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

5-06
9 August 2006

INITIAL ASSESSMENT REPORT

APPLICATION A578

ISOMALTULOSE AS A NOVEL FOOD

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 20 September 2006
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED
(See 'Invitation for Public Submissions' for details)

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

An Application has been received from PALATINIT GmbH 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 nutritive sweetener, made up of glucose and fructose. FSANZ has determined it to be a novel food based on its composition and structure, and potential patterns and levels of consumption. Standard 1.5.1 requires that novel foods undergo a risk-based safety assessment before they are permitted for retail sale in Australia and New Zealand.

The purpose of this Initial Assessment Report is to provide relevant information, supplied by the Applicant, to assist in identifying the affected parties and to outline the relevant issues necessary to complete assessment of the Application.

This Initial Assessment Report is not an assessment of the merits of the Application but rather is an assessment of whether the Application should be accepted for further consideration, according to criteria laid down in the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

Purpose

The purpose of the Application is to assess whether it is appropriate to amend Standard 1.5.1 - Novel Foods, to include isomaltulose.

Reasons for Assessment

After considering the requirements for Initial Assessment as prescribed in section 13 of the FSANZ Act, FSANZ has decided to accept the Application for the following reasons:

- The Application seeks approval of isomaltulose as a novel food. Such an approval, if accepted, would warrant a variation to Standard 1.5.1.
- There is currently no permission in the Code for isomaltulose as a novel food.
- The Application is not so similar to any previous application that it ought not be accepted.
- There are no other measures that would be more cost-effective than a variation to Standard 1.5.1 that could achieve the same end.
- At this stage no other relevant matters are apparent.

Consultation

Public submissions are now invited on this Initial Assessment Report. Comments are requested on any aspect of this Application, and in particular, information relevant to the potential costs and benefits of the proposed regulatory options.

Responses to this Initial Assessment Report will be used to develop the next stage of the Application and the preparation of a Draft Assessment Report.

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INVITATION FOR PUBLIC SUBMISSIONS

FSANZ invites public comment on this Initial Assessment Report for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Draft Assessment of this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions need to be received by FSANZ by 6pm (Canberra time) 20 September 2006.

Submissions received after this date will not be considered, unless agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

INTRODUCTION

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.

This Initial Assessment Report is not an assessment of the merits of the Application but rather is an assessment of whether the Application should be accepted for further consideration, according to criteria laid down in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act).

Public comment is now being sought to assist in the Draft Assessment of the Application.

1. Background

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*.

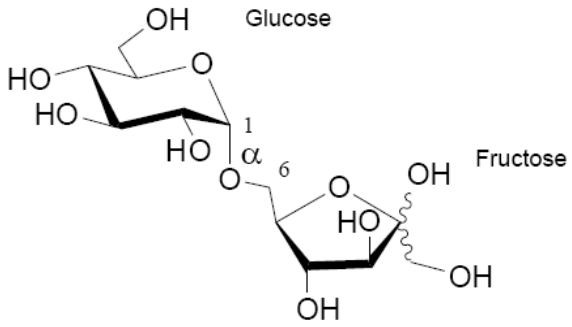
1.2 Properties of isomaltulose

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, and has a similar sweetness quality. 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, these 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 as consumed (%)
Beverages	Soft-drinks	1-10
	Energy drinks Sports and isotonic drinks	
	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
	Nutritive formulae	5-20
	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 Recognised 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 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 must therefore be assessed, and if approved, 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 will consider 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. Safety assessment

The Applicant has submitted safety data in relation to isomaltulose including:

- *in vitro* and *in vivo* data on how isomaltulose is metabolised in animals and humans;

- toxicity studies including a sub-chronic oral toxicity study and an oral embryotoxicity / teratogenicity study with isomaltulose in rats, a genotoxicity study, and summaries of studies on gastrointestinal tolerance in rats, pigs and human; and

- specifications and batch analyses.

The Applicant has indicated that there are no special requirements for processing or cooking of isomaltulose before consumption.

Although isomaltulose is metabolised to the same products as sucrose (glucose and fructose), some individuals lack the required enzyme (isomaltase) for its hydrolysis. Therefore there is the possibility of adverse effects in these individuals. In addition, individuals who are fructose intolerant would not recognise that isomaltulose is broken down into fructose and may inadvertently consume products containing isomaltulose. FSANZ needs to assess these risks and if necessary develop appropriate risk management options before permitting isomaltulose in food in Australia and New Zealand.

It appears that the potential dietary exposure to isomaltulose could be very high compared to traditional consumption of low levels in natural products such as honey. The possibility of incomplete hydrolysis leading to gastrointestinal effects needs to be assessed.

An evaluation of the safety data for isomaltulose will be presented in the Draft Assessment Report.

6. Dietary exposure assessment

The Applicant has provided the range of intended food uses and the levels of isomaltulose intended to be used in those foods. A dietary intake assessment based on these proposed food uses and levels will be presented in the Draft Assessment Report.

7. Nutritional considerations

The Applicant has provided information on the nutritional aspects of isomaltulose consumption, including information on the glycaemic index (GI), effects on mineral absorption and on lipid metabolism. This information will be considered as part of the Safety Assessment.

The Applicant suggests that as isomaltulose is fully hydrolysed to glucose and fructose, the same energy factor as used for other available carbohydrates should apply (17 kJ/g).

8. Food technology considerations

The Applicant has provided details about the manufacture of isomaltulose. It is produced from food grade sucrose through enzymatic isomerisation with sucrose-6-glucosylmutase. It is an intermediate in the production of isomalt (INS 953, a polyol) which is an approved food additive (sweetener) in the Code. Specifications and batch analysis have been provided. Information has been provided on the stability and other physical and chemical properties of isomaltulose.

An assessment of the food technology issues relating to isomaltulose will be prepared by FSANZ and presented in the Draft Assessment Report.

RISK MANAGEMENT

9. 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 have been 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.

10. Impact Analysis

10.1 Affected Parties

Parties possibly affected by the regulatory options outlined in Section 9 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.

10.2 Benefit Cost Analysis

In the course of developing food regulatory measures suitable for adoption in Australia and New Zealand, FSANZ is required to consider the impact of all options on all sectors of the community, including consumers, the food industry and governments in both countries. The Regulatory Impact Assessment identifies and evaluates, though is not limited to, the costs and benefits of the regulation, and its health, economic and social impacts.

To develop the analysis of the costs and benefits of the regulatory options proposed, FSANZ seeks comment on the following:

- What are the potential costs or benefits of this application to you as a stakeholder? Do the benefits outweigh the costs?

- What are the costs or benefits for consumers in relation to public health and safety, consumer information and labelling, etc?

- What are the costs or benefits for business – compliance, reporting, costs, savings, increased market opportunities both domestically and overseas?

- What are the costs or benefits for government – administration, enforcement, public health and safety, etc?

COMMUNICATION

11. Communication and Consultation Strategy

This is a routine approval matter. As a result, FSANZ has applied a basic communication strategy to Application A578. This will involve advertising the availability of assessment reports for public comment in the national press and making the reports available on the FSANZ website. We will issue a media release drawing journalists' attention to the matter.

The Applicant and individuals and organisations who make submissions on this Application will be notified at each stage of the Application. If approval is recommended, once the FSANZ Board has approved the Final Assessment Report, we will notify the Ministerial Council. The Applicant and Stakeholders, including the public, will be notified of the gazettal of 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.

12. Consultation

Public comment is sought on the Initial Assessment Report for this Application.

The purpose of the Initial Assessment Report is to seek early input on a range of specific issues known to be of interest to various stakeholders, to seek input on the likely regulatory impact at an early stage and to seek input from stakeholders on any matter of interest to them in relation to the Application.

All stakeholders that make a submission in relation to the Application will be included on a mailing list to receive further FSANZ documents in relation to the Application. If readers of this Initial Assessment Report are aware of others who might have an interest in this Application, they should bring this to their attention. Other interested parties as they come to the attention of FANZ will also be added to the mailing list for public consultation.

At this stage FSANZ is seeking public comment to assist it in assessing this Application. All stakeholders must observe the relevant due date for submissions.

Comments that would be useful could cover:

- **safety of isomaltulose in food**
- **nutritional and dietary issues associated with the use of isomaltulose in food;**
- **food technology issues associated with the use of isomaltulose in food;**
- **potential impacts; and**
- **labelling of foods and food products containing isomaltulose.**

12.1 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.

There are no relevant international standards and amending the Code to allow isomaltulose is unlikely to have a significant effect on international trade. This issue will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia's and New Zealand's obligations under the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) Agreements. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

CONCLUSION

13. Conclusion

This Initial Assessment Report is based mainly on information provided by the Applicant and discusses relevant issues in relation to approving isomaltulose as a novel food. After having regard to the requirements for Initial Assessment as prescribed in section 13 of the FSANZ Act, FSANZ has decided to accept the Application for the following reasons:

- The Application seeks approval for isomaltulose as a novel food. Such an approval, if accepted, would warrant a variation to Standard 1.5.1.
- There is currently no permission in the Code for isomaltulose.
- The Application is not so similar to any previous application that it ought not be accepted.
- There are no other measures that would be more cost-effective than a variation to Standard 1.5.1 that could achieve the same end.
- At this stage no other relevant matters are apparent.

Responses to this Initial Assessment Report will be used to develop the next stage of the Application and the preparation of a Draft Assessment Report.