



**09/02**  
**8 May 2002**

**INITIAL ASSESSMENT REPORT**  
**(PRELIMINARY ASSESSMENT – SECTION 13)**

**APPLICATION A453**

**TREHALOSE AS A NOVEL FOOD INGREDIENT**

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

**19 JUNE 2002**

*(See “Invitation for Public Submissions” for details)*

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## 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 (ANZFS) 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*.

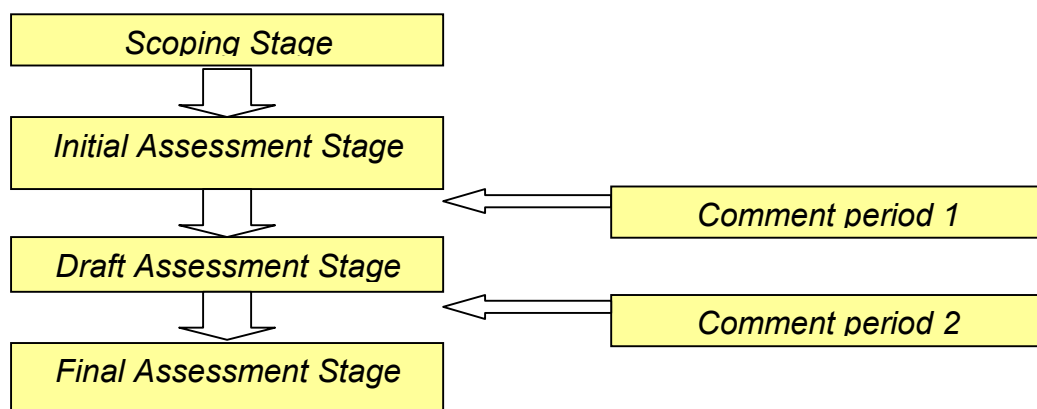
## INVITATION FOR PUBLIC SUBMISSIONS

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 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 reasonably 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](mailto: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](mailto: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](http://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](mailto: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 from Hayashibara Company Ltd. on 4 October 2001 seeking to amend Standards A19/1.5.1 of the *Food Standards Code* to permit the use of trehalose as a novel food ingredient. This application is at the preliminary assessment stage as detailed in the section 13 of the *Australia New Zealand Food Authority Act*.

## REGULATORY PROBLEM

The application is seeking approval of trehalose as a novel food ingredient. Under the current food regulations, novel foods and novel food ingredients are required to undergo a pre-market safety assessment, as per Standard A19/1.5.1 – Novel Foods. The purpose of Standard A19/1.5.1 is to ensure that non-traditional foods, which have features or characteristics that may raise safety concerns will undergo a risk-based safety assessment before they are offered for retail for consumption in Australia or New Zealand.

Novel Foods is defined in the Standard as:

A non-traditional food or food ingredient for which there is insufficient knowledge in the broad community to enable safe use in the form or context in which it is presented, taking into account-

- (a) the composition or structure of the product;
- (b) levels of undesirable substances in the product;
- (c) the potential for adverse effects in humans;
- (d) traditional preparation and cooking methods; or
- (d) patterns and levels of consumption of the product;

Trehalose is considered a novel food ingredient because it is a non-traditional food for which there is insufficient knowledge in the broad community to ensure safe use in the form in which it is presented. Thus, an assessment of its safety is required before it can be marketed.

## **OBJECTIVE**

The application received from Hayashibara Company Ltd. on 4 October 2001 is seeking to amend Standards A19/1.5.1 of the *Food Standards Code* to permit the use of trehalose as a novel food ingredient. The objective of this application is to determine whether the food regulations can be amended to approve the use of trehalose as a novel food ingredient.

Any amendment to the *FSC* needs to be consistent with the section 10 objectives of ANZFA Act. The three primary objectives of the Authority in developing food regulatory measures are:

- (a) the protection of public health and safety;
- (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 and varying standards, ANZFA must also have regard to:

- (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; and
- (d) the promotion of fair trading in food.

## **BACKGROUND**

### **Properties of trehalose**

Trehalose is a disaccharide consisting of 2 glucose units linked by a 1,1  $\alpha$ -glucosidic bond produced by a multi-step enzymatic process. Trehalose occurs widely in nature with small amounts found in certain foods (brewers and bakers yeast, bread, beer and wine, honey and mushrooms).

The applicant claims that trehalose exhibits the same technological properties as sucrose with a relative sweetness of 40-45% of that of sucrose. Therefore, it is useful in food applications where reduced sweetness is desired and has additional functions as a humectant, texturiser, stabiliser and formulation aid. Trehalose does not undergo Maillard (browning) reactions and the applicant claims that trehalose has excellent thermal and hydrolytic stability over a broad pH range for use in food processing. Trehalose can also be used as a cryo-protectant and as a rehydration aid for dehydrated products.

### **Proposed uses**

Trehalose is proposed to be used in the following foods for different applications (e.g : as a flavouring, stabiliser, cryoprotectant and for its rehydration abilities):

- Bakery Creams;
- Biscuits (reduced-fat)
- Cakes (sponge)



- Confectionary (Cream or fruit filled bars; chocolate covered bars);
- Confectionary (high-boils);
- Icings;
- Sugar Coatings;
- Ice-cream;
- Instant Noodles/Rice;
- Processed Fruit (jams, fillings, toppings);
- Restructured Sea Food

These properties and proposed food uses will be assessed at draft assessment.

### **Approval in other countries**

#### *USA*

A Generally Recognised As Safe (GRAS) notification was filed and accepted on 5 October 2000.

#### *EU*

An application was filed (25 May 2000) with the UK Advisory Committee for Novel Foods and Processes (ACNFP) and approval of trehalose as a novel food ingredient was granted (July 2001).

#### *Japan*

It is permitted as a food additive in Japan.

#### *South Korea and Taiwan*

Trehalose is considered as a food.

## **ISSUES TO BE ADDRESSED DURING ASSESSMENT**

### **Dietary considerations**

Based on the US Food consumption data (1989-1991) the Joint FAO/WHO Expert Committee on Food Additives (JECFA) has estimated that the mean estimated intake for trehalose in the proposed foods for adults was 7 grams per day (excluding chewing gum). The estimated daily intake for the 90<sup>th</sup> percentile group was about 16 grams per day. These estimates are based on the intake from all foods and at the highest levels. The realistic dietary intake would be much lower.

The expected dietary exposure for Australia and New Zealand consumers of trehalose will be considered during the Draft Assessment.

### **Nutritional considerations**

Trehalose is broken down (metabolised) to glucose by the enzyme trehalase in the small intestine and then readily absorbed. The metabolism of trehalose resembles maltose or starch

in that both products are absorbed in the form of glucose and very little is absorbed as the parent trehalose. Since trehalose is similar to maltose or starch it may be considered nutritionally equivalent. However, an assessment of any likely nutritional impacts will be considered at Draft Assessment, particularly, on subgroups such as trehalase efficient populations (see below).

### **Safety issues**

The safety of trehalose has been evaluated by JECFA in 2001. On the basis of the available toxicological data (which included human tolerance studies) and the close similarity between the metabolism of trehalose and maltose, JECFA concluded that trehalose did not present a significant risk to human health at the proposed dietary exposure levels from the proposed food uses. JECFA established an acceptable daily intake (ADI) of ‘not specified’, which is reserved for substances of low toxicity.

A small fraction of the population have trehalase deficiency and subsequently may experience gastro-intestinal effects after oral ingestion of large amounts of trehalose similar to individuals that are lactose intolerant. This issue was also considered by JECFA in its evaluation of trehalose.

Further information on the safety of trehalose will be provided at Draft Assessment.

### **REGULATORY OPTIONS**

ANZFA is required to consider the impact of various regulatory (and non-regulatory) options on all sectors of the community, which includes consumers, the food industry and governments in both Australia and New Zealand. The benefits and costs associated with the proposed amendment to the Food Standards Code will be analysed in a Regulatory Impact Assessment.

Parties possibly affected by the options outlined include:

1. Food industry wishing to promote food products with trehalose.
2. Consumers who may benefit from the use of trehalose-containing products.
3. Government agencies enforcing the food regulations.

The regulatory options identified thus far are as follows:

**Option 1.** Not permit the use of trehalose.

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

Although there is no perceived cost for the government, however lack of approval in Australia or New Zealand may be construed as a non-tariff barrier to trade. Industry may also suffer from the non-availability of this ingredient.

Parties disadvantaged by not permitting this substance, are the manufacturers of trehalose and producers who wish to use it in the manufacture of their final food products.

**Option 2.** Permit the use of trehalose.

This option would allow the use of trehalose with no cost to government, industry or consumers, if its safety can be ensured.

Approval of trehalose 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.

## **IMPACT ANALYSIS**

The benefits and costs associated with the proposed amendment to the *Food Standards Code* will be considered at the Draft Assessment.

## **CONSULTATION**

### **Public consultation**

ANZFA is seeking public comment in order to assist in assessing this application. Public submissions will also be sought when the Draft Assessment (Full Assessment – section 15) is released. Comments that would be useful could cover:

- Technological properties of trehalose;
- The safety of trehalose; and
- The labelling of foods and food products containing trehalose.

ANZFA also seeks comments on the following:

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

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

*What are the costs or benefits for business- compliance, reporting, costs, savings, alternative technologies, improved food safety and quality, trade etc?*

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

### **World Trade Organisation (WTO) Notification**

Australia and New Zealand are members of the World Trade Organization (WTO) and are signatories to the agreements on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and on Technical Barriers to Trade (TBT Agreement). In some circumstances, Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comments.

Amending the *Code* to approve the addition of trehalose to foodstuff 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 (formerly 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.

## **OTHER ISSUES**

### **Workplan Classification**

ANZFA's preliminary assessment of this application for placement on the Workplan was Group 2, Category 3 (see ANZFA website for further information about the workplan and the different groups and categories). Following Initial Assessment it is recommended that this is an appropriate grouping.

## **CONCLUSIONS**

The above application fulfils the requirements for Initial Assessment (formerly Preliminary Assessment) as prescribed in section 13 of the *Australia New Zealand Food Authority Act 1991*.

Accordingly the Authority has decided to accept the application and will now proceed to the Draft Assessment Report (formerly Full Assessment).

If subsequently recommended by the Authority and agreed to by the Australia New Zealand Food Standards Council, an amendment to the *Food Standards Code*, as suggested by the applicant, would permit the addition of trehalose to specific foods.