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

16 December 2009
[20-09]

APPLICATION A1033 MALTOTETRAOHYDROLASE AS A PROCESSING AID (ENZYME) ASSESSMENT 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 is being 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 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*.

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

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.

If approved, food produced using maltotetraohydrolase 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 the final enzyme preparation, they must be labelled in accordance with the requirements of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations.

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):

- 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; and
- any other relevant matters.

Preferred Approach

To prepare a 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 Preferred Approach

An amendment to the Code approving the use of the maltotetraohydrolase enzyme preparation 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 the production of food enzymes.

- Use of maltotetraohydrolase a genetically modified *B. licheniformis* 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.

Consultation

Public submissions are now invited on this Assessment Report. Comments are specifically requested on the scientific aspects of this 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.

As this Application is being assessed as a general procedure, there will be one round of public comment. Submissions to this Assessment Report will be used to develop the Approval Report for this Application.

Invitation for Submissions

FSANZ invites public comment on this Report and the draft variation to the Code based on regulation impact principles for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in further considering this Application/Proposal. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 of the FSANZ Act. 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 should be in sufficient detail as to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information, separate it from your submission and provide justification for treating it as confidential commercial material. Section 114 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Alternatively, you may email your submission directly to the Standards Management Officer at submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 10 Feruary 2010

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

Submissions received after this date will only be considered if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions relating to making submissions or the application process can be directed to the Standards Management Officer at standards.management@foodstandards.gov.au.

If you are unable to submit your submission electronically, hard copy submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 978 5636

CONTENTS

SUPPORTING DOCUMENTS

The following materials, which were used in the preparation of this Assessment Report, 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.

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 any new processing aid is permitted. Consideration of a safety assessment of the enzyme, including the source and donor organisms, as well as assessing the technological function of the enzyme for its purported use is required before any permission may be granted.

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* 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 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

The objective of this Assessment is to determine whether it is appropriate to amend Standard 1.3.3 to permit the use of the enzyme maltotetraohydrolase a genetically modified *B. licheniformis* strain for use as a processing aid.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 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: *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; and
- 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 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 microorganisms 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 (Acceptable Daily Intake) 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 acceptable background in food, 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 gelatinization.

Maltotetraohydrolase a genetically modified *B. licheniformis* strain has 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, of the Code

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 final enzyme preparation, they must be labelled in accordance with the requirements of 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.

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, 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 *Pseudomonas 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 shelflife 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 shelflife 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. Option 1 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. Option 2 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 developed and will apply a basic communication strategy to this Application. The strategy involves 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 making submissions on this Application will be notified at each stage of the Application. If the FSANZ Board approves the draft variation to the Code, FSANZ will notify its decision to the Ministerial Council. The Applicant and stakeholders, including the public, will be notified of the gazetted changes to the Code in the national press and on the FSANZ website.

10. Consultation

FSANZ is seeking comment from the public and other interested stakeholders to assist in assessing this Application. Once the public comment period has closed there will be no further round of public comment.

Comments are sought in relation to 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.

10.1 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 FCC.

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

Conclusion

11. Conclusion and Preferred Option

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 concludes 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 proposed draft variation is provided in **Attachment 1**.

Preferred Approach

To prepare a 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 Preferred Approach

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

Following the consultation period for this document, an Approval Report will be completed and the draft variation will be considered for approval by the FSANZ Board. The FSANZ Board's decision will then 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.

ATTACHMENT

1. Draft variation to the *Australia New Zealand Food Standards Code*

Attachment 1

Draft variation 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 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*

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