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

08/03
19 March 2003

FINAL ASSESSMENT REPORT

APPLICATION A466

FOOD ENZYME, TRANSGLUCOSIDASE

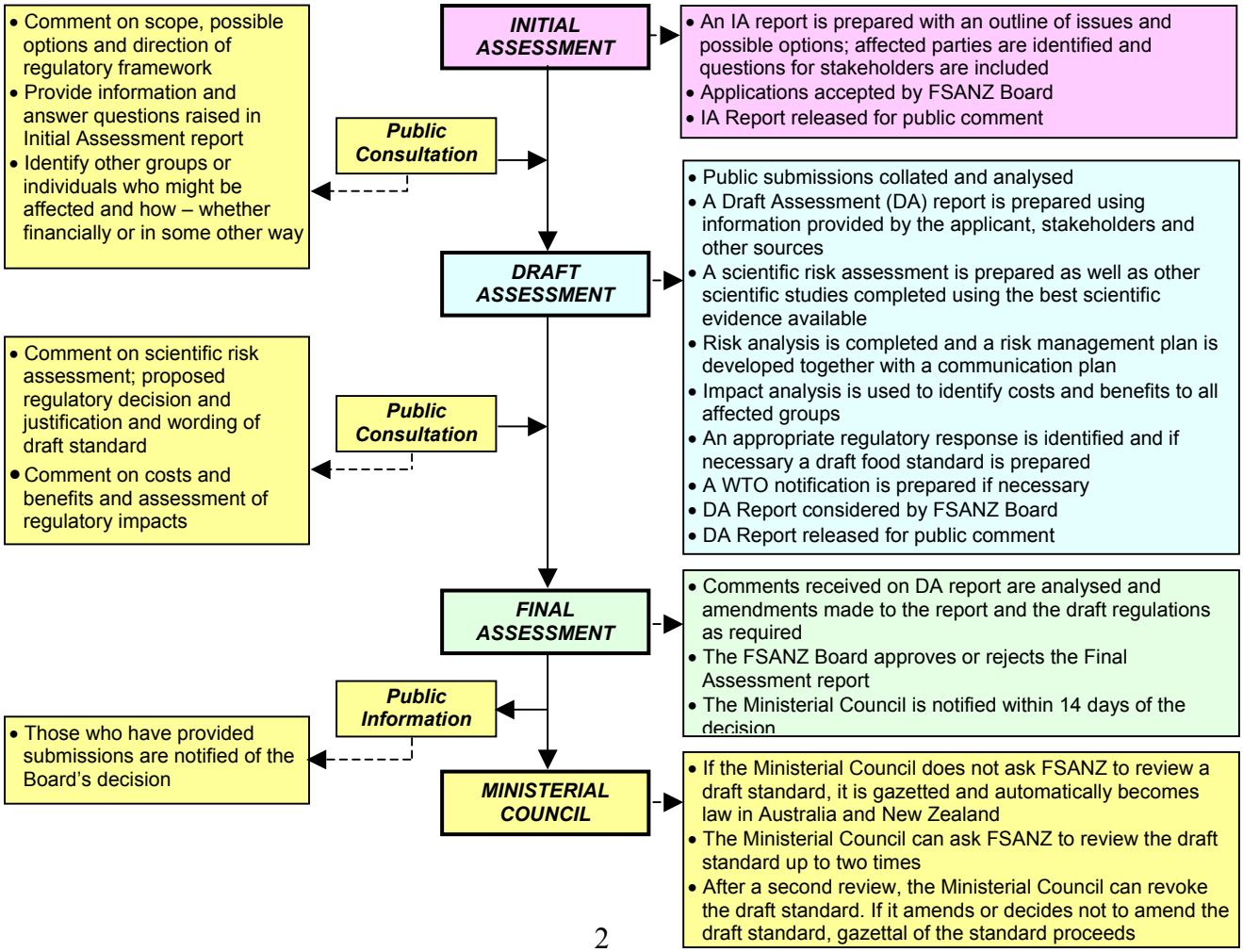
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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

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

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

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



Final Assessment Stage

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

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

In New Zealand the New Zealand Minister for Food Safety gazettes the food standard under the New Zealand *Food Act 1981*. Following gazettal, the standard takes effect 28 days later.

Submissions

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

Further Information

Further information on this and other matters should be addressed to the Standards Liaison Officer at the Food Standards Australia New Zealand at one of the following addresses:

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

CONTENTS

Executive Summary and Statement of Reasons

Food Standards Australia New Zealand (FSANZ) received an application from Genencor International to amend the *Food Standards Code* to approve the use of the enzyme transglucosidase sourced from *Aspergillus niger* (TG) as a processing aid.

The Application was received on 2 April 2002 and work commenced on 23 April 2002.

Standard 1.3.3 – Processing Aids of the A*ustralia New Zealand Food Standards Code* currently does not list this enzyme as approved from any source.

The objective of this assessment is to determine whether to amend the Code to permit the use of TG as a processing aid.

There are currently no other enzymes or chemical methods that can commercially produce isomalto-oligosaccharides (IMO) from high maltose syrups other than using TG. The Food Technology Report concluded that the use of the enzyme is technologically justified. The Safety Assessment Report concluded that the use of TG would pose no significant public health and safety risk. The source organism and the enzyme has a long history of safe use, while the enzyme preparation complies with FAO/WHO Joint Expert Committee on Food Additives (JECFA) specifications.

The only regulatory options considered were to approve or not approve this application. Approval of the use of TG has advantages to food manufacturers to be able to use TG to produce IMO and to other food manufacturers that can source locally produced IMO for use in their products. There are no significant disadvantages to food manufacturers, consumers or government agencies.

Public comment on the Initial Assessment Report was sought from 8 May to 19 June 2002. There were 4 submissions received which all supported the application. However, three submissions did have qualifications depending on the outcome of the Draft Assessment Report. In one case, support was dependent on the safety assessment confirming the safety of the enzyme and in the two other cases support was dependent on more information on the use of IMO in food.

Public comment on the Draft Assessment Report was sought from 9 October to 20 November 2002. Two submissions were received, both supporting the Application. No other comments or issues were raised.

The Final Assessment Report concludes that approval of the use of TG as a food processing aid is technologically justified and poses no significant risk to public health and safety.

The Australia New Zealand Food Authority (ANZFA) to FSANZ transitional requirements for an application at Full (Draft) Assessment stage have been followed and no additional submissions have been received.

Statement of Reasons

The draft variation to Standard 1.3.3 – Processing Aids, thereby giving approval for the use of TG as a processing aid is recommended for the following reasons.

- There are no significant public health and safety concerns associated with the use of the enzyme preparation.

- The use of TG is technologically justified, being an enzyme that is able to produce a type of sugar syrup - IMO - from starch. IMO are suitable for use as a food ingredient in a range of products.

- The source organism (*Aspergillus niger*) has a long history of safe use.

- TG has a history of safe use in other countries.

- TG complies with the specifications in the Compendium of Food Additives Specifications, Vol. 1, Annex 1, and FAO 1992 specifications (updated in Addendum 9, 2001).

- The proposed draft variation to the Food Standards Code is consistent with the section 10 objectives of the FSANZ Act. FSANZ protects public health and safety by assessing the safety of the enzyme preparations for its use in food manufacture. The assessment is based on the best available scientific data.

- The benefits of using the enzyme outweigh any costs associated with its use.

1. Introduction

FSANZ received an Application from Genencor International to amend the Food Standards Code to approve the use of TG as a processing aid. Genencor's representative in New Zealand is Zymus International (formerly Enzyme/Citrus Services). TG is produced from a non-genetically modified organism, *Aspergillus niger*.

TG can be used as a processing aid in the manufacture of IMO in the starch industry. These IMO syrups have use in a range of food industries (such as beverage, confectionery and baking) where their properties have advantages over other sugar solutions.

1.1 Transitional Requirements

This Application reached Preliminary (Initial) assessment stage under the operation of the *Australia New Zealand Food Authority Act 1991* (ANZFA Act), and was finalised in accordance with the provisions of the FSANZ Act. FSANZ therefore:

1. is taken to have made an Initial Assessment of the Application; and

2. any submissions made to ANZFA about the application in response to a notice under section 13A or 14 have effect as if those submissions had been made to FSANZ in response to a notice under section 13A or 14 under the FSANZ Act.

2. Regulatory Problem

A processing aid is a substance used in the processing of raw materials, foods or ingredients, to fulfil a technological purpose relating to treatment or processing, but does not perform a technological function in the final food. Processing aids are required to undergo a pre-market approval process before they can be used in food manufacture in Australia or New Zealand.

Standard 1.3.3 – Processing Aids currently does not list this enzyme as approved from any source.

3. Objective

The objective of this assessment is to determine whether it is appropriate to amend the Code to permit the use of TG as a processing aid.

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.

FSANZ protects public health and safety by ensuring that there is no significant health risks associated with use of the new enzyme. This evaluation uses the best available scientific data in conducting the risk assessment. The approval of this enzyme will allow manufacturers to use a new enzyme to produce a new range of sugar syrups encouraging an efficient and internationally competitive food industry, plus promoting consistency with other international food standards.

4. Background

IMO are a recently developed category of sugar syrups that have a number of advantages over other sugars and can be used in a number of industries. Their purported advantages are:

- non fermentable when used as an ingredient for alcoholic beverages;
- mildly sweet (about half as sweet as sucrose);
- a *Bifidus* growth factor (a factor in prebiotic functional foods which have been reported to provide health benefits by improving intestinal microbial balance);
- anti-cariogenic (preventing tooth decay);
- a high moisture retaining capacity conferring resistance to microbial infection; and
- acting as an anti-staling agent.

The use of TG to produce IMO is an alternative to a complex commercial process that converts starch to IMO that uses three enzymes (*alpha*-amylase, pullulanase and *alpha*-glucosidase). The Applicant states that use of TG is the only commercial way to convert high maltose syrups to IMO.

Commercial applications for IMO syrups are expected in a wide range of foods including beverage and brewing (mildly sweet and non fermentable properties), confectioneries (anti-cariogenic), baked goods (anti-staling properties) and health food industries (*Bifidus* growth factor).

IMO are used and are common in a number of prebiotic products produced and sold in Japan (and other Asian countries, specifically Taiwan and China) where there is a lot of interest in prebiotic products. However, they are not known to be used in commercial food products in Australia, New Zealand, USA or Europe, where there is not the same interest or culture of prebiotic products.

5. Relevant Issues

5.1 Nature of the enzyme

TG is produced using a non-genetically modified strain of *Aspergillus niger*.

TG is identified as EC [2.4.1.24] and CAS 9033-07-2.

TG is also called 1,4-α-glucan 6-α-glucosyltransferase, oligoglucan-branching glycosyltransferase, 1,4-α-D-glucan 6-α-D-glucosyltransferase, T-enzyme and D-glucosyltransferase.

The enzyme catalyses hydrolytic and transfer reactions to convert malto-oligosaccharides to isomalto-oligosaccharides (IMO). TG transfers a α-D-glucosyl residue most frequently to HO-6, so producing isomaltose from D-glucose and panose from maltose. Commercial productions of IMO will contain a range of various individual IMO, usually ranging from 1 to 5 glucosyl units, depending on the production conditions (see Attachment 4, Food Technology Report).

5.2 Efficacy and technological justification

There are currently no other enzymes or chemical methods that can commercially produce IMO from high maltose syrups other than using TG. A detailed Food Technology Report (Attachment 4) concludes that the use of the enzyme is technologically justified.

The usage rate of the enzyme is 0.5-1.0 kg per tonne of starch (0.05-0.1%) for IMO production. An experimental trial using the enzyme produced results where a syrup containing 71% maltose was converted to 40% IMO. This work was conducted with the Manildra Group in Nowra, NSW and they supplied a supporting letter with the Application.

TG is used (along with other enzymes) to produce IMO from starch and other sugars. Such IMO can be used in a variety of foods and food industries such as beverage and brewing, confectioneries, baked goods and health food products.

5.3 Safety assessment of the transglucosidase enzyme

The enzyme is produced from a non-genetically modified strain *Aspergillus niger*. *Aspergillus niger* is currently listed in Standard 1.3.3 as the source for other enzymes but not for TG. This microorganism has a history of safe use in the food industry.

The Safety Assessment Report (Attachment 3) concluded that the use of TG as a food processing aid would pose no significant public health and safety risk. The source organism has a long history of safe use while the enzyme also has a long history of safe use and its preparation complies with the FAO/WHO Joint Expert Committee on Food Additives (JECFA) specifications.

5.4 Dietary impact of isomalto-oligosaccharides (IMO)

This application is for the approval of TG as a processing aid however since the main use of the enzyme will be to produce IMO the dietary implications of IMO will be briefly addressed.

IMO occur naturally at low levels in foods such as miso, soy sauce, sake and honey. They can be prepared enzymatically from starch with the last part of the manufacture being a transformation of malto-oligosaccharides to isomalto-oligosaccharides by the action of TG. This is explained in more detail in the Food Technology Report (Attachment 4).

Trials have indicated that some proportion of IMO is digested and has 75% of the energy value of the sugar maltose. These results were found from adult feeding studies using 25 g of ^{13}C labelled IMO/day[1]. These studies and others indicate that some proportion of IMO is digested and absorbed but the balance remains undigested and is fermented in the large intestine. The trials also showed that IMO are fermented at about 25% the level of the indigestible saccharide, maltitol.

Commercial IMO products are claimed to have prebiotic properties. A definition of a prebiotic is:

> 'a non-digestible food ingredient that beneficially affects the host by selectively stimulating the growth and/or activity of one or a limited number of bacteria in the colon to improve host health'[2].

Such fermentation in the colon produces a range of small chain fatty acids, including butyrate.

IMO are added to a number of functional foods sold in Japan that are claimed to have health benefits, as a result of the prebiotic function of the IMO. It has been reported in clinical trials that IMO do not cause diarrhoea when consumed up to 10-20 g/day.

There are no reported commercial products sold in Australia or New Zealand or in the USA or Europe that use IMO as ingredients. In Australia and New Zealand, the use of IMO at significantly higher levels than normally found in foods may require their consideration under Standard 1.5.1 – Novel Foods. IMO used in this way would be regarded as a non-traditional food ingredient because they do not have a history of significant human consumption by the broad community. IMO may also be considered to be a novel food ingredient since their safety at higher levels of intake cannot be assured until a safety assessment is undertaken. While IMO are likely to be of low toxicity, high levels of intake could lead to a laxative effect because of their partial digestion in the gut. Such safety issues would be considered by FSANZ as part of the normal application process. In this regard, IMO are similar to two novel food applications currently before FSANZ, namely, D-tagatose and trehalose.

Clause 5 of Standard 1.2.3 requires advisory statements where a food contains polyols or polydextrose and may be used if it is considered that excessive consumption of IMO could have a laxative effect.

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[1] Kohomoto, T., Tsuji, K., Kaneko, T., Shiota, M., Fukui, F., Takaku, H., Nakagawa, T., Ichikawa, T. and Kobayashi, S. *Biosci. Biotech. Biochem*. 56(6), 937-940, 1992.

[2] Gibson, G.R. and Roberfroid, M.B. *Journal of Nutrition*, 125, 1401-1412, 1995.

5.5 Other international regulatory standards

TG has been a component (as a minor impurity) of a number of food enzyme preparations for decades. The Japanese government has approved the use of TG in food. The enzyme has been used in many EU countries as a processing aid. The FDA did not question the self-affirmed GRAS status of the TG enzyme for food uses.

The Applicant states that the TG enzyme preparations comply with the specifications for food enzyme preparations in Food Chemicals Codex (FCC), 4th Edition, 1996, and also the FAO/WHO Joint Expert Committee on Food Additives (JECFA), in the Compendium of Food Additives Specifications, Vol. 1, Annex 1, FAO 1992 (updated in Addendum 9, 2001).

5.6 Other relevant regulatory issues

Standard 1.3.4 – Identity and Purity requires a consequential change to update one of the relevant specifications monographs found in clause 2 that is used as a primary source.

The amendment is required to reflect the addition of an addendum 9 to the relevant monograph in subclause 2 (a) [Food and Nutrition Paper 52 Compendium of Food Additive Specifications Volume 1 and 2, including addenda 1 to 7, published by the Food and Agriculture Organization of the United Nations in Rome (1992)].

6. Regulatory Options

FSANZ is required to consider the impact of various regulatory (and non-regulatory) options on all sectors of the community, which includes consumers, food industries and governments in Australia and New Zealand. The benefits and costs associated with the proposed amendment to the Code have been analysed in the Impact Analysis section below.

The following two regulatory options are available for this application:

Option 1. Not approve the use of TG produced from *Aspergillus niger* as a food processing aid.

Option 2. Approve the use of TG produced from *Aspergillus niger* as a food processing aid.

7. Impact Analysis

The affected parties to this Application are:

1. The food manufacturing industries, which wish to use TG to produce IMO and those, that wish to use IMO in their products.

2. Commonwealth, State, Territory and New Zealand regulatory departments that enforce food regulations.

3. Consumers.

7.1 Option 1

There are no perceived benefits to industry, government regulators or consumers if this option is taken.

There are disadvantages to the food industries, essentially sugar syrup producers, wishing to use TG to produce IMO. Other food manufacturing industries that would be disadvantaged will be those that wish to use IMO as a food ingredient in their products.

7.2 Option 2

There are advantages to food manufacturers to be able to use TG to produce IMO and to others that can source locally produced IMO for use in their products. Consumers may also benefit by having a greater choice of food products.

There should be no added costs to government regulators.

Option 2, which supports the approval of TG sourced from *Aspergillus niger* as a food processing aid is the preferred option, since it has advantages for the food industry and consumers but has no significant cost for government regulators, consumers or manufacturers.

8. Consultation

Two rounds of public consultation have been undertaken for this application. The Initial Assessment Report was released for public comment between 8 May 2002 and 19 June 2002. Under the transitional provisions these submissions, which were made to ANZFA, have effect as if they had been made to FSANZ. Four submissions were received. All supported option 2 to approve the application and amend the Food Standards Code to include TG as a processing aid. These approvals did have qualifications depending on the Draft Assessment Report; in one case provided the safety assessment report confirmed the safety of the enzyme and in two cases requiring more information about the use of IMOs in food.

The second round of public consultation on the Draft Assessment report occurred between 9 October and 20 November 2002. Two submissions were received, both supporting the application.

Attachment 2 summarises the submissions received during the first and second rounds of public comment.

As a member 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.

Amending the Code to approve TG as a processing aid is unlikely to have a significant effect on trade. The enzyme preparations are also consistent with the international specifications for food enzymes of Food Chemicals Codex (4th Edition, 1996) and JECFA. FSANZ considers there is no need to notify the WTO.

9. Transitional Issues

This Application reached Preliminary (Initial) Assessment stage under the operation of the ANZFA Act, and will be finalised in accordance with the provisions of the FSANZ Act. Under the transitional provisions, FSANZ is considered to have made an Initial Assessment of the Application under the FSANZ Act. Any submissions received under the ANZFA Act have the same effect as if they had been received under the FSANZ Act.

10. Conclusion and Recommendation

The Final Assessment Report concludes that approval of the use of TG as a food processing aid is technologically justified and poses no significant risk to public health and safety.

The draft variation to Standard 1.3.3 – Processing Aids, thereby giving approval for the use of TG as a processing aid is recommended for the following reasons.

- There are no significant public health and safety concerns associated with the use of the enzyme preparation.

- The use of TG is technologically justified, being an enzyme that is able to produce a type of sugar syrup - IMO - from starch. IMO are suitable for use as a food ingredient in a range of products.

- The source organism (*Aspergillus niger*) has a long history of safe use.

- TG has a history of safe use in other countries.

- TG complies with the specifications in the Compendium of Food Additives Specifications, Vol. 1, Annex 1, and FAO 1992 specifications (updated in Addendum 9, 2001).

- The proposed draft variation to the Code is consistent with the section 10 objectives of the FSANZ Act. FSANZ protects public health and safety by assessing the safety of the enzyme preparations for its use in food manufacture. The assessment is based on the best available scientific data.

- The benefits of using the enzyme outweigh any costs associated with its use.

ATTACHMENTS

1. Draft variations to the *Australia New Zealand Food Standards Code*.
2. Summary of Public Submissions.
3. Safety Assessment Report.
4. Food Technology Report.

ATTACHMENT 1

Draft variations to the *Australia New Zealand Food Standards Code*

To commence: On gazettal

[1] ***Standard 1.3.3*** *of the Australia New Zealand Food Standards Code is varied by inserting in the* Table to clause 17, *the enzyme and source -*

Transglucosidase EC [2.4.1.24]	*Aspergillus niger*

[2] ***Standard 1.3.4*** *of the Australia New Zealand Food Standards Code is varied by omitting subclause 2(a)*, *substituting -*

(a) Food and Nutrition Paper 52 Compendium of Food Additive Specifications Volumes 1 and 2, including addenda 1 to 9, published by the Food and Agriculture Organisation of the United Nations in Rome (1992); or

ATTACHMENT 2

Summary of public submissions

Round One

Submitters

#	Submitter Organisation	Name
1	Australian Food and Grocery Council	Tony Downer
2	Food Technology Association of Victoria	David Gill
3	National Council of Women of Australia	Elaine Attwood
4	Consumers' Association of South Australia	Jill Bailey

Submitter	Comments
Australian Food and Grocery Council	Supports the application subject to an appropriate safety assessment.
Food Technology Association of Victoria	Agreed with option 2 – approve as a food processing aid.
National Council of Women of Australia	Supports the Initial Assessment since the enzyme is produced from a non-genetically modified strain and has been used for some time in the food supply. However they will reserve their final decision until after the Draft Assessment since IMOs are a relatively recent addition to the food supply.
Consumers' Association of South Australia	Support the submission made by the National Council of Women of Australia.

Round Two

Submitters

#	Submitter Organisation	Name
1	Australian Food and Grocery Council	Tony Downer
2	Food Technology Association of Victoria	David Gill

Submitter	Comments
Australian Food and Grocery Council	Supports the application. They agree with the safety assessment within the Draft Assessment Report that the enzyme would pose no public health or safety risk. They agree that the enzyme use is technologically justified, has been used and approved in other countries and complies with relevant specifications.
Food Technology Association of Victoria	Agreed with option 2 – approve as a food processing aid.

ATTACHMENT 3

Safety Assessment Report

A466 – FOOD ENZYME, TRANSGLUCOSIDASE AS A PROCESSING AID

INTRODUCTION

Application A466 seeks approval for the use of transglucosidase from a non-genetically modified strain of *Aspergillus niger*.

The enzyme is to be used as a processing aid only, and is not expected to be present in the final food. Any residue would be in the form of inactivated enzyme, which would be metabolised like any other protein.

The source (production) organism - *Aspergillus niger*

The organism from which the enzyme transglucosidase is derived is *Aspergillus niger*. This strain has a long history of safe use in the production of many enzymes used in foodstuff listed in Standard 1.3.3 – Processing Aids. The production strain AGME9 originated from a soil isolate and was directly derived from *Aspergillus foetidus* strain by conventional mutagenesis methods. No foreign DNA was introduced into the strain during its development.

Purity of enzyme preparation and proposed specifications

Historically, enzymes used in food processing have been found to be non-toxic, and the main toxicological consideration is in relation to possible contaminants. The production organism in this case is non-toxic and non-pathogenic.

Safety of Transglucosidase in food preparations

This enzyme has a long history of use by the food industry in the form of enzyme preparations containing transglucosidase in food processing. As a carbohydrase, transglucosidase derived from *Aspergillus niger* has been recognised as safe in food processing.

CONCLUSION

The assessment of the transglucosidase produced by *A. niger* found that:

- the source organism has a long history of safe use;
- the enzyme also has a long history of safe use and its preparation complies with the JECFA specifications;

From the available information, it is concluded that the use of the transglucosidase from this source as a processing aid would pose no significant public health and safety risk.

ATTACHMENT 4

Food Technology Report

Introduction

An application was received from Genencor International to amend the *Food Standards Code* to approve the use of the enzyme transglucosidase (TG) sourced from *Aspergillus niger* as a processing aid. The enzyme catalyses hydrolytic and transfer reactions to convert malto-oligosaccharides to isomalto-oligosaccharides (IMO). IMO syrups can be used in various food industries including beverage and brewing, confectionery, baking and health food industries.

Transglucosidase

TG is a D-glucosyltransferase which catalyses hydrolytic and transfer reactions of D-glucosyl units of oligosaccharides. The enzyme catalyses the hydrolysis and transfer of D-glucosyl units to convert 1,4 glucosidic linkages to 1,6 glucosidic linkages. The transfer of the glucosyl unit occurs most frequently to the HO-6. This means that the enzyme can form isomaltose (1,6 linkage) from maltose (1,4 linkage) as well as larger sugars with more glucosyl units. In such a way 1,4 linked oligosaccharides are converted to 1,6 linked isomalto-oligosaccharides, which will usually contain a range from one to five glucosyl units (see Fig 1 for a schematic representation of the transformation).

The use of the enzyme transglucosidase is the only commercially viable process that can manufacture IMO from oligosaccharides.

Isomalto-oligosaccharides (IMO)

TG is used in the sugar and starch industries as processing aids to produce the recently developed form of sugar, isomalto-oligosaccharides. I MO can be used as food ingredients in a variety of food industries such as beverages including brewing, confectionery, baking and health food industries.

Some of the reported advantages of IMO syrups are:

- non fermentable when used as an ingredient for alcoholic beverages;
- mildly sweet (about half as sweet as sucrose);
- a *Bifidus* growth factor (a factor in prebiotic functional foods claimed to provide health benefits);
- anti-cariogenic (preventing tooth decay);
- having a high moisture retaining capacity conferring improved resistance to microbial infection; and

- acting as an anti-staling agent.

The commercial applications for IMO syrups in food industries could include:

- beverage (mildly sweet);
- brewing (non-fermentable properties, so leaving some residual sweetness and mouth-feel);
- confectionery (anti-cariogenic properties, cause less tooth decay);
- baking (anti-staling properties); and
- health food industries, various functional foods and prebiotics [*Bifidus* bacteria (also called bifidobacteria) growth factor].

These applications are discussed in more detail below.

IMO syrups could replace part or all of liquid sugar syrups to produce different sweetness profiles for beverages since they are about half as sweet as sucrose. They could also be added during beer production as non-fermentable sugar syrups to replace some of the fermentable sugars altering the residual sweetness and mouth-feel of the resulting beers.

The anti-cariogenic properties could be employed by using IMOs as replacements for sugars in many confectionery products. Dental caries are caused by insoluble glucan gums forming on the surface of teeth (plaque), and the formation of acids under this plaque which attacks the tooth enamel. It has been shown that IMO in place of sucrose reduces the amount of plaque formed and also reduces the amount of enamel attacking acids formed[1].

The reported higher moisture retaining capacity which would confer improved resistance to bacterial infection could be an advantage to industry.

The reported anti-staling properties should be an advantage in the baking industries in developing products with slower staling rates.

However it would appear that the major advantages and the major areas of use and interest are in the functional food area covering prebiotic products. In Japan there are a number of so-called functional foods sold which have reported health benefits, some of which use IMO as ingredients. Prebiotics are nondigestible carbohydrates that pass through the small intestine undigested and are then fermented in the colon to produce a range of small chain fatty acids, including butyrate. It has been reported in clinical trials that IMO do not cause diarrhoea when used at recommended levels. IMO are food sources that are preferentially chosen by probiotic bacteria (live beneficial bacteria) such as bifidobacteria in the gut that reportedly help modulate the gut microflora and improve the intestinal microbial balance.

A good definition of a prebiotic is:

‘a non-digestible food ingredient that beneficially affects the host by selectively stimulating the growth and/or activity of one or a limited number of bacteria in the colon to improve host health’[2].

Mode of Action

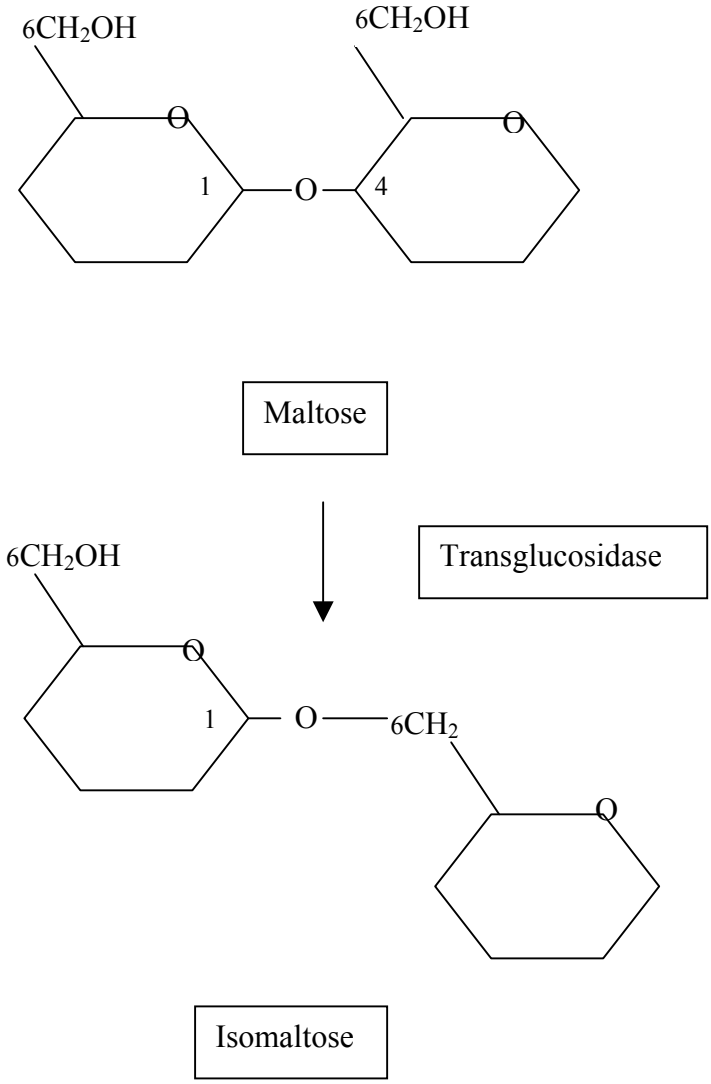

Fig 1. Simplified schematic of the formation of isomalto-oligosaccharides from oligosaccharides using the enzyme transglucosidase, with maltose and isomaltose as examples.

Production of the enzyme

TG enzyme preparations complies with the specifications and purity criteria recommended for enzyme preparations in the Food Chemicals Codex 4th Edition, 1996, and the General Specifications for Enzyme Preparations as proposed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), in the Compendium of Food Additives Specifications, Vol. 1, Annex 1, FAO 1992 (updated in Addendum 9, 2001).

The specifications for the enzyme are listed in Table 1.

Table 1
TG specifications

Item	Specification
pH	4.4-4.6
Percent solids	30% (w/w)
Appearance	Light to dark brown liquid
Microbiological	
Total viable organisms	<=50,000 cfu/ml
Total coliforms	<=30 cfu/ml
Escherichia coli	Negative/25 g
Salmonella	Negative/25 g
Production organism	<1 cfu/ml
Antibacterial activity	Negative
Mycotoxins	Negative
Metal analysis	
Arsenic	<=3.0 mg/kg
Cadmium	<=0.5 mg/kg
Mercury	<=0.5 mg/kg
Lead	<=5.0 mg/kg
Heavy metals (as lead)	<=30 mg/kg
Sodium benzoate	0.25-0.34% (w/w)
Sodium chloride	14-17% (w/w)

Conclusion

The use of TG as a processing aid is technologically justified to form IMO from sugar syrups.

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