *Protaminobacter rubrum*, non-viable cells of which are used a biocatalyst. This biocatalyst is the same as that used in the production of isomalt, a polyol, which is an approved food additive (sweetener) in the Code.

The potential pathogenicity and toxigenicity of *P. rubrum* was investigated. Up to 10^{10} viable cells were injected intravenously into mice and rabbits, which were then observed for 14 days (Porter *et al*., 1991). The results indicated that the production organism is not pathogenic and has only a low order of toxigenicity.

3. Biochemical data

3.1 Digestion of isomaltulose

Following oral intake, isomaltulose is completely hydrolysed to equal parts glucose and fructose by the sucrase/isomaltase enzyme complex anchored in the membrane of the brush border epithelial cells (Lina, 2000). The isomaltulose hydrolysing activity of sucrase/isomaltase has been demonstrated in rat, pig and human intestine (Dahlqvist, 1961; Dahlqvist *et al*., 1963; Dahlqvist, 1964; Goda and Hosoya, 1983; Yamada *et al*., 1985; Tsuji *et al*., 1986; Heymann and Heinz, 1987; Lina, 2000). These enzymes, which are encoded by a single gene, have varying specificities for disaccharides with the α-D-glucopyranoside structure. The isomaltase component of the enzyme complex is capable of hydrolysing maltose, isomaltose, isomaltotriose, oligo-(1,6)-glucosides and oligo-(1,4)-glucosides in addition to isomaltulose (Cheetam, 1982).

Hydrolysis of isomaltulose is much slower than that of sucrose. In the human small intestine, isomaltulose is hydrolysed with a V_{max} 26-45% that of sucrose (Lina, 2000). This results in slower increases and lower maximum levels in blood glucose and insulin levels, although the energy per gram is the same as sucrose (Macdonald and Daniel, 1983; Kawai *et al*., 1985; Kawai *et al*., 1989). Isomaltulose has a lower glycemic index (GI) value than sucrose (SUGiRS, 2002). It is also proposed as a non-cariogenic sweetener as it is not fermented by oral bacteria.

Following isomaltulose hydrolysis, the resulting glucose and fructose are absorbed in the intestine and metabolised via normal carbohydrate metabolism.

3.2 Gastrointestinal tolerance

3.2.1 Animal studies

Studies of isomaltulose consumption in rats indicates that it is well tolerated and does not cause gastrointestinal effects (Table 1).

Table 1: Gastrointestinal tolerance in rats

Species	***Number and sex of animals***	***Dose/duration***	***Results***	***Reference***
Rat	6 Wistar rats, sex not specified	56% in the diet for 2 months	No diarrhoea	(Takazoe *et al*., 1985)
	3 groups of 19-20 female Wistar rats	0, 17.5% or 56% in the diet for 8 weeks (half the group) or 14 weeks (remaining half group)	No diarrhoea or soft stools	(Sasaki *et al*., 1985)
	Groups of 10 Sprague Dawley rats, sex not specified	28% and 56% in the diet for 55 days	No diarrhoea or other clinical signs detected by visual examination	(Ooshima *et al*., 1983)

3.2.2 Human Studies

The gastrointestinal tolerance and acceptance of isomaltulose was tested in 60 volunteers who received either isomaltulose or sucrose in increasing doses either as pure substance or incorporated in nine different foods. The dose levels were: 12 g/day in weeks 1-2; 24 g/day in weeks 3-4; and 48 g/day in weeks 5-12. There was no statistically significant difference between the two groups in terms of body weight, blood pressure/pulse, stool frequency, frequency of flatulence or occurrence of diarrhoea. This indicated that the gastrointestinal tolerance of isomaltulose is similar to that of sucrose in healthy human subjects (Spengler and Sommerauer, 1989).

Other studies have indicated that isomaltulose is well tolerated in humans, and no signs of gastrointestinal discomfort have been reported (Table 2).

Table 2: Gastrointestinal tolerance in humans

Dose	***Duration***	***Number of participants***	***Results***	***Reference***
Increasing daily doses of isomaltulose or sucrose (control): 12 g/day in weeks 1-2; 24 g/day in weeks 3-4; and 48 g/day in weeks 5-12 (highest dose approximately 0.7g/kg bw/day)	12 weeks	60 healthy male and female volunteers	No effects observed	(Spengler and Sommerauer, 1989)
50 g (approximately 0.9g/kg bw)	Single dose	8 fasted healthy males and female volunteers	No effects observed	(Kawai *et al*., 1985)
50 g (approximately 1g/kg bw for healthy subjects and 0.8g/kg bw for diabetics)	Single dose	10 healthy and 10 diabetic male and female volunteers	No effects observed	(Kawai *et al*., 1989)
0.25, 0.5, 0.75 or 1 gm/kg body weight. Highest dose was approximately 70 g isomaltulose or sucrose (control)	Each subject had all doses in random order over 8 days	10 fasted, healthy male volunteers	No effects observed	(Macdonald and Daniel 1983)

3.3 Sensitive sub-populations

Although it appears that isomaltulose is well tolerated in healthy and diabetic subjects, there are two sub-populations which FSANZ believes may be affected by isomaltulose. These are individuals with sucrase-isomaltase deficiency, and individuals with hereditary fructose intolerance. These are discussed below.

3.3.1 Individuals with sucrase-isomaltase deficiency

Sucrase-isomaltase deficiency is a rare congenital metabolic disorder characterised by a complete lack of sucrase activity and a deficiency of isomaltase activity. It is an autosomal recessive condition, found in individuals homozygous for mutations in the gene which encodes the sucrase-isomaltase complex. Individuals with this condition cannot break down sucrose or related disaccharides such as isomaltose (alpha 1,6-linked glucose and glucose) and isomaltulose (alpha 1,2-linked glucose and fructose). These sugars are not absorbed as disaccharides and so pass to the large intestine where they are fermented and may cause watery acid diarrhoea. This deficiency is usually noticed in infants during weaning. In addition to diarrhoea, affected infants may refuse food, particularly sweet foods, and fail to thrive due to decreased absorption of nutrients (Cheetam, 1982).

Symptoms can vary in degree between individuals, but are usually more severe in infants and young children. They also depend on the amount of non-absorbable disaccharide ingested. Heterozygotes may have mild symptoms which generally decrease in adulthood.

Individuals with sucrase/isomaltase deficiency are likely to experience gastrointestinal effects from the consumption of isomaltulose and therefore options need to be developed to manage the risk to this group.

3.3.2 Individuals with hereditary fructose intolerance

Hereditary fructose intolerance (HFI) is due to a deficiency of either 1-phosphofructoaldolase (aldolase B) or fructose 1,6-diphosphatase. HFI is an inherited condition in which affected individuals develop hypoglycemic and severe abdominal symptoms after ingesting foods containing fructose and its cognate sugars (e.g. sucrose and sorbitol). The condition is considered to be quite rare, the incidence falling somewhere between 1 in 12,000 to 1 in 130,000 live births (James *et al*., 1996).

HFI is usually detected in early childhood when infants are weaned from breast milk or infant formula. If the condition remains undiagnosed continued ingestion of these sugars may lead to severe and irreversible liver and kidney damage as well as growth retardation. Once a diagnosis has been established, and provided the tissue damage has not been extensive, the introduction of a fructose-free diet results in rapid alleviation of the acute symptoms followed by recovery. Individuals with HFI typically develop a strong aversion to sweet foods, which serves to protect them from further exposure to the harmful sugars. In addition, diagnosed individuals typically receive dietary counselling to assist them to correctly identify and avoid problem foods.

Individuals with HFI would not necessarily recognise isomaltulose as a sugar to be avoided and could be adversely affected by the consumption of products containing isomaltulose. The management of risk to this population needs to be considered.

3.4 Conclusion

Isomaltulose is broken down to fructose and glucose in the small intestine. It is well tolerated in healthy and diabetic adults at doses up to 50 g or 1 g/kg body weight (around 70 g).

These were the highest doses tested. However, there is a small group of people with specific enzyme deficiencies who may be adversely affected by the consumption of isomaltulose and the risk to these individuals needs to be considered in the development of risk management options.

4. Toxicological studies on isomaltulose

4.1 Animal studies

As isomaltulose is completely hydrolysed in the gastrointestinal tract to fructose and glucose, it is not expected to cause any adverse effects in treated animals compared to controls. This is particularly true when sucrose, also completely hydrolysed to fructose and glucose, is used as the control substance. However a number of animal studies have been performed which consistently show that oral administration of relatively large doses of isomaltulose do not product any signs of toxicity. These are summarised in Table 3.

Table 3: Repeat-dose animal studies with isomaltulose

Animal sp., number and sex	*Dose*	*Duration*	*NOEL**	*Results*	*Reference*
Sprague-Dawley rats, 15 males and 15 females per group	0, 1500, 3000, 4500 mg/kg body weight/day (by gavage)	26 weeks	4500 mg/kg bw per day	No test substance related effects	(Yamaguchi *et al.,* 1986)
Wistar rats, 6 males per group	30% sucrose (control) 30% isomaltulose in diet. (approximately 15g/kg bw/day)	8 weeks	30% (approximately 15g/kg bw/day)	No test substance related effects	(Kashimura *et al*., 1990)
Wistar rats, males, number unspecified	30% sucrose (control), 7.5% and 15% isomaltulose (approximately 3.75 and 7.5 g/kg bw/day respectively)	13 weeks	7.5g/kg bw/day	No test substance related effects	(Kashimura *et al*., 1992)
Wistar rats (Crl:(WI)WU BR), 20 males and 20 females per test dose	0, 2.5, 5, or 10% isomaltulose in the diet replacing sucrose (equal to 1.7, 3.5 and 7 g/kg body weight in males and 2.0, 4.0 and 8.1 mg/kg body weight in females).	13 weeks	10% (equal to 7 g/kg bw/day in males and 8.1g/kg bw/day in females)	No test substance related effects	(Jonker, 1999)
Wistar rats (Hsd/Cpb:WU), 24 females per test dose	0, 2.5, 5, or 10% isomaltulose in the diet (equal to 0, 1.8, 3.5 and 6.9 g/kg body weight respectively)	21 days (embryotoxicity/ developmental study)	10%	No test substance related effects observed in the litters of mothers treated with isomaltulose during pregnancy	(Lina, 1992)

* In all cases the NOEL was the highest dose tested

4.2 Mutagenicity studies

4.2.1 Ames test

Isomaltulose was examined for mutagenic activity using the Ames test. *Salmonella typhimurium* strains TA1535, TA98, TA100, TA1537 and TA1538 were incubated with isomaltulose at four dose levels ranging from 100-4000 µg/plate, in the presence and absence of metabolic activation (S9 mix). Both negative and positive controls gave counts of revertants within the expected range. Isomaltulose gave no significant increase in revertants in any strain either with or without metabolic activation.

It was concluded that isomaltulose is not mutagenic under the conditions of this study (Sangster, 1986)

4.3 Conclusion of toxicological studies

Isomaltulose did not produce any measurable effects in rats under the conditions studied. The No Observed Effect Level was 30% in the diet, the highest dose tested in the 8 week study. This is approximately 15 g/kg bw per day. The embryotoxicity/developmental toxicity study did not reveal in test-substance related adverse effects at doses up to 10% (6.9 g/kg bw per day) in the diet of pregnant rats. Isomaltulose was not mutagenic in the Ames test.

5. Overall Conclusion

From the safety assessment of isomaltulose it has been concluded that:

- Isomaltulose is broken down into glucose and fructose by isomaltase in the digestive tract. The resulting glucose and fructose are then absorbed and metabolised in the same way as glucose and fructose derived from other sources such as sucrose.

- There was no evidence of toxicity in the repeat dose toxicity studies in rats. The highest dose tested, in an 8-week rat study, 30% isomaltulose in the diet, was considered the No Observed Effect Level (NOEL). This is equivalent to approximately 15 g isomaltulose/kg body weight/day.

- An embryotoxicity/developmental toxicity study showed no isomaltulose-related adverse effects on reproductive parameters at 10% isomaltulose in the diet, 6.9 g/kg bw per day, the highest dose tested).

- Isomaltulose produced no evidence of genotoxic potential in *in vitro* assays.

- There is no evidence of adverse effects in healthy or diabetic humans from the consumption of isomaltulose at doses up to 50 g or 1 g/kg body weight (the highest doses tested). However, it is anticipated that gastrointestinal effects may occur in individuals who lack the enzyme isomaltase and are unable to digest isomaltulose. Individuals with Hereditary Fructose Intolerance may also experience severe adverse effects if they consume isomaltulose. Risk management strategies will need to be developed to manage the risk to these individuals.

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Attachment 3

Dietary Exposure Assessment Report

An Application was received by FSANZ to amend the Food Standards Code to include isomaltulose as a novel food in Standard 1.5.1 Novel Foods.

A dietary exposure assessment was deemed necessary in order to estimate the impact of allowing the use of isomaltulose in the food supply on public health and safety.

EXECUTIVE SUMMARY

A dietary exposure assessment was undertaken by FSANZ to estimate dietary exposure to isomaltulose should it be approved as a novel food.

The Applicant estimated that isomaltulose will replace the use of sucrose in the market at levels of approximately 5-10%. Based on this the exposure assessment was conducted in two different ways; firstly using a sugar replacement model using total dietary sugar intakes and secondly using individual dietary records from nutrition surveys to derive exposures for individuals from which summary statistics for the population were derived. For the individual dietary records approach, two scenarios were examined:

1. 'Brand-loyal consumer' scenario; and
2. 'Market share' scenario.

Scenario 1 – Brand-loyal consumer, represents the situation where individual people always remove sugared or intensely sweetened foods and beverages from the diet and include isomaltulose-containing foods and beverages in their place. It therefore represents an extreme case and is not necessarily representative of the population as a whole, tending to overestimate potential mean consumption. *Scenario 2 – Market share* assumes that the sugar in foods is replaced with isomaltulose 10% of the time and represents the potential impact on isomaltulose dietary exposures over the long term and across the population.

The population groups assessed for total sugar replacement models were the Australian population (2-3 years, 4-7 years, 8-11 years, 12-15 years, 16-18 years, 19-24 years, 25-44 years, 45-64 years, 65 years & over and 19 years & over) and New Zealand population (5-6 years, 7-10 years, 11-14 years, 15-18 years, 19-24 years, 25-44 years, 45-64 years, 65 years & above and 15 years & above). The population groups assessed for individual dietary records approach were the Australian population (2 years and above), the New Zealand population (15 years and above) and Australian children (2-6 years).

Based on the sugar replacement scenario assuming 10% of total sugar intakes are replaced with isomaltulose, Australians two years and above would have an exposure of between 10-17 g/day depending on age, for Australian children 2-6 years exposure would be between 11-13 g/day, for New Zealanders 5 years and above an exposure of 10-15 g/day and 11 g/day for New Zealand children 5-6 years.

Of the population groups assessed for the individual dietary records assessment, Australians aged 2 years and above had the highest mean and 95th percentile dietary exposures to isomaltulose (in g/day) for both *Scenario 1 – Brand-loyal consumer* (39 g/day and 105 g/day) and *Scenario 2 – Market share* (3.9 g/day and 11 g/day). When estimated mean dietary exposures were considered in g/kg bw/day, Australian children aged 2-6 years had the highest mean and 95th percentile dietary exposures to isomaltulose for both *Scenario 1 – Brand-loyal consumer* (1.8 g/kg bw/day and 4.0 g/kg bw/day) and *Scenario 2 – Market share* (0.18 g/kg bw/day and 0.4 g/kg bw/day).

As expected, the estimated dietary exposures to isomaltulose were much higher for 'brand loyal' model than either market share or population estimates based on sugar replacement. These high estimates represent the top end of the expected range of possible exposures and not a population estimate. Although the results for market share and sugar replacement models were similar, the former estimates are considered more accurate and a better estimate

Major contributors to the estimated dietary exposure to isomaltulose, depending on the population groups assessed, were processed cereal & meal products (13-22%), confectionery (12-18%), beer & related products (13-16%) and ice cream & edible ices (7-14%).

1. Background

Isomaltulose (Palatinose^{TM}) is a nutritive, low glycemic sugar and, like sucrose, is composed of glucose and fructose. It can be used as a slow release carbohydrate source, particularly in those foods that contain significant amounts of carbohydrates like sucrose or other carbohydrates that are quickly absorbed to the blood stream. Isomaltulose occurs naturally in small quantities in honey and sugar cane juices. Naturally occurring sources of isomaltulose were not considered in this Application.

The Application states that isomaltulose is suitable for consumption by the general public, its cost, formulation and metabolic characteristics will lead to the development of foods in the healthy lifestyle segment and consumers interested in a slower glucose-fructose metabolic release (such as those engaged in athletics).

The main purpose of isomaltulose is related to its functional nutritional characteristics. Isomaltulose can be used in beverages, cereal products, milk-based products, confectionery, bakery products, marmalades, soups, dressings and desserts. The proposed concentrations of isomaltulose in food were provided by the Applicant as 'approximate use levels as consumed (%)' for each specific food/food group (refer to Table 1). The Applicant estimated that isomaltulose will replace the use of sucrose in the market at levels of approximately 5-10%.

Isomaltulose has been used as food in Asia, mainly Japan, since 1985 and in Europe since mid-2005.

Table 1: Proposed uses of isomaltulose in foods, as provided by the Applicant

Food Name	Isomaltulose concentration, as consumed (% final food)
Carbonated non-cola soft drinks (e.g. lemonade)	1-2
Carbonated cola soft drinks	1-2
Brewed soft drinks (e.g. ginger beer)	1-2
Energy drinks	1-8
Sports and isotonic drinks	1-5
Powdered cocoa drinks, malt drinks	1-10
Instant (powdered) sport and protein drinks, "specialized fitness-studio-products"	1-5
Teas, iced teas	1-5
Beer	1-2
Malt beer, beer mixed drinks	1-3
Biscuits, sweet	1-15
Dry packet cake and muffin mixes	1-10
Breakfast cereals	15-35
Breakfast muesli	15-30
Breakfast cereal bars	5-20
Muesli bars	5-20
Toppings	15-30
Jelly	5-15
Dairy based (mousse, cheesecake)	5-15
Non-dairy based (e.g. short cake, pavlova)	15-30
Milk – flavoured	1-5
Yoghurt – flavoured	1-5
Ice confection	15
Hard candies	99
Soft candies, toffees, gelees	8-50
Chewing gum	5-60
Chocolate and related products	25-50
Compressed goods, tablets	98-99
Fondants fillings and crèmes	10-50
Ice creams	10-15
Jams and marmalades	25-40
Nutritive formulae – clinical enteral nutrition for specific medical purposes	5-20
Energy-reduced foods – clinical enteral nutrition for specific medical purposes	5-40
Energy-reduced foods – solid types (e.g. biscuits, bars)	5-20
Energy-reduced foods – liquid types (e.g. shakes, drinks)	5-20

2. Dietary modelling conducted to estimate dietary exposures to isomaltulose

2.1 What is dietary modelling?

Dietary modelling is a tool used to estimate exposures to food chemicals from the diet as part of the risk assessment process.

To estimate dietary exposure to food chemicals, records of what foods people have eaten are required along with information on how much of the food chemical is in each food. The accuracy of these exposure estimates depends on the quality of the data used in the dietary models. Sometimes, not all of the data required are available or there is uncertainty about the accuracy. Therefore, assumptions are made, either about the foods eaten or about chemical levels, based on previous knowledge and experience. The models are generally set up according to international conventions for food chemical exposure estimates. However, each modelling process requires decisions to be made about how to set the model up and what assumptions to make. A different decision may result in a different answer. Therefore, FSANZ documents clearly all such decisions and model assumptions to enable the results to be understood in the context of the data available and so that risk managers can make informed decisions.

2.2 Population groups assessed

The dietary exposure assessment was conducted for both Australian and New Zealand populations. An assessment was conducted for the Australian population aged 2 years and above, the New Zealand population aged 15 years and above and Australian children aged 2-6 years. Dietary exposure assessments were conducted for the Australian population 2 years and above and the New Zealand population 15 years and above as a proxy for lifetime exposure. An exposure assessment was conducted on children aged 2-6 years because children generally have higher dietary exposures due to their smaller body weight and they consume more food per kilogram of body weight compared to adults. They also consume many of the foods proposed to contain isomaltulose, such as soft drinks, cereals and milk-based products. It is important to note that, while children aged 2-6 years have been assessed as a separate group, this group has also been included in the dietary exposure assessment for Australians two years and above.

2.3 Dietary modelling approach

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

Dietary exposure = food chemical concentration x food consumption

The exposure was estimated by combining usual patterns of food consumption, as derived from national nutrition survey (NNS) data, with the proposed concentrations of isomaltulose in foods.

2.4 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 the NNSs used a 24-hour food recall methodology. It is recognised that these survey data have several limitations. For a complete list of limitations see the Section 5: *Limitations*.

2.5 Isomaltulose concentration levels

The levels of isomaltulose in foods that were used in the dietary exposure assessment were derived from information provided by the Applicant.

Concentrations of isomaltulose were assigned to food groups using DIAMOND food classification codes. These codes are based on the Australian New Zealand Food Classification System (ANZFCS) used in Standard 1.3.1 Food Additives (for example, 6.2 represent processed cereal and meal products). The foods proposed by the Applicant to contain isomaltulose (as shown in Table 1) were matched to the most appropriate ANZFSC codes for dietary modelling purposes. The foods and concentrations of isomaltulose in those foods (as consumed) which were used in the dietary exposure assessment are shown in Table 2.

Where the Applicant provided a range of possible concentrations, the highest level in the range was used for calculating the dietary exposures in order to assume a worst-case scenario. The concentrations of isomaltulose in foods, as provided by the Applicant, relate to foods 'as consumed' and are expressed as a percentage. These percentage concentrations were converted to mg/kg concentrations for use in the DIAMOND program.

Table 2: Proposed levels of isomaltulose in foods (%) and the concentrations used in the dietary exposure assessment (mg/kg)

DIAMOND Food Code	Food Name	Concentration Level	
		%*	(mg/kg)
1.1.2	Liquid milk products and flavoured liquid milk	5	50,000
1.2.2	Fermented milk products and rennetted milk product	5	50,000
3	Ice cream and edible ices	15	150,000
4.3.4.3	Jams and marmalades	40	400,000
5	Confectionery	50	500,000
5.2.1	Bubble gum and chewing gum	60	600,000
5.2.3	Sugar confectionery, hard boiled	99	990,000
6.3	Processed cereal and meal products	35	350,000
7.2.1	Biscuits	15	150,000
7.2.2	Cakes & muffins	10	100,000
11.4.2	Tabletop sweeteners, tablets, powder, granules/port	99	990,000
13.3	Formula meal replacements & supplementary foods	20	200,000
13.4.2	Liquid formulated supplementary sports foods	5	50,000
14.1.3.1	Brewed soft drinks	2	20,000
14.1.3.2	Soft drinks, cola type	2	20,000
14.1.3.3	Soft drinks, non-cola type	2	20,000
14.1.3.5	Electrolyte/sports drinks & electrolyte drink base	5	50,000
14.2.1	Beer & related products	3	30,000
20.1.1	Beverages made up from beverage flavouring	10	100,000
20.2.1.1	Desserts, dairy only	15	150,000

DIAMOND Food Code	Food Name	Concentration Level	
		%*	(mg/kg)
20.2.1.2	Desserts	30	300,000
20.2.1.3	Desserts artificially sweetened	15	150,000
20.2.2	Jelly	15	150,000
20.2.4.3	Toppings only	30	300,000
20.2.5.7	Cakes (commercial)	10	100,000
20.3.1	Cereal products (commercial)	30	300,000
20.3.1.1	Breakfast, muesli & fruit & nut based bars	20	200,000

* Note that higher level of proposed range used.

2.6 Scenarios for dietary modelling

Estimates of dietary exposure were calculated in two ways. Firstly, by a total sugar replacement model, and secondly, by using individual dietary records from the individual dietary records from the NNS and concentration data in Table 2 and calculating individuals' and then population dietary exposures.

2.6.1 Exposure assessment for isomaltulose, based on total sugar intakes

The first method was a total sugar replacement model. The Applicant stated that 5-10% of sugar in foods could be replaced by isomaltulose. Therefore total sugar intakes from the NNSs were used to estimate likely exposures of isomaltulose should it replace 5-10% of sugars in the diet. This is a worst case estimate of exposures based on sugar replacement as it assumes 5-10% replacement of all sugars, both natural and added.

2.6.2 Exposure assessment for isomaltulose, based on individual records

For the purpose of this Application, dietary exposures to isomaltulose using individual dietary records were calculated for two different scenarios:

1. 'Brand-loyal consumer' scenario; and
2. 'Market share' scenario'.

2.6.2.1 Scenario 1 – Brand-loyal consumer

In this scenario, the proposed concentrations of isomaltulose as shown in Table 2 were assigned to each of the requested foods/food groups. This represents the situation where people always remove sugared or intensely sweetened foods and beverages from the diet and includes the isomaltulose-containing foods and beverages in their place. This type of modelling represents a 'worst case' approach and is used to determine the upper end of possible isomaltulose dietary exposures and, therefore, the likelihood of potential safety concerns.

2.6.2.2 Scenario 2 – Market share

The Applicant stated that 5-10% of sugar in the foods would be replaced by isomaltulose. Based on this information, the isomaltulose concentration for each food was calculated for use in the modelling was 10% of the specified concentration by multiplying the concentration assigned to the food group from Table 2 by 0.1.

Scenario 2 – Market share assesses the potential impact on isomaltulose dietary exposures over the long term and across the population.

2.7 How were the estimated dietary exposures calculated?

A detailed explanation of how the estimated dietary exposures were calculated can be found in Appendix 1.

3. Assumptions in the dietary modelling

The aim of the dietary exposure assessment was to make as realistic an estimate of dietary exposure as possible. However, where significant uncertainties in the data existed, conservative assumptions were generally used to ensure that the dietary exposure assessment did not underestimate exposure.

The assumptions made in the dietary modelling using individual dietary records are listed below, broken down into several categories.

3.1 Concentration data

- Where a permission is given to a food classification code, all foods in that group contain isomaltulose;
- all the foods within the group contain isomaltulose at the levels specified in Table 2. Unless otherwise specified, the maximum proposed concentration of isomaltulose in each food category has been used;
- where a food was not included in the exposure assessment, it was assumed to contain a zero concentration of isomaltulose; and
- where a food has a specified isomaltulose concentration, this concentration is carried over to mixed foods where the food has been used as an ingredient e.g. ice cream used in a milkshake.

3.2 Consumption data

- Consumption of foods as recorded in the NNS represent current food consumption patterns.

3.3 Consumer behaviour

- Consumers always select the products containing isomaltulose;
- consumers do not alter their food consumption habits besides to substitute non-isomaltulose-containing products with isomaltulose-containing products; and
- consumers do not increase their consumption of foods/food groups upon foods/food groups containing isomaltulose becoming available.

3.4 General

- All isomaltulose present in food is absorbed by the body;
- naturally occurring sources of isomaltulose have not been included in the dietary exposure assessment;
- there is a 10% market share for the use of isomaltulose in the foods/food categories listed in Table 2;
- there are no reductions in isomaltulose concentrations from food preparation or due to cooking;
- for the purpose of this assessment, it is assumed that 1 millilitre is equal to 1 gram for all liquid and semi-liquid foods (e.g. milk, yoghurt); and
- there is no contribution to isomaltulose exposure through the use of complementary medicines (Australia) or dietary supplements (New Zealand).

These assumptions are likely to lead to a conservative estimate for isomaltulose dietary exposure.

4. Results

4.1 Dietary exposure estimates for isomaltulose, based on total sugar intakes.

The Applicant stated that sugar use in 2001 in Australia, was estimated at 50.8 kg per capita. Due to the Applicant noting that the Government of Australia does not publish official national consumption figures, their estimations were made based on anecdotal evidence resulting in estimated domestic sugar consumption in 2003/04 of 1.05 million metric tonnes (MMT). Based on 20,000,000 inhabitants this leads to 52.5 kg per capita per year consumption or
144 g/person/day. Based on the assumption that isomaltulose replaces 5-10% of sugar, this would result in an intake of 2.6 to 5.3 kg per capita per year or approximately 7-15 g/person/day.

FSANZ determined the total sugar intake figures (that include natural and added sugars) from the 1995 Australian and the 1997 and 2002 New Zealand NNSs (McLennan and Podger, 1998; Ministry of Health (MOH), 1999; Ministry of Health (MOH), 2003).

The total sugar intakes were different for each population sub-group assessed and ranged between 96 and 173 g/day for Australia and between 100 and 150 g/day for New Zealand. Sugar intakes for all population groups assessed are shown in Appendix 2, Table A2.1. Based on the replacement of 10% of total sugar intakes, mean estimated exposures to isomaltulose were between 10-17 g per day for the Australian population aged 2 years and above depending on the population group assessed, 11-13 grams per day for Australian children aged 2-6 years and 10-15 g per day for New Zealand population aged 15 years and above depending on the population group assessed, and 11 g/day for New Zealand children 5-6 years. Exposure calculations for this model are also shown in Appendix 2, Table A2.1.

The exposures estimated by FSANZ using the sugar replacement methodology were similar to the exposures estimated by the Applicant using a similar methodology.

4.2 Dietary exposure estimates to isomaltulose based on individual dietary records

The dietary exposure assessment for isomaltulose was conducted for the Australian population (2 years and above) and the New Zealand population (15 years and above), as well as for children aged 2-6 years (Australia only). Not possible to use 2002 New Zealand survey as individual survey data not yet available in DIAMOND program. Dietary exposures to isomaltulose were calculated for:

- *Scenario 1 – Brand-loyal consumer*; and
- *Scenario 2 – Market share*.

4.2.1 Scenario 1– Brand-loyal consumer

The estimated dietary exposures for isomaltulose are shown in Figure 1a (full results in Table A2. 2 in Appendix 2).

Australia - 2 years and above:
Estimated mean and 95th percentile exposures for consumers of isomaltulose were 39 g/day (0.7 g/kg bw/day) and 105 g/day (2.3 g/kg bw/day), respectively.

Australia – 2-6 years:
Estimated mean and 95th percentile exposures for consumers of isomaltulose were 34 g/day (1.8 g/kg bw/day) and 75 g/day (4.0 g/kg bw/day), respectively.

New Zealand - 15 years and above:
Estimated mean and 95th percentile exposures for consumers of isomaltulose were 36 g/day (0.5 g/kg bw/day) and 104 g/day (1.4 g/kg bw/day), respectively.

4.2.2 'Scenario 2 – Market share'

The estimated dietary exposures for isomaltulose are shown in Figure 1b (full results in Table A2. 3 in Appendix 2).

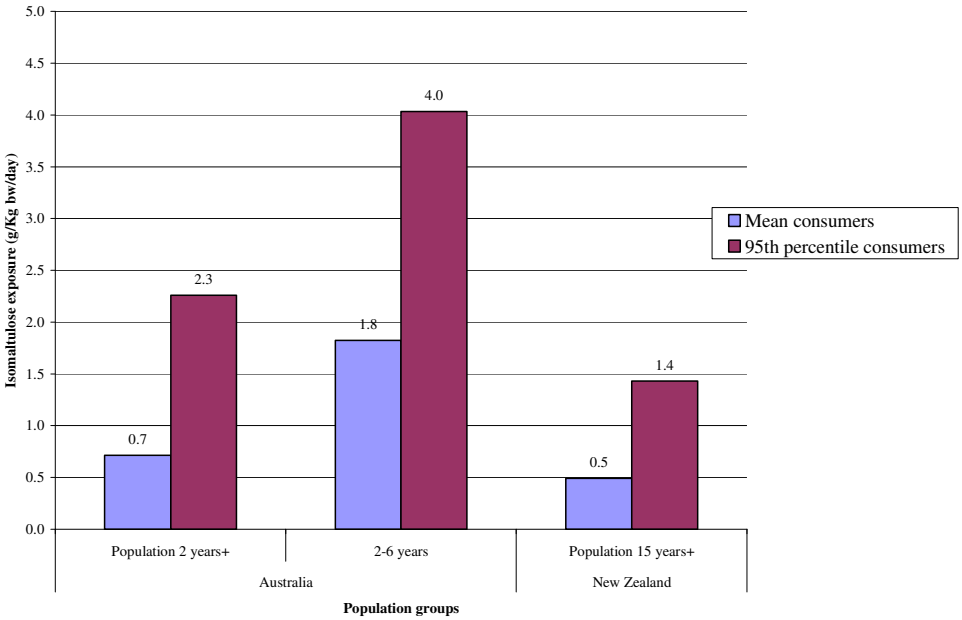
Australia - 2 years and above:
Estimated mean and 95th percentile exposures for consumers of isomaltulose were 3.9 g/day (0.07 g/kg bw/day) and 11 g/day (0.2 g/kg bw/day), respectively.

Australia – 2-6 years:
Estimated mean and 95th percentile exposures for consumers of isomaltulose were 3.4 g/day (0.18 g/kg bw/day) and 7.5 g/day (0.4 g/kg bw/day), respectively.

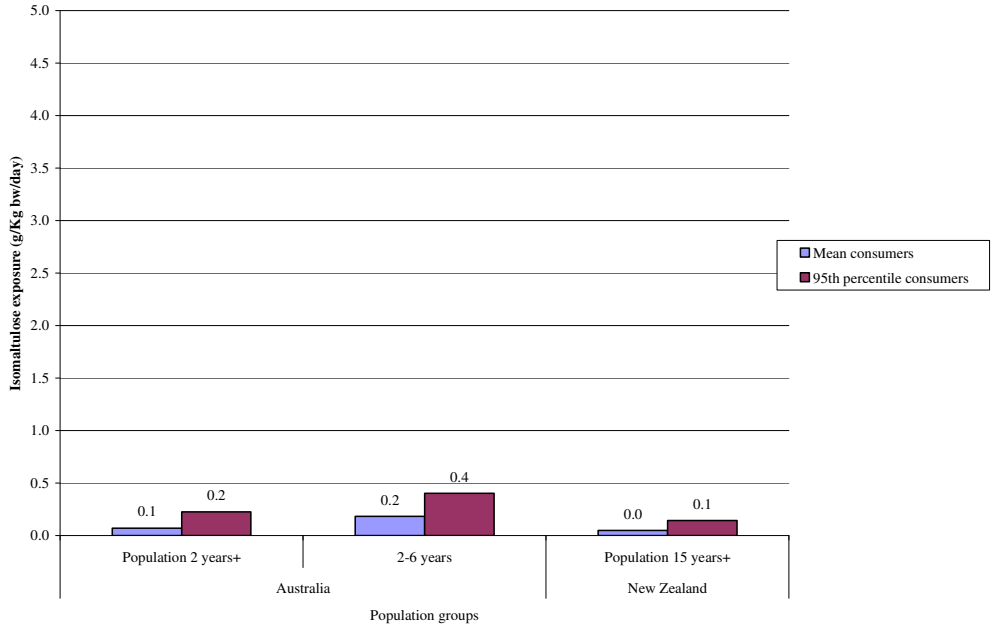
New Zealand - 15 years and above:
Estimated mean and 95th percentile exposures for consumers of isomaltulose were 3.6 g/day (0.05 g/kg bw/day) and 10 g/day (0.14 g/kg bw/day), respectively.

Figure 1: Estimated mean and 95th percentile dietary exposures (g/kg bw/day) for consumers of isomaltulose for the Australian and New Zealand population groups

a. *Scenario 1 – Brand-loyal consumer*



b. *Scenario 2 – Market share*



4.2.3 Major contributing foods to total estimated dietary exposures

A full list of all of the food groups and their contributions to total isomaltulose dietary exposures can be found in Table A2 in Appendix 2. The major contributors (≥5%) for *Scenario 1 – Brand-loyal* and *Scenario 2 – Market share* were the same and are shown in Figure 2a for Australians aged 2 years and above, Figure 2b for Australians aged 2-6 years and Figure 2c for New Zealanders aged 15 years and above.

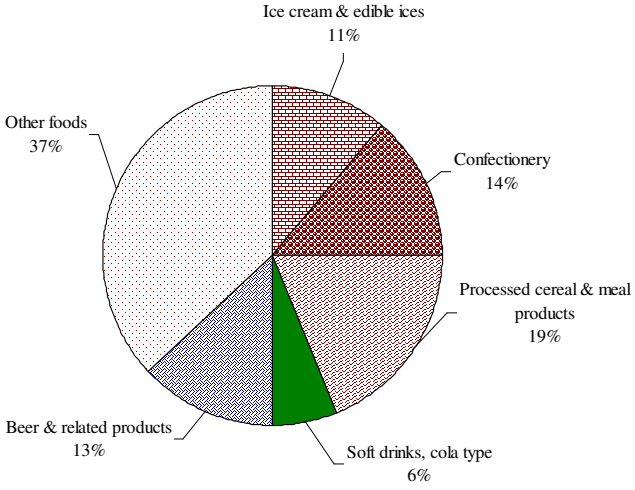
Australia – 2 years and above
The major contributors (≥5%) to total isomaltulose dietary exposures were processed cereal & meal products (19%), confectionery (14%), beer & related products (13%), ice cream & edible ices (11%) and soft drinks, cola type (6%).

Australia – 2-6 years
The major contributors (≥5%) to total isomaltulose dietary exposures were processed cereal & meal products (22%), confectionery (18%), ice cream & edible ices (14%) and beverages made up from beverage flavouring (6%).

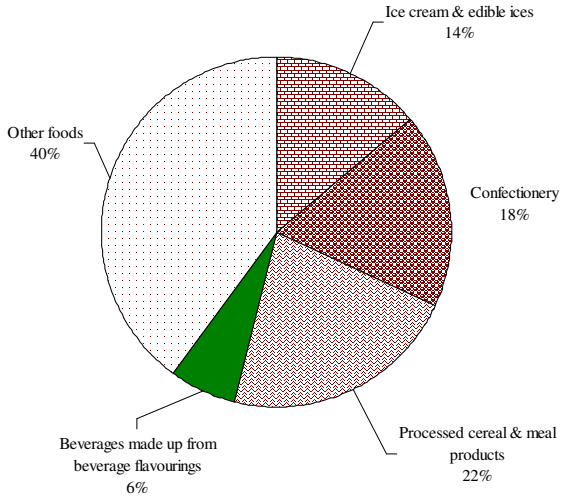
New Zealand - 15 years and above
The major contributors (≥5%) to total isomaltulose dietary exposures were beer & related products (17%), processed cereal & meal products (13%), confectionery (12%), cereal products-commercial (8%), cakes & muffins (8%), ice cream & edible ices (7%), jams & marmalades (6%), biscuits (6%) and desserts (6%).

Figure 2: Major contributors to total isomaltulose dietary exposures

a. Australia - 2 years and above.[2]

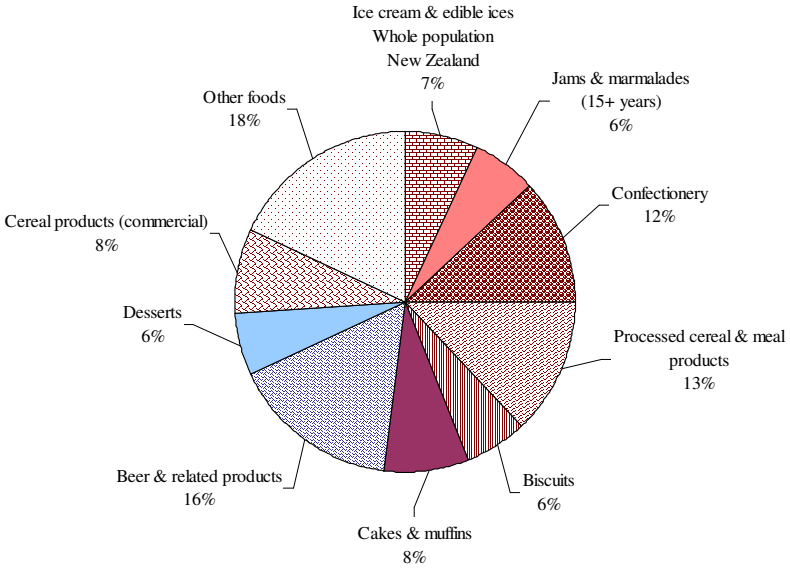


b. Australia – 2-6 years.[1]



[2] Note: The percent contribution of each food group is based on total isomaltulose exposures for all consumers in the population groups assessed. Therefore the total isomaltulose exposures differ for each population group.

c. New Zealand - 15 years and above[3]



As expected, the estimated dietary exposures to isomaltulose were much higher for 'brand loyal' model than either market share or population estimates based on sugar replacement. These high estimates represent the top end of the expected range of possible exposures and not a population estimate. Although the results for market share and sugar replacement models were similar, the former estimates are considered more accurate and a better estimate.

5. Limitations of the dietary modelling

Dietary modelling based on 1995 or 1997 NNS food consumption data provides the best estimate of actual consumption of a food and the resulting estimated dietary exposure to a food chemical for the population. However, it should be noted that the NNS data does have its limitations. These limitations relate to the age of the data and the changes in eating patterns that may have occurred since the data were collected. Generally, consumption of staple foods such as fruit, vegetables, meat, dairy products and cereal products, which make up the majority of most people's diet, is unlikely to have changed markedly since 1995/1997.(Cook *et al*., 2001a; Cook *et al*., 2001b) However, there is uncertainty associated with the consumption of foods that may have changed in consumption since 1995/1997, or that have been introduced to the market since 1995/1997.

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.

[3] Note: The percent contribution of each food group is based on total isomaltulose exposures for all consumers in the population groups assessed. Therefore the total isomaltulose exposures differ for each population group.

Daily food consumption amounts for occasionally consumed foods based on 24-hour food consumption data would be higher than daily food consumption amounts for those foods based on a longer period of time. This specifically affects the food groups in this assessment such as sauces, toppings and confectionery.

Over time, there may be changes to the ways in which manufacturers and retailers make and present foods for sale. Since the data were collected for the Australian and New Zealand NNSs, there have been significant changes to the Code to allow more innovation in the food industry. As a consequence, another limitation of the dietary modelling is that some of the foods that are currently available in the food supply were either not available or were not as commonly available in 1995/1997.

Where the NNSs collected data on the use of complementary medicines (Australia) or dietary supplements (New Zealand), it was either not in a robust enough format to include in DIAMOND or has simply not been included in the DIAMOND program. Consequently, intakes of substances consumed via complimentary medicines or dietary supplements could not be included in the dietary exposure assessment.

While the results of NNSs can be used to describe the usual intake of groups of people, they cannot be used to describe the usual intake of an individual (Rutishauser, 2000). In particular, they cannot be used to predict how consumers will change their eating patterns as a result of an external influence such as the availability of a new type of food.

FSANZ does not apply statistical population weights to each individual in the NNSs in order to make the data representative of the population. This prevents distortion of actual food consumption amounts that may result in an unrealistic intake estimate. Maori and Pacific Islanders were over-sampled in the 1997 New Zealand National Nutrition Survey so that statistically valid assessments could be made for these population groups. As a result, there may be bias towards these population groups in the dietary exposure assessment because population weights were not used.

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Appendix 1

How were the estimated dietary exposures calculated for the individual dietary records approach?

A1.1 How were estimated dietary exposures calculated for brand loyal and market share models?

The DIAMOND program allows isomaltulose concentrations to be assigned to food groups.

Exposure to isomaltulose was calculated for each individual in the NNSs using his or her individual food records from the dietary survey. The DIAMOND program multiplies the specified concentration of isomaltulose by the amount of food that an individual consumed from that group in order to estimate the exposure to isomaltulose from each food. Once this has been completed for all of the foods specified to contain isomaltulose, the total amount of isomaltulose consumed from all foods is summed for each individual. Population statistics (mean and high percentile exposures) are then derived from the individuals' ranked exposures.

Where estimated dietary exposures are expressed per kilogram of body weight, each individuals' total dietary exposure is divided by their own body weight, the results ranked, and population statistics derived. A small number of NNS respondents did not provide a body weight. These respondents are not included in calculations of estimated dietary intakes that are expressed per kilogram of body weight.

Food consumption amounts for each individual take into account where each food in a classification code is consumed alone and as an ingredient in mixed foods. For example, cheese eaten as a slice of cheese, cheese in a cheese sandwich, and cheese on a pizza are all included in the consumption of cheese. Where a higher level food classification code (e.g. 6.3 Processed cereal and meal products) is given an isomaltulose concentration, as well as a sub-category (e.g. 6.3.2 Breakfast bars), the consumption of the foods in the sub-classification is not included in the higher level classification code.

In DIAMOND, all mixed foods in classification codes 20 and 21 have a recipe. Recipes are used to break down mixed foods into component ingredients which are in classification codes 1-14. The data for consumption of the ingredients from the recipe are then used in models and multiplied by isomaltulose concentrations for each of the component foods. This only occurs if the *Mixed food* classification code (classification code 20) is not assigned its own isomaltulose permission. If the *Mixed foods* classification is assigned an isomaltulose concentration, the total consumption of the mixed food is multiplied by the proposed level of use of isomaltulose and the recipes are not used for that food group.

When a food that does not have a recipe is classified in two food groups in classification codes 1-14, and these food groups are assigned different permissions, DIAMOND will assume the food is in the food group with the highest assigned isomaltulose level to assume a worst-case scenario. If the food groups have the same permitted isomaltulose level, DIAMOND will assume the food is in the food group that appears first, based numerically on the ANZFCS.

In DIAMOND, hydration factors are applied to some foods to convert the amount of food consumed in the dietary survey to the equivalent amount of the food in the form to which a food chemical permission is given. For example, consumption figures for instant coffee powder are converted into the equivalent quantities of a coffee beverage.

A1.2 How were percentage contributions calculated?

Percentage contributions of each food group to total estimated exposures are calculated by summing the exposures for a food group from each individual in the population group who consumed a food from that group and dividing this by the sum of the exposures of all individuals from all food groups containing isomaltulose, and multiplying this by 100.

Appendix 2

Complete information on dietary exposure assessment results

Table A2. 1. Estimated dietary exposures to isomaltulose based on a sugar replacement model

a. Australia

NNS age group (years)	Mean body weight (kg)	Mean Total sugars intake* (g/d) all respondent	Mean Total sugars intake (g/kg bw/d)	Percent of sugar replaced by isomaltulose	Resulting exposure to isomaltulose (g/d)	Resulting exposure to isomaltulose (g/kg bw/d)	Percent of sugar replaced by isomaltulose	Resulting exposure to isomaltulose (g/d)	Resulting exposure to isomaltulose (g/kg bw/d)
2-3yrs	16	115.4	7.2	5	5.8	0.4	10	11.5	0.7
4-7yrs	22	128.7	5.9	5	6.4	0.3	10	12.9	0.6
8-11yrs	36	142.1	3.9	5	7.1	0.2	10	14.2	0.4
12-15yrs	56	159.9	2.9	5	8	0.1	10	16	0.3
16-18yrs	67	173.4	2.6	5	8.7	0.1	10	17.3	0.3
19-24yrs	71	147.4	2.1	5	7.4	0.1	10	14.7	0.2
25-44yrs	74	118.6	1.6	5	5.9	0.1	10	11.9	0.2
45-64yrs	77	105.5	1.4	5	5.3	0.1	10	10.6	0.1
65 & over	72	96.4	1.3	5	4.8	0.1	10	9.6	0.1
19 & over	74	115	1.6	5	5.8	0.1	10	11.5	0.2

* From NNS publication "Nutrient intakes and physical measurements"

b. New Zealand

NNS age group (years)	Mean body weight *(kg)	Mean Total sugars intake* (g/d) all respondent	Mean Total sugars intake (g/kg bw/d)	Percent of sugar replaced by isomaltulose	Resulting exposure to isomaltulose (g/d)	Resulting exposure to isomaltulose (g/kg bw/d)	Percent of sugar replaced by isomaltulose	Resulting exposure to isomaltulose (g/d)	Resulting exposure to isomaltulose (g/kg bw/d)
5-6yrs	23	107.5	4.7	5	5.4	0.2	10	10.8	0.5
7-10yrs	34	122.5	3.6	5	6.1	0.2	10	12.3	0.4
11-14yrs	54	134	2.5	5	6.7	0.1	10	13.4	0.2
15-18yrs	65	147	2.3	5	7.4	0.1	10	14.7	0.2
19-24yrs	68	150	2.2	5	7.5	0.1	10	15	0.2
25-44yrs	71	127.5	1.8	5	6.4	0.1	10	12.8	0.2
45-64yrs	76	106	1.4	5	5.3	0.1	10	10.6	0.1
65 & over	67	99.5	1.5	5	5	0.1	10	10	0.1
15 & over	72	122	1.7	5	6.1	0.1	10	12.2	0.2

* From NNS publication "NZ Food:NZ People" for 15 years+ and 'NZ Food NZ Children' for 5-14 years.

Notes to Table A2.1

This estimate is based on total sugar consumed from the NNS (natural + added) and the replacement of sucrose at 5-10%.
This will be an overestimate as only added sugar will be replaced, however, the NNS results do not separate added and natural sugar.

Table A2. 2: Estimated dietary exposures to isomaltulose for *Scenario 1 – Brand-loyal consumer*

Country	Population group	Number of consumers of isomaltulose	Consumers♦ as a % of total respondents#	Mean consumers	95th percentile consumers
				g/day (g/kg bw/day)	g/day (g/kg bw/day)
Australia	2 years and above	12,686	92	39 (0.7)	105 (2.3)
	2-6 years	973	98	34 (1.8)	75 (4.0)
New Zealand	15 years and above	4,164	90	36 (0.5)	104 (1.4

Total number of respondents for Australia: 2 years and above = 13,858, 2-6 years = 989; New Zealand: 15 years and above = 4,636. Respondents include all members of the survey population whether or not they consumed a food that contains isomaltulose.

♦ Consumers only – This only includes the people who have consumed a food that contains isomaltulose.

Table A2. 3: Estimated dietary exposures to isomaltulose for *Scenario 2 – Market share*

Country	Population group	Number of consumers of isomaltulose	Consumers♦ as a % of total respondents#	Mean consumers	95th percentile consumers
				g/day (g/kg bw/day)	g/day (g/kg bw/day)
Australia	2 years and above	12,686	92	3.9 (0.1)	10.5 (0.2)
	2-6 years	973	98	3.4 (0.2)	7.5 (0.4)
New Zealand	15 years and above	4,164	90	3.5 (0.05)	10.4 (0.14)

Total number of respondents for Australia: 2 years and above = 13,858, 2-6 years = 989; New Zealand: 15 years and above = 4,636. Respondents include all members of the survey population whether or not they consumed a food that contains isomaltulose.

♦ Consumers only – This only includes the people who have consumed a food that contains isomaltulose.

Table A2. 4: Contribution of foods to total isomaltulose dietary exposures for Australia and New Zealand, and for different population groups

DIAMOND Food Code	Food Name	% contribution		
		Australia		New Zealand
		2 yrs and above	2-6 years	15 yrs and above
1.1.2	Liquid milk products and flavoured liquid milk	3	2	<1
1.2.2	Fermented milk products and rennetted milk product	2	3	<1
3	Ice cream and edible ices	11	14	7
4.3.4.3	Jams and marmalades	3	2	6
5	Confectionery	14	18	12
5.2.1	Bubble gum and chewing gum	<1	<1	<1
5.2.3	Sugar confectionery, hard boiled	2	5	2
6.3	Processed cereal and meal products	19	22	13
7.2.1	Biscuits	4	4	6
7.2.2	Cakes & muffins	3	2	8
11.4.2	Tabletop sweeteners, tablets, powder, granules/port	<1	<1	<1
13.3	Formula meal replacements & supplementary foods	1	1	<1
13.4.2	Liquid formulated supplementary sports foods	Included in formula meal replacements & supplementary foods*	Included in formula meal replacements & supplementary foods *	<1
14.1.3.1	Brewed soft drinks	<1	<1	0
14.1.3.2	Soft drinks, cola type	6	2	5
14.1.3.3	Soft drinks, non-cola type	3	3	3
14.1.3.5	Electrolyte/sports drinks & electrolyte drink base	<1	<1	<1
14.2.1	Beer & related products	13	<1	16
20.1.1	Beverages made up from beverage flavouring	3	6	4
20.2.1.1	Desserts, dairy only	3	5	2
20.2.1.2	Desserts	1	1	6
20.2.1.3	Desserts artificially sweetened	Included in desserts*	Included in desserts *	Included in desserts *
20.2.2	Jelly	1	2	1
20.2.4.3	Toppings only	1	1	<1
20.2.5.7	Cakes (commercial)	<1	<1	0
20.3.1	Cereal products (commercial)	4	4	8
20.3.1.1	Breakfast, muesli & fruit & nut based bars	<1	1	<1

* Concentration levels for these foods were combined with major food group in the category, so that % contribution for this food is combined with other food group.

Attachment 4

Food Technology Report

Application A578 – Isomaltulose as a Novel Food

Introduction

Isomaltulose (Palatinose™) is a reducing disaccharide which is composed of a glucose and fructose molecule linked by an α-1,6 glycosidic bond. It is manufactured from sucrose by an enzymatic process and is an intermediate in the production of isomalt, a sugar alcohol (polyol). Isomalt is an approved food additive (INS 953) in the Code.

The chemical name of isomaltulose is 6-O-α-D-glucopyranosyl-D-fructofuranose, its Chemical Abstract Service (CAS) Registration Number is 13718-94-0 and its molecular weight is 360.3. The structural formula of isomaltulose is given below:

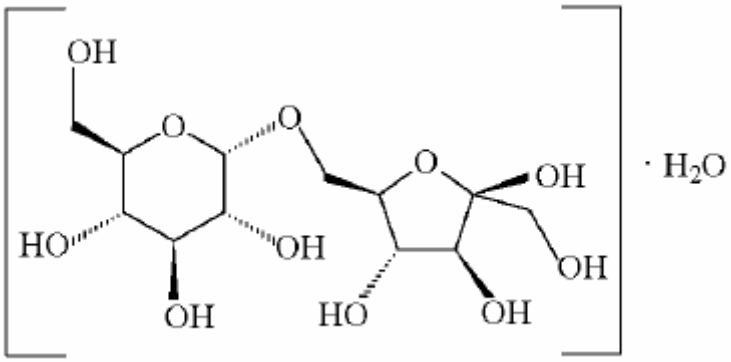

Figure 1: Structural Formula of Isomaltulose

Isomaltulose occurs naturally in honey, at levels of up to 1%, and is also found in sugar cane juice.

Isomaltulose is a nutritive sugar and the Applicant intends that it be used to replace either totally or partially, sucrose or other highly digestible carbohydrates in foods. Isomaltulose can be considered to fall within the definition of 'sugars' as defined in Standard 2.8.1 - Sugars in the Code and hence is considered a food. It does not fit within the classification of an 'intense sweetener' as defined in Standard 1.3.1 – Food Additives in the Code. The consideration of isomaltulose as a novel food under Standard 1.5.1 is consistent with the regulation of other sweeteners, namely, trehalose (Application A453) and D-tagatose (Application A472).

Specification

There is no specification for isomaltulose in any of the monographs (primary and secondary sources) within Standard 1.3.4 – Identity and Purity in the Code.

The Applicant provided the following specification requirements for the identity and purity of isomaltulose. This will be included in Standard 1.3.4:

Chemical name	6-O-α-D-glucopyranosyl-D-fructofuranose
Description	White or colourless, crystalline, sweet substance, faint isomaltulose specific odour
Isomaltulose (%)	Not less than 98% on a dry weight basis
Water Other saccharides Ash Lead	Max. 6% Max. 2% on the dry weight basis Max. 0.01% on the dry weight basis Max. 0.1 ppm on the dry weight basis

Physical properties

Isomaltulose is white or colourless crystalline powder with an appearance similar to sucrose. Its melting point (122-124°C) is lower than that of sucrose (160-185°C). Isomaltulose has low hygroscopicity, and as such, does not readily absorb water from the atmosphere under normal environmental conditions. Isomaltulose is easily ground, an important property in many applications.[1]

Isomaltulose is soluble in water, although its solubility is lower than that of sucrose. The solubility increases with increasing temperatures, reaching 85% of that of sucrose at approximately 80°C. [1]

The viscosities of aqueous solutions of both sucrose and isomaltulose are similar[1].

Chemical Properties

Isomaltulose is more stable than sucrose under acidic conditions. At pH 2.0 with HCl, a 20% isomaltulose solution is stable for more than 60 minutes when heated at 100°C, whereas a 20% sucrose solution is almost completely hydrolysed under these conditions.[1]

Isomaltulose has also shown to be more heat stable and more resistant towards bacterial fermentation than sucrose.[1]

Isomaltulose is a reducing disaccharide and therefore undergoes Maillard reactions in the presence of nitrogen compounds, which leads to a distinct browning effect in food.[1]

Sensory properties

Isomaltulose has a similar sweetness quality to sucrose. It is perceived quickly, is refreshing and leaves no after taste. Isomaltulose has a sweetening power of 48% in comparison to a 10% sucrose solution, however there is an increase in sweetening power as the concentration increases.[1]

Other characteristics

In vitro and *in vivo* human and animal studies have demonstrated that isomaltulose is slowly but almost completely hydrolysed and absorbed in the small intestine as glucose and fructose. The slower hydrolysation and digestibility in the small intestine compared to sucrose, occurs as result of the α-1,6 glycosidic bond, which in turn, leads to lower and slower increases in blood glucose and insulin levels in comparison with other sugars or digestible starch products.

The Glycemic Index (GI) of isomaltulose, as determined by the University of Sydney, is 32 ('low'), when measured against the GI of glucose, which has a reference value of 100. The Applicant advises that the low glycemic properties of isomaltulose make it a useful metabolisable sugar that helps to reduce the negative health effects associated with high glycemic diets, such as insulin resistance, diabetes and obesity.

The Applicant also advises that the stability of the α-1,6 glycosidic bond in isomaltulose renders it more resistant to oral fermentation by plaque forming bacteria, therefore, acid formation is minimised. This factor contributes to the lower cariogenicity of isomaltulose when compared with other traditional forms of sugar.

Production of isomaltulose

Isomaltulose is manufactured from food-grade sucrose by enzymatic rearrangement of the glycosidic linkage from a α-1,2 fructoside to a α-1,6 fructoside. The raw material for the food grade sucrose is traditional sugarbeet. The enzyme, sucrose-6-glucosylmutase, which is used to carry out the reaction, is obtained from the micro-organism, *Protaminobacter rubrum*. This enzyme is not listed in Standard 1.3.3 – Processing Aids.

The production process initially involves passing an aqueous sucrose solution through a column containing immobilised, non-viable *Protaminobacter rubrum cells*. The enzyme, sucrose-6-glucosylmutase converts the α-1,2 glycosidic bond of sucrose into the α-1,6 glycosidic bond of isomaltulose. This processing step, enzymatic isomerisation, produces "liquid isomaltulose". The resultant solution is purified by filtration and ion-exchange, and evaporated by crystallisation and drying to obtain commercial isomaltulose.

Applications

Isomaltulose can be used as a nutritive sweetener to substitute for sucrose in the manufacture of most foods. With the exception of traditional jams and jellies, its solubility is adequate for most applications. Its higher bacterial and chemical stability than sucrose means that it can be used as a sweetener in dairy products containing active cultures with acidophilus and bifidus bacteria. These bacteria cannot split isomaltulose in the dairy product so that the sweetness level remains constant.[1]

The Applicant intends that isomaltulose be used as a slow release carbohydrate source, replacing totally or partially, sucrose or other highly digestible carbohydrates in foods. The Applicant intends to use isomaltulose in foods such as beverages, baked goods and baking mixes, cereals and cereal products, soups, toppings and desserts, milk-based products, fruit and water ices, confectionery/bakery, snack foods and other products such as jams and energy-reduced foods.

International regulation of isomaltulose

Isomaltulose has been used as a food ingredient in Japan since 1985 and has recently been authorised as a novel food in Europe.[2] Isomaltulose has been granted GRAS (Generally Recognised as Safe) status by the U.S. Food and Drug Administration (FDA) for use as a nutritive sweetener in a variety of foods.[3]

Conclusion

Based on its combined physical, chemical, sensory and nutritional properties, there is justification for the use of isomaltulose as a nutritive sweetener in a wide variety of foods.

References

1. Irwin, W.E., and Sträter, P.J. (2001) Isomaltulose. In: Nabors, L.O., ed. *Alternative Sweeteners*. Marcel Dekker, New York, 3rd edition, pp 413-422.

2. Commission Decision of 25 July 2005 authorising the placing on the market of isomaltulose as a novel food ingredient under regulation (EC) No 258/97 of the European Parliament and of the Council.

3. U.S. Food and Drug Administration Agency Response Letter GRAS Notice No. GRN 000184 http://www.cfsan.fda.gov/~rdb/opa-g184.html

Attachment 5

Public Submissions

First Round of Public Comment

Thirteen submissions were received following Initial Assessment. Seven were in support of approval of isomaltulose, two opposed the use of isomaltulose and the others reserved comment until following Draft Assessment.

Submitter	Option supported	Comments
1. Australian Food and Grocery Council	2	-
2. Cadbury Schweppes	2	Supports the use of isomaltulose in beverages and confectionary products.
3. Confectionery Manufacturers of Australasia	2	Supports the option 2 providing isomaltulose is shown to be safe. Suggests that isomaltulose may encourage product innovation and consumer choice.
4. Country Women's Association of NSW	1	Suggests that stronger evidence of safety for human consumption is required as many Australians have diabetes.
5. Department of Human Services, Victoria	2	-
6. Dietitians Association of Australia	1	Concerned that isomaltulose is as high in energy as sucrose but less sweet. Suggest that therefore it might be used in conjunction with intense sweeteners or in greater quantities than sucrose would be used. Concerned that the low GI of isomaltulose may be misleading to consumers, particularly if products contain double the amount of isomaltulose as they might traditionally contain sucrose. Believes that isomaltulose confers no advantage over currently available sweeteners.
7. Food Technology Association of Victoria	2	-
8. Human Nutrition Unit, University of Sydney	2	Supports the application and suggest that the low GI value of isomaltulose will provide a benefit for consumers

Submitter	Option supported	Comments
9. Mandurah Australia	2	Supports the Application. Suggests that isomaltulose will allow the development of new low GI/energy sustaining products.
10. New Zealand Food Safety Authority	-	Will comment on the Draft Assessment Report. Notes that the same energy factor as for other carbohydrates (17 kJ/g) should apply to Isomaltulose. Notes that FSANZ's dietary exposure assessment will be crucial to the outcome of this application.
11. Queensland Health	-	Will comment on the Draft Assessment Report, once dietary exposure and safety have been assessed. Questions whether isomaltulose could be more cheaply produced from genetically modified sugarcane expressing sucrose isomerase.
12. South Australian Department of Health	-	No objection to Application progressing to Draft Assessment
13. Unilever Australasia	-	Supports the application and will comment further on the Draft Assessment Report. Suggests FSANZ make use of reviews of the safety of isomaltulose conducted by international regulatory agencies in conducting a risk assessment and determining risk management plans.

Second Round of Public Comment

The Draft Assessment was advertised for public comment between 13 December 2006 and 7 February 2007. Ten submissions were received during this period. Seven of these supported the application, three expressed no preference and no submitters opposed the approval of isomaltulose. All submissions are summarised below.

Submitter	Option supported	Comments
Australia Food and Grocery Council	2	Approval of isomaltulose is unlikely to impose significant costs on industry, consumers, public health professionals or government. There may be significant benefits in terms of the potential for innovation and development in a wide range of products, and provision of healthy alternatives for consumers.

Confectionery Manufacturers of Australasia Limited	2	Suggests that isomaltulose has potential benefits for consumers, and may encourage scope for both product innovation and increased consumer choice. Endorse the communication and risk management strategy.
Department of Health, South Australia	2	Asks that the Final Assessment Report make it clear that isomaltulose is a sugar under the definition in Standard 2.8.1 – Sugars. It will need to be included in the energy calculations used to product the Nutrition Information Panel. No 'sugar free' claims will be permitted. Concerned about the risk management strategy for individuals with HFI or sucrase-isomaltase deficiency, and suggest that advisory labelling would better inform these populations. Although a similar risk management strategy has been used previously for similar products, there is no evidence that this approach is effective.
Dietitians Association of Australia	-	Expresses concern about misunderstandings by consumers of the meaning of low GI, who may assume that isomaltulose is low in kilojoules. States that isomaltulose is a refined carbohydrate with no nutritional value other than energy and that cariogenicity is multifactorial. Recommends that isomaltulose be included in Standard 2.8.1 – Sugars, so that manufacturers cannot make 'sugar free' claims. Recommend that isomaltulose be required to be labelled advising consumers that isomaltulose is a source of fructose.
Food Technology Association of Victoria	2	No comments
New South Wales Food Authority	2	Notes that it is very important to adequately advise consumers with HFI and sucrase-isomaltase deficiency that they will need to avoid isomaltulose-contain products.
New Zealand Food Safety Authority	-	Believes the range of foods in which isomaltulose is permitted should be limited as the widespread use of isomaltulose is unnecessary and limiting the range of available products will limit exposure, especially in children. Concerned about effects on children at levels above 1g/kg body weight per day. Considers that slower glucose-fructose metabolic release foods are not suitable for the general public. Concerned that due to its decreased sweetness compared to sucrose, isomaltulose may be used in greater volume than sucrose, leading to higher energy intake. Suggests that isomaltulose be labelled as a source of fructose and glucose (as it is in the European Union). Notes that 'sugar free' claims will not be permitted.

		Suggests that isomaltulose not be permitted in beer and other alcoholic beverages as these products do not have ingredient listings and individuals with HFI or sucrase-isomaltase will not be able to identify isomaltulose as an ingredient in these products.
Queensland Health	2	Appropriate risk management strategies need to be employed for individuals with HFI or sucrase-isomaltase deficiency
Unilever	2	States that the FSANZ assessment is consistent with the results of other regulatory bodies.
Victorian Department of Human Services	-	Suggests a clause to prohibit the association of isomaltulose with weight loss. Concerned that consumers may be confused by GI claims and think that isomaltulose is lower in energy than sugar, particularly if products are less sweet. Questions whether it is appropriate to allow the use of isomaltulose in a wide range of products where low joule products are already available. Suggests that isomaltulose be defined as a sugar under Standard 2.8.1 – Sugars, to prevent the use of 'sugar free' claims being made by manufacturers. To support the use of isomaltulose in sports drinks, evidence should be presented that isomaltulose enhances gastrointestinal water absorption in a similar manner to glucose and sucrose. Suggests that requiring isomaltulose to be labelled as a source of fructose would be a more appropriate risk management strategy.