

13 March 2002
08/02

INITIAL ASSESSMENT
[PRELIMINARY ASSESSMENT - S.13]

**APPLICATION A458 – GLUCOSE OXIDASE AS A
PROCESSING AID**

Applicant: Novozymes A/S
7/F Chinachem Century Tower
178 Gloucester Road
Wanchai, Hong Kong

Date received: 6 November 2001

Workplan start date: December 2001

DEADLINE FOR PUBLIC SUBMISSIONS to the Authority in relation to this matter:
24 APRIL 2002 (see 'Invitation for Public Submissions' for details)

SUMMARY

An application has been received from Novozymes A/S to amend the Australia New Zealand *Food Standards Code* to approve the use of the enzyme, glucose oxidase, as a processing aid under Standard A16 (Volume 1 – *Food Standards Code*) and Standard 1.3.3 (Volume 2 – Australia New Zealand *Food Standards Code*). The enzyme was produced using recombinant DNA techniques from the host bacterial strain, *Aspergillus oryzae*, and contains a donor gene coding for glucose oxidase from *Aspergillus niger*.

ANZFA's primary objective is to ensure that the proposed use of the enzyme as a processing aid is safe for human consumption. The purpose of this initial report is to publicly notify receipt of a new application by ANZFA. It is not an assessment of the application. It is therefore based on available information provided by the applicant. The report is designed to assist in identifying the affected parties, any alternative regulatory options, and the potential impacts of any regulatory or non-regulatory provisions. The information needed to make an assessment of this application will include information from public submissions.

Public submissions are now invited on this preliminary assessment report.

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, in order to make recommendations to the Australia New Zealand Food Standards Council (Ministerial Council), and to review standards. The Ministerial Council then may decide to adopt the 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, the Ministerial Council adopted the *Australia New Zealand Food Standards Code* (known as Volume 2 of the *Food Standards Code*) that applies both in 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 food standards, there are two standards operating in Australia and three in New Zealand (including the New Zealand Food Regulations).

PROBLEM

Standards A16 (Volume 1) and Standard 1.3.3 (Volume 2) of the *Food Standards Code* makes provision for the appropriate use of approved processing aids in food manufacture. 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. There is currently no permission for the use of glucose oxidase sourced from *Aspergillus oryzae* which carries a gene coding for a glucose oxidase isolated from *Aspergillus niger*.

OBJECTIVE

The application from Novozymes A/S is seeking to amend Standard A16 (Volume 1) and Standard 1.3.3 of the recently adopted joint *Australia New Zealand Food Standards Code* (Volume 2) to approve a new source of the enzyme, glucose oxidase (EC 1.1.3.4), as a processing

aid. The application is for glucose oxidase sourced from *Aspergillus oryzae* that carries a gene coding for glucose oxidase isolated from *Aspergillus niger*.

The objective of this application is to determine whether the food regulatory measures can be amended to approve the use of a new source of the enzyme glucose oxidase. Such an amendment to the *Food Standards Code* will need to be consistent with the section 10 objectives of ANZFA Act. The three primary objectives of the Authority 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, ANZFA 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; and
- the promotion of fair trading in food.

ISSUES TO BE ADDRESSED DURING ASSESSMENT

Purpose and Efficacy of the Processing Aid

The applicant has indicated that the enzyme is to be used in the baking industry as a processing aid to strengthen gluten in dough systems. It causes a more elastic and stronger gluten network similar to that obtained by traditional oxidising agents such as potassium bromate or ascorbic acid. The enzyme is active in the dough and the leavening of the unbaked bread, but normally inactivated by high temperatures during the baking. The enzyme is 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 applicant has stated that glucose oxidase complies with the purity criteria recommended for enzyme preparations in Food Chemicals Codex (FCC) 4th Edition, 1996, and also conforms to 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.

The source (production) organism - *Aspergillus oryzae*

The safety of the source organism is an important consideration in the safety assessment for recombinant lipase. *A. oryzae* is not considered to be pathogenic, is widely distributed in nature and is commonly found in foods (Barbetsgaard et al, 1992). Enzymes from *A. oryzae* are extensively used in production of a variety of foods such as syrups, alcohol, fruit juices, brewing, chocolate syrup, baking and meat tenderising, and have been for many years (Rogers, 1977). Further information on the safety of *A. oryzae* will be provided at Draft Assessment.

The donor organism – *Aspergillus niger*

The organism from which the glucose oxidase gene is derived is *Aspergillus niger*. Glucose oxidase from a non-genetically modified *Aspergillus niger* is already permitted by Standard 1.3.3 of the Australia New Zealand *Food Standards Code* and has been evaluated by JECFA (http://apps3.fao.org/jecfa/additive_specs/docs/0/additive-0206.htm). The nature of the DNA fragment from the donor strain used in the construction of the genetically modified strain of *A. oryzae* will be considered during Draft Assessment.

Nature of the genetic modification

The genetic modification process involved the transfer of the glucose oxidase gene from *A. niger* to *A. oryzae*. The applicant has provided information to indicate that the recombinant organism was found to be stable during production fermentations. Southern blotting was used to investigate the stability of the integration of the glucose oxidase gene after large-scale fermentation, and found that the inserted DNA was stably integrated into the host genome. The DNA used for transforming the *A. oryzae* host strain does not contain antibiotic resistance genes. These issues will be further considered during Draft Assessment.

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.

Labelling of food when glucose oxidase is used

Processing aids are not currently required to appear in ingredient lists under general labelling provisions in the *Food Standards Code* and the *New Zealand Food Regulations*. There are a number of enzyme processing aids derived from genetically modified organisms used by the food industry. Processing aids are generally present to fulfil a technological purpose relating to treatment or processing, but do not perform a technological function in the final food.

The labelling of foods produced using gene technology, was decided on at the Australia New Zealand Food Standards Council (ANZFSC) meeting on 28 July 2000. The ANZFSC decided to exempt processing aids and food additives except where novel DNA and/or protein is present in the final food. While the gene coding for the glucose oxidase enzyme from the donor strain is novel, neither the gene nor the enzyme is expected to be present in the final food, nor is the enzyme itself considered novel.

OPTIONS

Parties affected by the options listed below include:

- State, Territory and New Zealand Health Departments;
- manufacturers and producers of food products that use glucose oxidase as a processing aid;
- suppliers and importers; and
- consumers.

The suggestions in the sections below under possible options, affected parties and potential impacts are preliminary only and are based on available information or on information supplied by

the applicant. These sections are designed to assist in the process of identifying the affected parties, alternative options apart from the objective of the application, and the potential impacts of any regulatory or non-regulatory provisions.

The information needed to make an assessment of this application will include information from public submissions. This initial assessment now invites public comment on these areas.

Option 1. Not approve the use of glucose oxidase produced by *Aspergillus oryzae* carrying the lipase gene from *Aspergillus niger*.

There are no perceived benefits to the stakeholders, government, consumers and industry, by maintaining the *status quo* and not giving specific permission in the *Food Standards Code* for the use of this enzyme.

Although there is no perceived cost for the government at present, if, in the future, other countries approve glucose oxidase from the new genetically modified source organism, lack of approval in Australia or New Zealand may be construed as a non-tariff barrier to trade. Industry would also suffer from the non-availability of an alternative source of glucose oxidase.

Parties disadvantaged by not permitting this particular processing aid, are the manufacturers of glucose oxidase and producers who wish to use it in the manufacture of their final food products.

Option 2. Approve the use of glucose oxidase produced by *Aspergillus oryzae* carrying the glucose oxidase gene from *Aspergillus niger*.

This option would allow an alternative safe source of glucose oxidase with no cost to government, industry or consumers.

Approval of glucose oxidase from a new genetically modified source organism would promote international trade and reduce technical barriers to trade, while continuing to protect public health and safety. From the industry point of view, this option will promote fair trade in food and will allow manufacturers to use an alternative source of glucose oxidase.

IMPACT ANALYSIS

The objective of regulatory impact analysis is to examine the impact of the options to permission or not permit the use of glucose oxidase from a new source organism, as a processing aid in Standard 1.3.3.

As the use of glucose oxidase from genetically modified source organism *A. oryzae* requires pre-market approval, it is not appropriate to consider non-regulatory options to address this application. Processing aids used in Australia and New Zealand are required to be listed in Standard 1.3.3. – Processing Aids. New entries in the schedule to Standard 1.3.3 are required to undergo an evaluation to ensure there are no public health and safety concerns.

Option 2, which supports the use of glucose oxidase produced by *Aspergillus oryzae* carrying the glucose oxidase gene from *Aspergillus niger* is the preferred option, as approval would allow an alternative safe source of glucose oxidase with no additional cost to government, industry or consumers.

CONSULTATION

ANZFA is seeking public comment in order to assist in assessing this application. A further call for public submissions will be made when the Draft Risk Assessment is released. Comments that would be useful could cover:

- Scientific aspects of this application;
- Other issues, including labelling of processing aids.

Commercial in Confidence (C-I-C) data

Commercial-in-confidence claims have been made in relation to this application. These relate to the genetic modification and the method of production of the enzyme.

Workplan Classification

ANZFA's initial assessment of this application for placement on the Workplan was Group 3, Category 2 (see ANZFA website for further information about the workplan and the different groups and categories). The initial assessment confirms that this grouping is appropriate.

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 *Code* to approve foods developed using processing aids such as glucose oxidase is unlikely to have a significant effect on trade, however this issue will be fully considered in the context of the Regulatory Impact Statement at Draft Assessment (i.e. Full 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.

CONCLUSIONS

The above application fulfils the requirements for preliminary assessment as prescribed in section 13 of the *Australia New Zealand Food Authority Act 1991*.

Accordingly the Authority will now proceed to the Draft Assessment Report (ie Full Assessment).

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*.

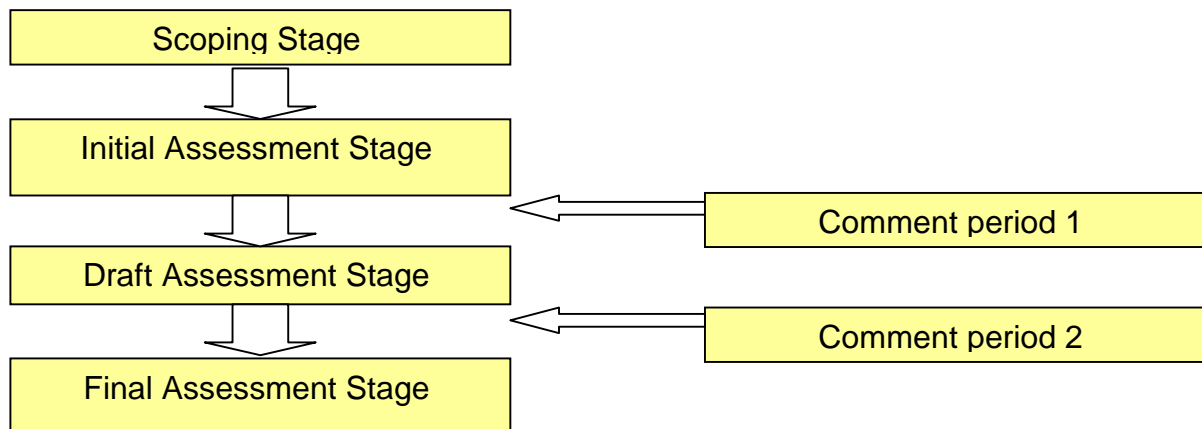
INVITATION FOR PUBLIC SUBMISSIONS

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:

- (a) the need for standards to be based on risk analysis using the best available scientific evidence;
- (b) the promotion 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.

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 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: 24 APRIL 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.