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

7 May 2010
[11-10]

APPLICATION A1033 MALTOTETRAOHYDROLASE AS A PROCESSING AID (ENZYME) APPROVAL REPORT

Executive Summary

Purpose

Food Standards Australia New Zealand (FSANZ) received an Application from Danisco A/S via Axiome Pty Ltd on 3 August 2009. This Application seeks to amend Standard 1.3.3 – Processing Aids of the *Australia New Zealand Food Standards Code* (the Code) to include a new processing aid (enzyme), maltotetraohydrolase, produced from *Bacillus licheniformis* containing a gene encoding for a protein engineered variant of maltotetraohydrolase from *Pseudomonas stutzeri.* (The organism had been previously misclassified as *Pseudomonas saccharophila* in the Application).

The proposed use of the enzyme preparation is in bakery products such as bread, bread buns, whole wheat toast bread, soft rolls and tortillas to delay staling, thereby extending the acceptable eating quality period. To achieve significant anti-staling effects, anti-staling enzymes have to be sufficiently heat-stable to be active during baking after initial starch gelatinization. The Applicant claims this maltotetraohydrolase has superior anti-staling properties due to its improved thermostability and baking performance.

A pre-market assessment of the safety of the enzyme, including the source and donor organisms, as well as assessing the technological function of the enzyme, is required prior to any approval being granted. Processing aids used in food manufacture are regulated under Standard 1.3.3. Maltotetraohydrolase from any source is currently not permitted in accordance with Standard 1.3.3.

To date, there has been no evaluation of maltotetraohydrolase from *B. licheniformis* by the Joint FAO/WHO Expert Committee on Food Additives and Contaminants (JECFA). The maltotetraohydrolase enzyme preparation complies with relevant international specifications for enzyme preparations prepared by the FAO/WHO Expert Committee on Food Additives at its sixty-seventh meeting (2006) for publication in FAO JECFA Monographs 3 (JECFA, 2006) and specifications of the Food Chemicals Codex (FCC), 6th Ed, 2008.

Maltotetraohydrolase produced by *B. licheniformis* containing the gene for maltotetraohydrolase from *P. stutzeri* has been approved for use in baking in Mexico (publication pending); has received a 'no-questions' letter to an assessment for self-GRAS determination (GRN: 277) in the USA; and is under consideration for approval in Canada and Denmark.

The Application was assessed under the General Procedure.

Risk Assessment

The risk assessment has considered the technological function, identity and safety of the donor and host microorganisms and safety of the maltotetraohydrolase enzyme preparation.

Based on suitable data, it was concluded no toxicological or hazard-related concerns with the enzyme or the donor or host micro-organisms were revealed which would preclude permitting use of the enzyme as a food processing aid. The absence of any specific hazards being identified is consistent with maltotetraohydrolase undergoing normal proteolytic digestion in the gastrointestinal tract. It was further concluded that the proposed use of the enzyme, namely to retard the staling process of baked goods, was technologically justified and demonstrated to be effective.

Key findings of the evaluation are:

- There is no evidence of toxicity associated with the enzyme preparation in either the acute or 90 day toxicity studies.
- In the absence of any treatment-related effects in the 90-day study, the No Observed Adverse Effect Level (NOAEL) is 79 mg total protein/kg bw/day, which corresponds to the highest dose level tested. This is equivalent to 90.9 mg Total Organic Solids (TOS)/kg bw/day or 241318 Betamyl Units[1](BMU) /kg bw/day.
- The Acceptable Daily Intake (ADI) for maltotetraohydrolase derived from a genetically modified *B. licheniformis* is 'not specified' indicating a food substance of very low toxicity which does not represent a hazard to health.
- There is no evidence of genotoxicity in two *in vitro* studies with the enzyme preparation.
- There is no evidence of any immunologically significant amino acid similarity between maltotetraohydrolase and known allergens.
- The source organism, *B. licheniformis*, is regarded as non-pathogenic and non-toxigenic and has a safe history of use in the production of food enzymes.
- Maltotetraohydrolase produced from genetically modified *B. licheniformis* has greater thermostability and baking performance over the wild type maltotetraohydrolase.
- Maltotetraohydrolase produced from genetically modified *B. licheniformis* meets international specification requirements for enzyme preparations.
- The taxonomic identity of the donor organism based on molecular techniques is *P. stutzeri*.

Assessing the Application

In assessing the Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters as prescribed in section 29 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act):

[1] Betamyl Unit is the unit of measure used for defining the enzyme activity of the preparation

- whether costs that would arise from a food regulatory measure developed or varied as a result of the Application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure

- whether other measures (available to the Authority or not) would be more cost-effective than a variation to Standard 1.3.3

- any relevant New Zealand standards

- any other relevant matters.

Decision

To approve the draft variation to the Table to clause 17 of Standard 1.3.3 – Processing Aids, to permit the use of maltotetraohydrolase produced by a genetically modified *Bacillus licheniformis* strain containing the gene for a protein-engineered variant of maltotetraohydrolase isolated from *Pseudomonas stutzeri*.

Reasons for Decision

An amendment to the Code approving the use of the maltotetraohydrolase enzyme preparation as a processing aid in Australia and New Zealand is approved on the basis of the available evidence for the following reasons:

- A detailed safety assessment has concluded that the use of the enzyme does not raise any public health and safety concerns.

- The source organism, *B. licheniformis,* is regarded as non-pathogenic and non-toxigenic and has a safe history of use in the production of food enzymes.

- Use of this maltotetraohydrolase is technologically justified and would be expected to provide benefits to food manufacturers and consumers.

- Permitting use of the enzyme would not impose significant costs for government agencies, consumers or manufacturers.

- The proposed draft variation to the Code is consistent with the section 18 objectives of the FSANZ Act.

- There are no relevant New Zealand standards.

Labelling

Labelling addresses the objective set out in section 18(1)(b) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act); the provision of adequate information relating to food to enable consumers to make informed choices.

Standard 1.5.2 – Food produced using Gene Technology, outlines provisions for labelling of foods produced using gene technology. Although processing aids are not normally subject to labelling on the final food, under clause 4(1)(d) of Standard 1.5.2, labelling requirements do apply for processing aids where novel DNA and/or novel protein from the processing aid remains present in the final food.

Food produced using maltotetraohydrolase produced from a genetically modified *B. licheniformis* strain containing a gene encoding a protein engineered variant of maltotetraohydrolase from *P. stutzeri* would be required to be labelled 'genetically modified' in conjunction with the name of the processing aid where novel protein remains in the final food.

Maltotetraohydrolase produced by a genetically modified strain of *B. licheniformis* is not considered to be allergenic. During production of the enzyme sorbitol and glucose (derived from gluten containing cereals), soy flour and lactose are used as fermentation nutrients. Should these products be present in foods produced using this enzyme, the food must be labelled in accordance with the requirements of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations.

Consultation

Public submissions were invited on the Assessment Report between 16 December 2009 and 10 February 2010. Comments were specifically requested on the scientific aspects of the Application, including the technological function and any information relevant to the safety assessment of the enzyme maltotetraohydrolase produced by a genetically modified strain of *B. licheniformis* to be used as a processing aid.

A total of nine submissions were received as a result of the public consultation. A summary of these is included at **Attachment 2** of this report.

Opposition to the Application was recorded from four submitters, all consumers and all stating general opposition to foods produced using gene technology. Three government agencies, one industry organisation and one professional organisation all supported the application. Those who supported the Application uniformly agreed that the enzyme was technologically justified, demonstrated to be effective for the stated purpose and that no public health and safety concerns had been identified.

As this Application was assessed under a General Procedure, there was one round of public comment. Responses to the Assessment Report were used to develop the Approval Report for the Application. The main issues raised in public comments are discussed in the Approval Report.

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SUPPORTING DOCUMENTS

The following materials were used in the preparation of the Approval Report for this Application and are available on the FSANZ website at http://www.foodstandards.gov.au/foodstandards/applications/applicationa1033malt4586.cfm:

SD1: Risk Assessment Report: Application A1033 Maltotetraohydrolase as a processing aid (enzyme).

Introduction

Food Standards Australia New Zealand (FSANZ) received an Application from Danisco A/S via Axiome Pty Ltd on 3 August 2009. This Application seeks to amend Standard 1.3.3 – Processing Aids of the *Australia New Zealand Food Standards Code* (the Code) to include a new processing aid (enzyme); maltotetraohydrolase. This enzyme has been produced by a non-pathogenic and non-toxigenic genetically modified strain of *B. licheniformis* and is proposed to be used as a processing aid to retard staling in baked goods. The Applicant refers to the enzyme preparation containing this maltotetraohydrolase as Amylase SAS3.

Maltotetraohydrolase (EC 3.2.1.60) is an enzyme belonging to the amylase or glycoside hydrolase family. This enzyme catalyses the hydrolysis of (1,4)-α-D-glucosidic linkages in amylaceous polysaccharides to remove successive maltotetraose residues from the non-reducing chain ends. Shortening the amylopectin side chains and releasing maltooligosaccharides reduces staling by lowering the rate of amylopectin retrogradation without disadvantageous side effects caused by excessive weakening of the amylose network. The Applicant claims this maltotetraohydrolase has improved thermostability and baking performance over the wild type maltotetraohydrolase.

FSANZ completed a safety assessment of the enzyme, including the source and donor organisms, as well as an assessment of the technological function of the enzyme. The Assessment Report was released in December 2009, with public comment sought on the safety assessment and proposed recommendations. Comments received were considered in the completion of this Approval Report

1. The Issue / Problem

The Applicant proposes the use of maltotetraohydrolase produced from a non-toxigenic genetically modified strain of *B. licheniformis* as a processing aid to retard staling in baked goods.

A pre-market assessment and approval is required before permission may be granted for any new processing aid.

2. Current Standard

2.1 Current Standard

Processing aids used in food manufacture are regulated under Standard 1.3.3.

A processing aid is described in clause 1 of Standard 1.3.3 as:

A substance listed in clauses 3 to 18, where –

(a) the substance is 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; and

(b) the substance is used in the course of manufacture of a food at the lowest level necessary to achieve a function in the processing of that food, irrespective of any maximum permitted level specified.

Table to clause 17- Permitted enzymes of microbial origin, contains a list of permitted enzymes and the microorganism/s (including genetically modified organisms) from which they can be derived.

Maltotetraohydrolase from any source is currently not permitted as a processing aid in Standard 1.3.3.

2.2 International regulations

To date, there has been no evaluation of maltotetraohydrolase from *B. licheniformis* by the Joint FAO/WHO Expert Committee on Food Additives and Contaminants (JECFA). However, amylase from *B. licheniformis* has been reviewed by JECFA in 1986 with an acceptable daily intake (ADI) of 'not specified' determined.

Maltotetraohydrolase produced by *B. licheniformis* which contains the gene for maltotetraohydrolase from *P. stutzeri* has been approved for use in baking in Mexico (publication pending); has received a 'no-questions' letter to an assessment for self-GRAS determination (GRN: 277) in the United States; and is under consideration for approval in Canada and Denmark.

Specifications written for the maltotetraohydrolase enzyme preparation comply with the relevant international specifications for enzyme preparations prepared by the FAO/WHO Expert Committee on Food Additives at its sixty-seventh meeting (2006) for publication in FAO JECFA Monographs 3 (JECFA, 2006) and specifications of the Food Chemicals Codex, 6th Ed, 2008.

2.3 Nature of the Enzyme and Source of Organism

Maltotetraohydrolase (EC 3.2.1.60) is a hydrolase enzyme that catalyses the hydrolysis of (1, 4)–α–D-glucosidic linkages in amylaceous polysaccharides to remove successive maltotetraose residues from the non-reducing chain ends.

The source organism is a non-pathogenic and non-toxigenic strain of *B. licheniformis* with a history of safe use in the production of food enzymes.

2.4 Technological purpose

The enzyme preparation is proposed to be used in bakery products such as bread, bread buns, whole wheat toast bread, soft rolls and tortillas to delay staling and thereby extend the acceptable eating quality period. To achieve significant anti-staling effects, anti-staling enzymes have to be sufficiently heat-stable to be active during baking after initial starch gelatinization. The Applicant claims this maltotetraohydrolase has superior anti-staling properties due to its improved thermostability and baking performance.

3. Objectives

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. These are:

- the protection of public health and safety; and
- 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

The Ministerial Council Policy Guideline on the Addition to Food of Substances other than Vitamins and Minerals includes policy principles in regard to substances added to achieve a solely technological function such as food additives and processing aids. According to these guidelines, permissions should be granted where:

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the 'stated purpose')
- the addition of the substance to food is safe for human consumption
- the amounts added are consistent with achieving the technological function
- the substance is added in a quantity and a form which is consistent with delivering the stated purpose
- no nutrition, health or related claims are to be made in regard to the substance.

4. Questions to be answered

For this Application, FSANZ has considered the following key questions:

- What is the risk to public health and safety from the use of maltotetraohydrolase produced by a genetically modified strain of *B. licheniformis* as a processing aid?
- Is the new genetically modified strain of *B. licheniformis* safe for producing maltotetraohydrolase?
- Does the final enzyme product contain any allergenic materials?
- Does the enzyme achieve its technical function?

RISK ASSESSMENT

A detailed assessment of the safety and functionality of maltotetraohydrolase has been undertaken for this Application. The summary and conclusions from this risk assessment (Supporting Document 1) are presented below.

In addition to information supplied by the Applicant, other available resource material including published scientific literature and general technical information was used in this assessment.

5. Risk Assessment Summary

The risk assessment has considered the technological function, identity and safety of the donor and host micro-organisms and safety of the maltotetraohydrolase enzyme preparation.

Based on suitable data, it was concluded no toxicological or hazard-related concerns with the enzyme or the donor or host micro-organisms were revealed which would preclude permitting use of the enzyme as a food processing aid. The absence of any specific hazards being identified is consistent with maltotetraohydrolase undergoing normal proteolytic digestion in the gastrointestinal tract. It was further concluded that the proposed use of the enzyme, namely to retard the staling process of baked goods, was technologically justified.

Sufficient information was available to provide an acceptable level of confidence in the conclusions of this risk assessment.

5.1 Safety Assessment

B. licheniformis, strain Bra7, was modified using recombinant DNA techniques to contain the gene for an engineered form of maltotetraohydrolase PS4wt (hereafter referred to as 'wild type') from *P. stutzeri*.

The hazard assessment concluded that:

- there is no evidence of toxicity associated with the enzyme preparation in either the acute or 90 day toxicity studies
- in the absence of any treatment related effects in the 90-day study, the NOAEL is 79 mg total protein/kg bw/day, which corresponds to the highest dose level tested. This is equivalent to 90.9 mg TOS/kg bw/day or 241318 BMU/kg bw/day
- there is no evidence of genotoxicity in two *in vitro* studies with the enzyme preparation
- there is no evidence of any immunologically significant amino acid similarity between maltotetraohydrolase and known allergens.

Based on the available evidence, which did not reveal any specific hazards, it is concluded that no safety concerns are associated with the proposed use of maltotetraohydrolase from *B. licheniformis*. The absence of any specific hazards is consistent with maltotetraohydrolase undergoing normal proteolytic digestion in the gastrointestinal tract.

The ADI for maltotetraohydrolase is 'not specified'. An ADI 'not specified' is applicable to a food substance of very low toxicity which, on the basis of the available data (chemical, biochemical, toxicological, and other), the total dietary intake of the substance arising from its use at the levels necessary to achieve the desired effect and from its usage in different foods, does not represent a hazard to health.

5.2 Dietary Exposure Assessment

The Applicant provided dietary exposure information based on consumption of wheat and rye based bakery products data obtained from national food surveys and consumption statistics from a range of countries including Australia and New Zealand. The data indicate that even with a maximum daily exposure of 0.098 mg total protein/kg body weight/day, the NOAEL (79 mg total protein/kg bw/day) offers a greater than 800x margin of safety.

This is predicated on the assumptions that active enzyme remains in the food, 100% market penetration and the consumption information detailed in the Application.

The large margin of safety evidenced from the above consumption data and the ADI indicate that further dietary exposure assessment is unnecessary.

Processing aids perform their technological function during the manufacture of food and are therefore either not present in the final food or present only at very low levels. Maltotetraohydrolase is expected to be largely inactivated during baking and have no further technical effect after baking. Any residual enzyme would be present as denatured protein and would undergo normal proteolytic digestion in the gastrointestinal tract.

5.3 Technological Justification

Maltotetraohydrolase (EC 3.2.1.60) is a hydrolase enzyme that catalyses the hydrolysis of (1, 4)–α–D-glucosidic linkages in amylaceous polysaccharides to remove successive maltotetraose residues from the non-reducing chain ends. The commercial enzyme product has been observed to have no other enzymatic activities.

The enzyme preparation is proposed to be used in bakery products such as bread, bread buns, whole wheat toast bread, soft rolls and tortillas to delay staling and thereby extend the acceptable eating quality period. To achieve significant anti-staling effects, anti-staling enzymes have to be sufficiently heat-stable to be active during baking after initial starch gelatinisation.

Maltotetraohydrolase derived from a genetically modified *B. licheniformis* strain has been shown to have greater thermostability and baking performance over the wild type maltotetraohydrolase. The half-life and crumb firmness and resilience data presented by the Applicant provides adequate assurance that the stated purpose for this maltotetraohydrolase, namely to reduce staling, is technologically justified and the enzyme has been demonstrated to be effective in achieving this purpose.

5.4 Production of the enzyme

The maltotetraohydrolase is produced by a submerged fermentation of *B. licheniformis* carrying the gene encoding a protein engineered variant of the wild type maltotetraohydrolase from *P. stutzeri*. The fermentation process uses appropriate substrates and nutrients followed by several filtration and purification steps. The isolated enzyme concentrate is stabilised with potassium sorbate and then dried and agglomerated using any one of the common drying methods, such as spray drying, fluid bed agglomeration or fluid bed spray drying.

Specifications written for this maltotetraohydrolase comply with the international specifications relevant for enzymes prepared by the FAO/WHO Expert Committee on Food Additives at its sixty-seventh meeting for publication in FAO JECFA Monographs 3 (JECFA, 2006). These specifications are primary reference sources listed in clause 2 of Standard 1.3.4 – Identity and Purity.

The source organism is a non-pathogenic and non-toxigenic organism with a history of safe use for the production of food enzymes.

5.5 Allergenicity

The Applicant has provided an allergen statement indicating that sorbitol and glucose (derived from gluten containing cereals), soy flour and lactose are used as fermentation nutrients during the fermentation process.

Should these products be present in the enzyme preparation and carry over into final food products, the food must be labelled in accordance with requirements set out in Standard 1.2.3.

Risk Management

6. Issues raised

6.1 Risk Management Strategy

The risk assessment concludes that use of maltotetraohydrolase, sourced from genetically modified *B. Licheniformis,* as a processing aid does not pose a public health and safety risk and that its proposed use is technologically justified.

Maltotetraohydrolase produced by a genetically modified *B. licheniformis* strain containing the gene encoding a protein engineered variant of maltotetraohydrolase from *P. stutzeri* was developed to have increased temperature stability and baking performance over the wild type maltotetraohydrolase. This maltotetraohydrolase contains sixteen amino acid changes compared to the sequence of the catalytic core of the wild type maltotetraohydrolase. The Applicant claims this modification is well within the natural variation observed in nature. Nevertheless since there is no evidence that these specific changes occur in nature, the protein produced by this genetically modified organism is considered novel.

Labelling addresses the objective set out in section 18(1)(b) of the FSANZ Act; the provision of adequate information relating to food to enable consumers to make informed choices.

Standard 1.5.2, outlines provisions for labelling of foods produced using gene technology. Although processing aids are not normally subject to labelling on the final food, under clause 4(1)(d) of Standard 1.5.2, labelling requirements do apply for processing aids where novel DNA and/or novel protein from the processing aid remains present in the final food. Novel DNA and/or novel protein is defined in clause 4(1) of Standard 1.5.2 as being DNA or a protein which, as a result of the use of gene technology, is different in chemical sequence or structure from DNA or protein present in counterpart food which has not been produced using gene technology.

If approved, food produced using this maltotetraohydrolase would be required to be labelled 'genetically modified' in conjunction with the name of the processing aid where novel protein remains in the final food.

Processing aid approvals are not regulated under Standard 1.5.2. Therefore no variation or amendment to the Table to clause 2 is considered necessary.

Information provided within Section 2 of Appendix B of the Application state results of 16s rDNA sequencing indicate the donor organism strain, IAM1504, more closely resembles *P. stutzeri* species rather than *P. saccharophila* as originally stated and should be reclassified as such (Refer to Microbiological Assessment in Risk Assessment Report [Supporting Document 1]). In the USA, a similar application submitted for self-GRAS (Generally Recognised as Safe) status for this enzyme identified the donor organism as *P. saccharophila*, whilst approval was granted under *P. stutzeri*.

After consideration of the 16s rDNA evidence and to maintain consistency with international permissions, FSANZ will refer to the donor organism as *P. stutzeri*. This has been discussed with, and endorsed by, the Applicant.

7. Options

As processing aids require a pre-market approval under Standard 1.3.3, it is not appropriate to consider non-regulatory options. Consequently, two regulatory options have been identified for this Application:

Option 1: Reject the Application

Option 2: Amend Standard 1.3.3 to permit the use of maltotetraohydrolase produced by *B. licheniformis* containing the gene for maltotetraohydrolase isolated from *P. stutzeri*, as a processing aid.

8. Impact Analysis

FSANZ is required to consider the impact of various regulatory and non-regulatory options on all sectors of the community, especially relevant stakeholders who may be affected by this Application. The benefits and costs associated with the proposed amendment to the Code have been analysed using regulatory impact principles.

In accordance with the Best Practice Regulation Guidelines, completion of a preliminary assessment for this application indicated a low or negligible impact. The Office of Best Practice Regulation has advised that the application appears to be of a minor or machinery nature; notified approval of the preliminary assessment (RIS ID: 10857) and further advised that a Regulatory Impact Statement (RIS) is not required.

8.1 Affected Parties

The affected parties may include:

- those sectors of the food industry wishing to use maltotetraohydrolase as a processing aid
- consumers of food products in which maltotetraohydrolase is used as a processing aid
- Government agencies with responsibility for compliance and enforcement of the Code.

8.2 Benefit Cost Analysis

8.2.1 Option 1: Reject the Application

This option is the *status quo*, with no changes required to the Code.

- Food industries and consumers may be disadvantaged as they would be unable to capture the benefits conferred by the technological function of the new enzyme.
- There is no identified impact on government agencies.

8.2.2 Option 2: Amend Standard 1.3.3 to permit the use of maltotetraohydrolase produced by B. licheniformis containing the gene for maltotetraohydrolase isolated from P. stutzeri, as a processing aid

- allows food industry choice

- manufacturers may benefit as improvements to product quality and shelf life may increase marketability of the final food product and improve market share

- consumers may benefit from foods produced using maltotetraohydrolase through reduced wastage associated with staling; longer product shelf life and therefore extended periods of acceptable eating quality

- there should be no additional costs imposed on consumers

- there is not predicted to be any significant cost impost on jurisdictions to determine compliance with the proposed amendment compared with current monitoring and compliance activities.

8.3 Comparison of Options

Option 1 appears to provide no apparent benefits to industry, consumers or government. It denies industry access to a safe, technologically justified processing aid for use in bakery applications to retard the staling process.

Option 2 does not appear to impose any significant costs on industry, consumers or government. It provides benefits to industry in terms of product innovation and potential benefits for industry and consumers in prolonging the acceptable eating quality of baked goods and reducing wastage associated with staling.

In considering the costs and benefits associated with both options, Option 2 would be the preferred option as it conveys benefits for the food industry and consumers without imposing significant costs for government agencies, consumers or manufacturers.

Communication and Consultation Strategy

9. Communication

FSANZ has applied a basic communication strategy to this Application. The strategy involved advertising the availability of the assessment reports for public comment in the national press and placing the reports on the FSANZ website.

The process by which FSANZ considers standard matters is open, accountable, consultative and transparent. The purpose of inviting public submissions is to obtain the views of interested parties on the issues raised by the application and the impacts of regulatory options. The issues raised in the public submissions are evaluated and addressed in FSANZ assessment reports.

The Applicant, individuals and organisations that made submissions on this Application will be notified at each stage of the Application. The decision of the FSANZ Board to approve the draft variation to Standard 1.3.3 will be notified to the Ministerial Council. If a request to review the decision is not made by the Ministerial Council, the variation to the Code will be gazetted. Stakeholders (including the Applicant) and submitters will be advised of the notification and gazettal in the national press and on the FSANZ website.

10. Consultation

10.1 Public Consultation

The Assessment Report was notified for public comment between 16 December 2009 and 10 February 2010. Comments were specifically requested on the scientific aspects of the Application including the technological function and any safety considerations, as well as information relating to any potential costs or benefits associated with use of maltotetraohydrolase as a processing aid. As this Application was assessed under a General Procedure, only one round of public comment was held.

Nine submissions were received in response to the public consultation on the Assessment Report. A summary of these is provided in **Attachment 2** to this Report.

Opposition to the Application was recorded from four submitters, all consumers and all stating general opposition to foods produced using gene technology.

Three government agencies, one industry body and one professional organisation all supported the application. Those who supported the Application uniformly agreed that the enzyme was technologically justified, demonstrated to be effective for the stated purpose and that no public health and safety concerns had been identified.

Responses to general GM food issues are available from the FSANZ website[2]. FSANZ has taken submitters' comments into account in preparing the Approval Report for this Application. Discussed below are specific concerns raised in submissions for further consideration.

10.1.1 Deferment of all considerations pending the Food Labelling Review

Some submitters disagreed with the current labelling requirements for GM foods and requested deferment of all future approval processes pending publication of the Food Labelling Review and outcomes of a report being prepared by Dr Judy Carman, spokesperson on genetically modified (GM) foods for the Public Health Association of Australia (PHAA), on the safety aspects of GM foods.

10.1.1.1 Response

FSANZ has a statutory obligation to consider all applications within a statutory timeframe and cannot hold up a consideration process on the grounds that information may become available at a future point. FSANZ is therefore unable to comply with this request.

10.1.2 Clarification of labelling for allergenic substances

One jurisdiction considered the wording used in the Assessment Report does not clearly indicate that the onus is on the food manufacturer to ensure labelling of allergenic substances is in compliance with Standard 1.2.3. It proposed the processing aid producer be advised to provide advice to food manufacturers to enable them to comply with clause 4 of Standard 1.2.3.

[2] http://www.foodstandards.gov.au/foodmatters/gmfoods/frequentlyaskedquest3862.cfm

10.1.2.1 Response

Approvals are given to the actual enzyme and the sources from which it is produced, not the enzyme preparation. It is the responsibility of the food manufacturer to ensure that food produced complies with all relevant provisions of the Code by sourcing appropriate information from their suppliers.

Standard 1.2.3 sets out mandatory advisory statements and declarations which must be made in relation to certain foods or foods containing certain substances. The Applicant has stated that sorbitol and glucose (derived from gluten containing cereals), soy flour and lactose are used as fermentation nutrients during the fermentation process and therefore these substances may be present in the final enzyme preparation.

In order to comply with Standard 1.2.3, food manufacturers using this enzyme preparation would have to declare the presence of any allergenic substance on the label of a food product should these allergenic substances be present in the final food.

10.1.3 Provision of details for residual novel protein in the final food

One jurisdiction stated that whilst they agreed that food produced using this maltotetraohydrolase would be required to be labelled as genetically modified where novel protein remains in the final food, they proposed that the applicant provide details of any residual novel DNA and/or novel protein to the food manufacturer as it was claimed it would be unreasonable and costly for food manufacturers to undertake such determinations.

10.1.3.1 Response

It is the responsibility of the food manufacturer to ensure that food produced complies with all relevant provisions of the Code by sourcing appropriate information from their suppliers.

It is clear from the proposed permission in the Code that this is a novel protein and therefore no question that it is present in the enzyme preparation. Consequently there is no need to make such a determination and therefore no cost to manufacturers. It is up to the manufacturer of the final product to determine if the protein is still present; the enzyme supplier could not do that.

FSANZ considers that amendment to this Approval Report is therefore unnecessary.

10.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

Amending the Code to allow maltotetraohydrolase as a permitted processing aid (enzyme) is unlikely to have a significant effect on international trade as the enzyme preparation complies with international standards for food enzymes as gazetted by JECFA and the Food Chemicals Codex.

Notification to WTO under FSANZ's obligations under the WTO Technical Barriers to Trade (TBT) or Sanitary and Phytosanitary Measures (SPS) Agreements was not considered necessary.

Conclusion

11. Conclusion and Decision

This Application has been assessed against the requirements of section 29 of the FSANZ Act with FSANZ recommending the proposed draft variation to Standard 1.3.3.

The Assessment Report concluded that use of maltotetraohydrolase produced by *B. licheniformis* containing the gene for maltotetraohydrolase from *P. stutzeri*, as a processing aid, is technologically justified and does not pose a public health and safety risk.

An amendment to the Code giving permission for the use of maltotetraohydrolase as a processing aid in Australia and New Zealand is recommended on the basis of the available scientific information.

The variation is provided in **Attachment 1**.

Decision

To approve the draft variation to the Table to clause 17 of Standard 1.3.3 – Processing Aids, to permit the use of maltotetraohydrolase produced by a genetically modified *Bacillus licheniformis* strain containing the gene for a protein-engineered variant of maltotetraohydrolase isolated from *Pseudomonas stutzeri*.

11.1 Reasons for Decision

An amendment to the Code approving the use of maltotetraohydrolase as a processing aid in Australia and New Zealand is proposed on the basis of the available evidence for the following reasons:

- A detailed safety assessment has concluded that the use of the enzyme does not raise any public health and safety concerns.
- The source organism, *B. licheniformis* is regarded as non-pathogenic and non-toxigenic and has a safe history of use in production of food enzymes.
- Use of maltotetraohydrolase a genetically modified *B. licheniformis* strain as a processing aid is technologically justified and would be expected to provide benefits to food manufacturers and consumers.
- Permitting use of the enzyme would not impose significant costs for government agencies, consumers or manufacturers.
- The proposed draft variation to the Code is consistent with the section 18 objectives of the FSANZ Act.
- There are no relevant New Zealand standards.

12. Implementation and Review

The FSANZ Board's decision will be notified to the Ministerial Council. Following notification, the proposed draft variation to the Code is expected to come into effect on gazettal, subject to any request from the Ministerial Council for a review of FSANZ's decision.

ATTACHMENTS

1. Draft variations to the *Australia New Zealand Food Standards Code*
2. Summary of issues raised in public submissions

Attachment 1

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

Subsection 87(8) of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunsetting

To commence: on gazettal

[1] ***Standard 1.3.3*** *of the Australia New Zealand Food Standards Code is varied by –*

[1.1] *inserting in the* Table to clause 17 –

Maltotetraohydrolase, protein engineered variant EC 3.2.1.60	*Bacillus licheniformis*, containing the gene for maltotetraohydrolase isolated from *Pseudomonas stutzeri*

[1.2] *inserting after* subclause 17(2) –

Editorial note:

See Division 2 of Standard 1.5.2 – Food produced using Gene Technology for labelling requirements that apply to processing aids produced using gene technology.

Attachment 2

Summary of Public Submissions on Assessment Report

Nine submissions were received in response to the public consultation on the Assessment Report.

Opposition to the Application was recorded from four submitters, all consumers; all stating general opposition to foods produced using gene technology.

Three Government agencies, one industry organisation and one professional organisation all supported the application. Those who supported the Application uniformly agreed that the enzyme was technologically justified, demonstrated to be effective for the stated purpose and that no public health and safety concerns had been identified.

A summary of all submissions received is provided in the below table.

Submitter	Group	Comments
Paul Elwell-Sutton	Private	• Opposes Application • Claims little or no evidence has been presented to demonstrate absence of degenerative cellular aging from consumption of GM food in the long term • Claims an absence of robust GM labelling protocols deprive consumers of informed purchasing options
NSW Food Authority	Government	• Supports progression • Rationale for position cited includes: – Demonstrated effective technological function – No evidence of toxicity associated with enzyme – Source organism has long history of safe use – No evidence to suggest donor organism is associated with food-borne illness – International approvals currently exist – Notes requirement for GM labelling if present in final food – Notes enzyme expected to be largely inactivated in final food
NZFSA	Government	• Supports Option 2 • Satisfied the proposed use is technologically justified • Satisfied there are no public health and safety concerns identified
Shirley Collins	Private	• Requests an embargo be placed on GM foods
Michelle Denise	Private	• Requests deferment of approval pending outcome of Food Labelling Review and Dr Judy Carman report
AFGC	Industry Association	• Supports the Application

Submitter	Group	Comments
Queensland Health	Government	• Agrees with preferred approach • Notes that allergenic substances are used as fermentation nutrients. States that if these substances are present in final enzyme preparation, then the processing aid producer must supply advice to food manufacturers of their presence in order for the food manufacturer to comply with Standard 1.2.3 (4). • Notes the Code currently places the onus on the food manufacturer or relevant authority to secure such information in order to comply at retail level. • Claims the wording in the Assessment Report does not clearly highlight this shortcoming of the Code and requests this be addressed • Agrees that food produced using this enzyme would require GM labelling where novel protein remains in the final food. • Suggests that it is appropriate for the applicant to provide details of any residual novel protein. • Claims it would be unreasonable and costly for food manufacturers to undertake such determinations and requests this be addressed
The Hon Lynn MacLaren MLC	Greens (WA)	• Opposes any new submission that pre-empts release/outcomes of labelling review. • Biotech industry failed to demonstrate safe ethical procedures/practices • Supports consumer driven approach to labelling – GM labelling
Food Technology Association of Australia	Industry Association	• Accepts Option 2