

04/03 9 October 2002

DRAFT ASSESSMENT REPORT

APPLICATION A466

FOOD ENZYME, TRANSGLUCOSIDASE

DEADLINE FOR PUBLIC SUBMISSIONS to the Authority in relation to this matter: **20 NOVEMBER 2002**

(See "Invitation for Public Submissions" for details)

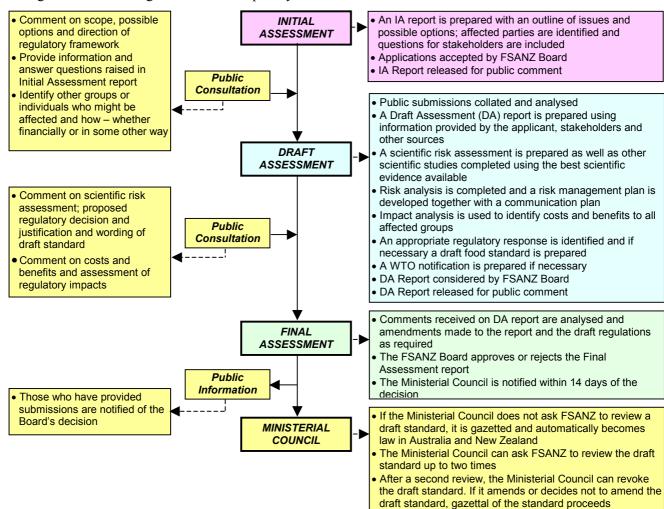
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 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 *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.



INVITATION FOR PUBLIC SUBMISSIONS

The Authority has prepared a Draft Assessment Report of Application A466 and prepared a draft variation to Volume 2 of the *Food Standards Code*.

The Authority invites public comment on this Draft Assessment Report based on regulation impact principles and the draft variation to Volume 2 of the *Food Standards Code* for the purpose of preparing an amendment to the *Food Standards Code* for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist the Authority in preparing the Final Assessment for this application. Submissions should, where possible, address the objectives of the Authority as set out in section 10 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the *Food Standards Code* (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 the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for inspection. If you wish any information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires the Authority 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 should be received by the Authority by: **20 November 2002**. Submissions received after this date may not be considered unless the Project Manager has given prior agreement for an extension. Submissions may also be sent electronically through the FSANZ website using the <u>Food Standards</u> tab and then through <u>Documents for Public Consideration</u>. Questions relating to making submissions or the application process can be directed to the Standards Liaison Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website or alternatively paper copies of reports can be requested from the Authority's Information Officer at either of the above addresses or by emailing including other general enquiries and requests for information.

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EXECUTIVE SUMMARY AND STATEMENT OF REASONS

Food Standards Australia and New Zealand (FSANZ) received an application 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 Application was received on 2 April 2002 and work commenced on 23 April 2002.

There is currently no approval for the use of TG as a processing aid in Standard A16 of the Australian *Food Standards Code* (Volume 1) and Standard 1.3.3 of the *Australia New Zealand Food Standards Code* (Volume 2). Because Volume 1 is expected to be repealed in December 2002 when Volume 2 will become the sole food regulatory Code for Australia and New Zealand, it has been decided to only amend Volume 2 and not Volume 1. '*Food Standards Code*' will be used to refer only to the Volume 2 for the rest of this report.

The objective of this assessment is to determine whether to amend the Food Standards Code to permit the use of the enzyme transglucosidase sourced from *Aspergillus niger* as a processing aid.

The regulatory options considered are to:

- 1. Not approve, or
- 2. Approve

this Application.

Option 2 has advantages to food manufacturers to be able to use the enzyme TG to produce isomalto-oligosaccharides (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.

The Initial Assessment went out for a round of public comment (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 Draft Assessment Report. In one case providing the safety assessment confirmed the safety of the enzyme and in two cases requiring more information on the use of IMO (which are produced by the action of the enzyme) in food.

FSANZ is now seeking public comment on this Draft Assessment to assist in the Final Assessment. Comments that will be useful would include:

- Technological justification;
- Safety considerations; and
- Interest from industry in using the enzyme to produce IMO and using IMO in food products.

Statement of Reasons

The draft variation to Standard 1.3.3 – Processing Aids of the Food Standards Code, thereby giving approval for the use of the transglucosidase sourced from *Aspergillus niger* as a processing aid is recommended for the following reasons:

- There are no public health and safety concerns associated with the use of the enzyme preparation.
- The use of the transglucosidase enzyme is technologically justified.
- The source organism (Aspergillus niger) has a long history of safe use.
- The transglucosidase enzyme has a history of safe use in other countries.
- Transglucosidase derived from *Aspergillus niger* complies with the specifications in the Compendium of Food Additives Specifications, Vol. 1, Annex 1, 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.
- The benefits of using the enzyme for food manufacturers outweigh any costs associated with its use.

The Australia New Zealand Food Authority (ANZFA) to FSANZ transitional requirements for an application at preliminary (initial) stage provide that FSANZ is taken to have made an initial assessment of the Application. Any submissions received by ANZFA about an Application in response to a notice given under section 13A or 14 of the *Australia New Zealand Food Authority Act 1991*, are taken to be submissions made to FSANZ about the application/proposal in response to a notice under section 13A or 14 under the *Food Standards Australia New Zealand Act 1991*.

1. Introduction

An application was received from Genencor International to amend the Food Standards Code to approve the use of an enzyme, transglucosidase (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 is used as a processing aid in the manufacture of isomalto-oligosaccharides (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 will be finalised in accordance with the provisions of the *Food Standards Australia New Zealand Act 1991* (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.

There is currently no approval for the use of TG as a processing aid in Standard A16 (Volume 1) and Standard 1.3.3 (Volume 2) of the Food Standards Code. Because Volume 1 is expected to be repealed in December 2002 when Volume 2 will become the sole food regulatory Code for Australia and New Zealand, it has been decided to only amend Volume 2 and not Volume 1.

An Initial Assessment Report for this application was issued and went out for public comment on the 8 May 2002 with the comment period ending 19 June 2002. This Draft Assessment Report, prepared with input from public submissions, contains a more detailed evaluation including Food Technology and Safety Assessment reports. This Draft Assessment Report will also go out for another round of public comment.

3. Objective

The objective of this assessment is to determine whether it is appropriate to amend the Food Standards Code to permit the use of the enzyme transglucosidase sourced from *Aspergillus niger* 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.

4. Background

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

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

There are no other commercially viable processes (either enzymatic or chemical) that can be used to manufacture IMO from high maltose syrups apart from the use of the TG enzyme.

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

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 an 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 the TG enzyme. A detailed Food Technology Report is attached (Attachment 4) which concluded that the use of the enzyme is technologically justified.

The use rate of the enzyme is 0.5-1.0 kg per tonne of starch (0.05-0.1%) for IMO syrup 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.

The TG enzyme is used (along with other enzymes) to produce isomalto-oligosaccharide (IMO) syrups 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

The enzyme is produced from a non-genetically modified strain *Aspergillus niger*. *Aspergillus niger* is currently listed in Standard A16 (Volume 1) and Standard 1.3.3 (Volume 2) 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 the enzyme transglucosidase from *Aspergillus niger* as a food processing aid would pose no 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 Other international regulatory standards

The TG enzyme has been a component 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).

5.5 Other relevant regulatory issues

There needs to be a consequential change to Standard 1.3.4 – Identity and Purity in the *Food Standards Code* to incorporate updating one of the relevant specifications monographs found in clause 2 that is used as a primary source (to reflect the update mentioned in the above section).

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 Organisation 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 Food Standards 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 the enzyme 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 the enzyme 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

One round of public consultation has 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 the enzyme transglucosidase 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.

Attachment 2 at the back of this report summarises the submissions received during the first round of public comment.

FSANZ is now seeking further public comment on this Draft Assessment Report to assist in assessing this application at Final Assessment.

Comments that would be useful could include:

- Technological justification;
- Safety considerations; and
- Interest from industry in using the enzyme to produce IMO and using IMO in food products.

Amending the *Food Standards Code* to approve the enzyme transglucosidase derived from *Aspergillus niger* 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 JEFCA so there is not considered a 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 Draft Assessment Report concludes that approval of the use of transglucosidase sourced from *Aspergillus niger* as a food processing aid is technologically justified and poses no risk to public health and safety.

The draft variation to Standard 1.3.3 – Processing Aids of the *Food Standards Code*, thereby giving approval for the use of the transglucosidase sourced from *Aspergillus niger* as a processing aid is recommended for the following reasons:

- There are no public health and safety concerns associated with the use of the enzyme preparation.
- The use of the transglucosidase enzyme is technologically justified.
- The source organism (*Aspergillus niger*) has a long history of safe use.
- The transglucosidase enzyme has a history of safe use in other countries.
- Transglucosidase derived from *Aspergillus niger* complies with the specifications in the Compendium of Food Additives Specifications, Vol. 1, Annex 1, 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.
- The benefits of using the enzyme for food manufacturers outweigh any costs associated with its use

ATTACHMENTS:

- 1. Draft variations to Food Standards Code.
- 2. Summary of Public Submissions.
- 3. Safety Assessment Report.
- 4. Food Technology Report.

DRAFT VARIATIONS TO THE FOOD STANDARDS CODE

To commence: On gazettal

[1] **Standard 1.3.3** of Volume 2 is varied by inserting in the Table to clause 17, the enzyme and source -

Transglucosidase	Aspergillus niger
EC [2.4.1.24]	

- [2] **Standard 1.3.4** of Volume 2 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	Supports the application subject to an appropriate safety
Council	assessment.
Food Technology	Agreed with option 2 – approve as a food processing aid.
Association of Victoria	
National Council of Women	Supports the Initial Assessment since the enzyme is produced
of Australia	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	Support the submission made by the National Council of
South Australia	Women of Australia.

SAFETY ASSESSMENT REPORT

APPLICATION A466 - FOOD ENZYME, TRANSGLUCOSIDASE L-500 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 public health and safety risk.

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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 sourced from *Aspergillus niger* as a processing aid. The enzyme catalyses hydrolytic and transfer reactions to convert maltooligosaccharides to isomalto-oligosaccharides (IMO). IMO syrups can be used in various food industries including beverage and brewing, confectionery, baking and health food industries

Transglucosidase

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

Transglucosidase 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 standard 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).

Isomalto-oligosaccharides (IMO)

The transglucosidase enzyme is used in the sugar and starch industries as processing aids to produce the recently developed form of sugar syrups, isomalto-oligosaccharides. Such IMO sugar syrups 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;
- mildly sweet (about half as sweet as sucrose);
- a *Bifidus* growth factor (an important factor in prebiotics, functional foods claimed to provide health benefits);
- anti-cariogenic (prevents tooth decay):
- having a high moisture retaining capacity conferring improved resistance to microbial infection; and
- acts as an anti-staling agent.

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

• beverage (mildly sweet);

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- 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 formed¹.

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, specifically butyrate. It has been reported in clinical trials that IMO do not cause diarrhoea when used in recommended doses. 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"

Mode of Action

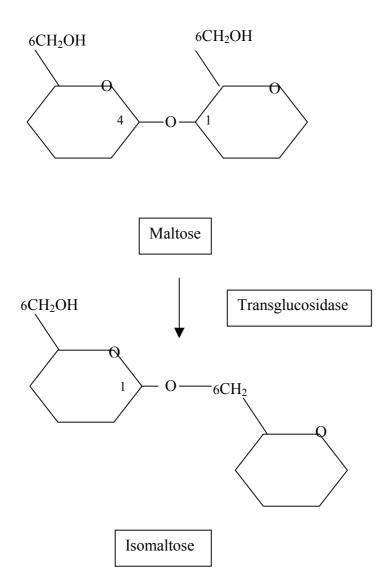


Fig 1. Simplified schematic of the formation of isomalto-oligosaccharides from oligosaccharides using the enzyme transglucosidase, with maltose and isomaltose as examples.

Production of the enzyme

The transglucosidase enzyme preparation 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
рН	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 the enzyme transglucosidase as a processing aid is technologically justified to form IMO from sugar syrups.

References

- 1. Japanese Patent, Kokoku Patent No. SHO 62 (1987) 51584, Toshio Miyake, Mikihiko Yoshida and Kano Takeuchi, 'Low Cariogenic Food and Drink'.
- 2. Gibson, G.R. and Roberfroid, M.B. Journal of Nutrition, 125, 1401-1412, 1995.