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INITIAL ASSESSMENT REPORT
(PRELIMINARY ASSESSMENT - S.13)

APPLICATION A466

FOOD ENZYME,
TRANSGLUCOSIDASE L-500

DEADLINE FOR PUBLIC SUBMISSIONS to the Authority in relation to this matter:

19 JUNE 2002

(See "Invitation for Public Submissions" for details)

TABLE OF CONTENTS

FOOD STANDARDS SETTING IN AUSTRALIA AND NEW ZEALAND	3
INVITATION FOR PUBLIC SUBMISSIONS	4
Content of Submissions	5
Transparency	5
Deadlines	5
Delivery of Submissions	6
FURTHER INFORMATION	6
INTRODUCTION	7
REGULATORY PROBLEM	7
OBJECTIVE	7
BACKGROUND	8
ISSUES RELEVANT TO THIS APPLICATION	8
Nature of the enzyme	8
Efficacy and technological justification	9
Safety assessment	9
REGULATORY OPTIONS	9
IMPACT ANALYSIS	10
CONSULTATION	10
WTO Implications	11

FOOD STANDARDS SETTING IN AUSTRALIA AND NEW ZEALAND

The Governments of Australia and New Zealand entered an Agreement in December 1995 establishing a system for the development of joint food standards. On 24 November 2000, Health Ministers in the Australia New Zealand Food Standards Council (ANZFSC) agreed to adopt the new *Australian New Zealand Food Standards Code*. The new Code was gazetted on 20 December 2000 in both Australia and New Zealand as an alternate to existing food regulations until December 2002 when it will become the sole food code for both countries. It aims to reduce the prescription of existing food regulations in both countries and lead to greater industry innovation, competition and trade.

Until the joint *Australia New Zealand Food Standards Code* is finalised the following arrangements for the two countries apply:

- **Food imported into New Zealand other than from Australia** must comply with either Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as the joint *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code*, as gazetted in New Zealand, or the *New Zealand Food Regulations 1984*, but not a combination thereof. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the *New Zealand (Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard 1999*.
- **Food imported into Australia other than from New Zealand** must comply solely with Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as the joint *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code*, but not a combination of the two.
- **Food imported into New Zealand from Australia** must comply with either Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code* as gazetted in New Zealand, but not a combination thereof. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the *New Zealand Food Regulations 1984*.
- **Food imported into Australia from New Zealand** must comply with Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code*, but not a combination of the two. However, under the provisions of the Trans-Tasman Mutual Recognition Arrangement, food may **also** be imported into Australia from New Zealand provided it complies with the *New Zealand Food Regulations 1984*.
- **Food manufactured in Australia and sold in Australia** must comply with Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code* but not a combination of the two. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the *New Zealand Food Regulations 1984*.

In addition to the above, all food sold in New Zealand must comply with the New Zealand *Fair Trading Act 1986* and all food sold in Australia must comply with the Australian *Trade Practices Act 1974*, and the respective Australian State and Territory *Fair Trading Acts*.

Any person or organisation may apply to ANZFA to have the *Food Standards Code* amended. In addition, ANZFA may develop proposals to amend the Australian *Food Standards Code* or to develop joint Australia New Zealand food standards. ANZFA can provide advice on the requirements for applications to amend the *Food Standards Code*.

INVITATION FOR PUBLIC SUBMISSIONS

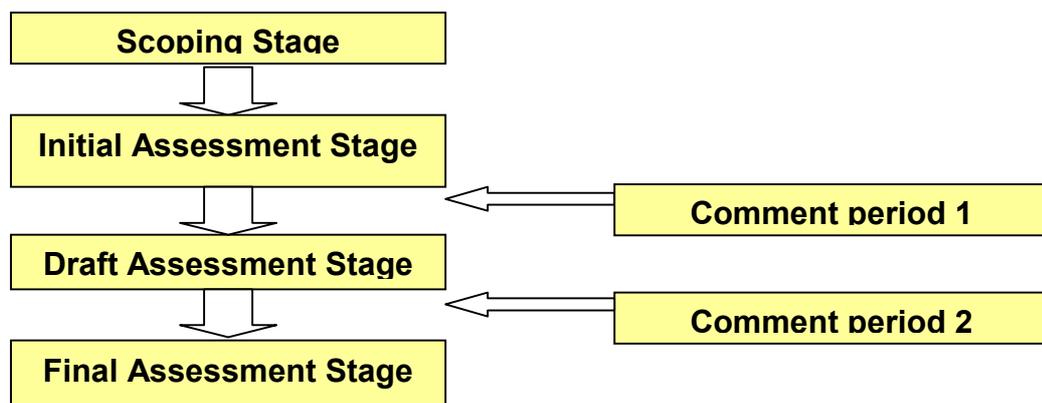
The process for amending the *Australia New Zealand Food Standards Code* (the Code) is prescribed in the ANZFA Act 1991. Open and transparent consultation with interested parties is a key element in the process involved in amending or varying the Code.

Any individual or organization may make an ‘application’ to the Australia New Zealand Food Authority (the Authority) seeking to change the Code. The Authority itself, may also seek to change the Code by raising a ‘proposal’. In the case of both applications and proposals there are usually two opportunities for interested parties to comment on proposed changes to the Code during the assessment process. This process varies for matters that are urgent or minor in nature.

Following the initial assessment of an application or proposal the Authority may decide to accept the matter and seek the views of interested parties. If accepted, the Authority may then undertake a draft assessment including preparing a draft standard or draft variation to a standard (and supporting draft regulatory impact statement). If a draft standard or draft variation is prepared, it is then circulated to interested parties, including those from whom submissions were received, with a further invitation to make written submissions on the draft. Any such submissions will then be taken into consideration during the final assessment, which the Authority will hold to consider the draft standard or draft variation to a standard.

Comment opportunities in the usual assessment process to change the Australia New Zealand Food Standards Code

(Note: this process may vary for matters that are urgent or minor)



Content of Submissions

Written submissions containing technical or other relevant information which will assist ANZFA in undertaking an assessment on matters relevant to the application, including consideration of its regulatory impact, are invited from interested individuals and organizations. 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 presented should be in sufficient detail to allow independent scientific assessment.

Submissions may provide more general comment and opinion on the issue although those framing their submissions should bear in mind ANZFA's regulatory role specifically relates to food supplied for human consumption in Australia and New Zealand. The ANZFA Act 1991 sets out the objectives of the Authority in developing food regulatory measures and variations of food regulatory measures as:

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

In developing food regulatory measures and variations of food regulatory measures The Authority must also have regard to the following:

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

Submissions addressing the issues in the context of the objectives of the Authority as set out in the *ANZFA Act 1991* will be more effective in supporting their case.

Transparency

The processes of ANZFA are open to public scrutiny, and any submissions will ordinarily be placed on the public register of ANZFA and made available for inspection. If you wish any confidential information contained in a submission to remain confidential to ANZFA, you should clearly identify the sensitive information and provide justification for treating it in confidence. The *Australia New Zealand Food Authority Act 1991* requires ANZFA 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 reasonable be expected to be destroyed or diminished by disclosure.

Contact details for submitters are recorded so that the Authority can continue to keep them informed about progress of the application or proposal.

Deadlines

The deadlines for submissions are clearly indicated in the advertisements calling for comment and in the relevant Assessment Reports. While the Authority often provides comment periods of around 6 weeks, the periods allowed for comment may vary and may be limited to

ensure critical deadlines for projects can be met. Unless the Project Manager has given specific consent for an extension, the Authority cannot guarantee that submissions received after the published closing date will be considered.

Delivery of Submissions

Submissions must be made in writing and should be clearly marked with the word '**Submission**' and **quote the correct project number and title**. Submissions may be sent by mail to the Standards Liaison Officer at one of the following addresses:

Australia New Zealand Food Authority
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2258
email: slo@anzfa.gov.au

Australia New Zealand Food Authority
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
email: anzfa.nz@anzfa.gov.au

Submissions should be received by the Authority by: 19 JUNE 2002

Submissions may also be sent electronically through the submission form on the ANZFA website www.anzfa.gov.au. Electronic submissions should also include the full contact details of the person making the submission on the main body of the submission so that the contact details are not separated.

FURTHER INFORMATION

Further information on the application and submission process should be addressed to the Standards Liaison Officer at the Australia New Zealand Food Authority at one of the above addresses.

Assessment reports are available for viewing and downloading from the ANZFA website or alternatively paper copies of reports can be requested from the Authorities Information Officer at info@anzfa.gov.au.

INTRODUCTION

The Australia New Zealand Food Authority (ANZFA) is a bi-national statutory body responsible for developing draft food standards and draft variations of standards, to make recommendations to the Australia New Zealand Food Standards Council (ANZFSC) in relation to those drafts, and to review standards. ANZFSC may then decide to adopt the draft standards or draft variations of standards, which results in their incorporation into food laws of the Australian States and Territories, and New Zealand.

On 24 November 2000, ANZFSC adopted the *Australia New Zealand Food Standards Code* (known as Volume 2 of the *Food Standards Code*) that will apply in both Australia and New Zealand. A two-year transitional period has been implemented at the conclusion of which Volume 2 of the *Food Standards Code* will be the sole code for both countries. In the interim, for the majority of the food standards, there is a system of dual standards operating in both Australia and New Zealand.

An application has been received on 2 April 2002, 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 for Australia and New Zealand is Enzyme/Citrus Services from NZ. This would involve amending 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). TG is produced with the use of a non-genetically modified organism, *Aspergillus niger*.

Transglucosidase is used as processing aids 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.

REGULATORY PROBLEM

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*. There may be no need to amend Volume 1 for the purposes of this application since it is expected that Volume 1 will be rescinded by December 2002. 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. An application is required to assess whether the *Food Standards Code* can be amended to permit the use of TG as a processing aid.

OBJECTIVE

The applicant is seeking to amend Standard A16 (Volume 1) and Standard 1.3.3 (Volume 2) of the *Food Standards Code* to approve the use of TG sourced from *Aspergillus niger* as a processing aid.

Such an amendment will need to be consistent with the section 10 objectives of the ANZFA Act, which are given below.

- (1) The objectives (in descending priority order) of the Authority in developing food regulatory measures and variations of food regulatory measures are:
 - (a) the protection of public health and safety; and
 - (b) the provision of adequate information relating to food to enable consumers to make informed choices; and
 - (c) the prevention of misleading or deceptive conduct.

- (2) In developing food regulatory measures and variations of food regulatory measures, the Authority must also have regard to the following:
 - (a) the need for standards to be based on risk analysis using the best available scientific evidence;
 - (b) the promotion of consistency between domestic and international food standards;
 - (c) the desirability of an efficient and internationally competitive food industry;
 - (d) the promotion of fair-trading in food.

BACKGROUND

There are no other commercially viable processes (either enzymatic or chemically) that can manufacture IMO from maltose apart from the use of the TG enzyme.

IMO are a relatively recent 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 (this microorganism is claimed to provide health benefits);
- anti-cariogenic (prevents tooth decay);
- having a high moisture retaining capacity conferring resistance to microbial infection; and
- acting as an anti-staling agent.

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) and baked goods (anti-staling properties) and health food industries (*Bifidus* growth factor).

ISSUES RELEVANT TO THIS APPLICATION

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.

Efficacy and technological justification

There are currently no other enzymes or chemical methods that can commercially produce IMO from maltose other than using the TG enzyme.

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 have supplied a supporting letter with the application.

A Food Technology report will be written at Draft Assessment to investigate more fully the purpose and efficacy of the enzyme.

Safety assessment

The enzyme is produced from the use of the 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 Transglucosidase. This microorganism has a history of safe use in the food industry.

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 does not question the GRAS status of the TG enzyme for food uses. The TG enzyme can currently be used in New Zealand, as most enzymes are not specifically regulated in the *New Zealand Food Regulations 1984*.

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 Committee on Food Additives (JECFA), in the Compendium of Food Additives Specifications, Vol. 1, Annex 1, FAO 1992.

A more detailed Safety Assessment report will be prepared at the Draft Assessment stage.

REGULATORY OPTIONS

The regulatory options are as follows:

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

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

IMPACT ANALYSIS

The affected parties to this Application are:

1. The food manufacturing industries which wish to use (or are currently using in New Zealand) the enzyme to produce IMO and those that wish to use IMO in their products.
2. State, Territory and New Zealand regulatory departments that need to enforce food regulations.
3. Consumers.

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, which wish 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.

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 Transglucosidase 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 cost for government regulators.

CONSULTATION

ANZFA is now seeking public comment on this Application to further assist in the assessment process. There will also be a further round of public comment after the Draft Assessment report is completed.

Areas of interest that would be helpful include:

- technological justification;
- safety considerations; and
- interest from industry in using the enzyme to produce IMO and using IMO in food products.

WTO Implications

As a member of the World Trade Organisation (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.

The Australia New Zealand *Food Standards Code* is mandatory legislation applying to both domestic and imported food products. Suppliers of food products are not required to take up permissions granted through amendments to the *Code* however food products not complying with the *Code* cannot legally be supplied in Australia.

Amending the *Food Standards Code* to approve foods developed using Transglucosidase as a processing aids is unlikely to have a significant effect on trade, however this issue will be fully considered at Draft Assessment and, if necessary, notification will be made in accordance with the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) agreements.