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

2 November 2011
[21-11]

APPLICATION A1061
AMYLOMALTASE AS A PROCESSING AID (ENZYME)
ASSESSMENT REPORT

Executive Summary

Purpose

Food Standards Australia New Zealand (FSANZ) received an Application from DSM Food Specialties on 21 April 2011. This Application seeks to amend Standard 1.3.3 – Processing Aids of the *Australia New Zealand Food Standards Code* (the Code) to allow the use of a new enzyme, amylomaltase, sourced from a genetically modified (GM) *Bacillus amyloliquefaciens* microorganism containing the gene for amylomaltase from *Thermus thermophilus, as* an approved food processing aid.

The proposed use of the enzyme is to produce modified potato starch by converting glucose units from amylose to amylopectin. The Applicant claims the modified potato starch has excellent thermo-reversible gelling properties and may be used as a replacement for fat and casein and other fat and casein substitutes in food. Typical applications in which the modified potato starch is proposed to be used as an ingredient include yoghurts and yoghurt drinks, ice cream, cheese analogues and low fat spreads. The production organism (*B. amyloliquefaciens*) has a history of safe use in production of enzyme processing aids.

A pre-market assessment and approval of any new processing aid, including new enzymes which are regulated as processing aids, is required before they can be used in the production of food sold in Australia and New Zealand.

Risk and Technical Assessment

A safety assessment of the enzyme, including the donor/host microorganism, and an assessment of the technological justification for use of the enzyme has been carried out. The risk assessment considered the technological suitability of amylomaltase as a food processing aid and the potential hazards of the production microorganism and amylomaltase protein.

No food safety concerns were identified by FSANZ with the use of amylomaltase sourced from GM *B. amyloliquefaciens* as a processing aid. It was determined that amylomaltase fulfils its intended technological function. It is effective as a processing aid in the production of modified potato starch.

The specific findings of the risk assessment are:

- *B. amyloliquefaciens* has a history of safe use in the production of enzyme processing aids.

- Any low levels of residual, inactive enzyme that may be present in the final food would be susceptible to digestion similar to any other dietary protein.

- Bioinformatic analysis indicated that amylomaltase has no biologically relevant homology to known protein allergens or toxins.

- There was no evidence of toxicity from the enzyme preparation at the highest doses tested in 14- and 90-day toxicity studies in rats. The No-Observed-Adverse-Effect-Level (NOAEL) in both studies was 1000 mg total organic solids (TOS)/kg bw per day, the highest dose tested.

- The enzyme preparation was not genotoxic *in vitro*.

- Based on the reviewed toxicological data it was concluded that, in the absence of any identifiable hazard, an ADI (Acceptable Daily Intake) 'not specified' is appropriate.

- The amylomaltase preparation meets international specifications for enzyme preparations used in the production of food.

Labelling

There are no labelling requirements for amylomaltase, as substances used as processing aids in accordance with Standard 1.3.3 – Processing Aids are exempt from labelling under clause 3 of Standard 1.2.4 – Labelling of Ingredients. The enzyme preparation does not contain any substance that requires mandatory declaration under clause 4 of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations. There are no GM labelling aspects for the enzyme preparation under Standard 1.5.2 – Food produced using Gene Technology.

Assessing the Application

The Application is being assessed under the General Procedure which includes one round of public comment.

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 amending the Code to allow amylomaltase sourced from GM *B. amyloliquefaciens* as a processing aid outweigh the direct and indirect benefits to the community, Government or industry.

- Whether there are any other measures that would be more cost-effective than a variation to Standard 1.3.3 that could achieve the same end.

- Whether there are any relevant New Zealand standards.

- 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 amylomaltase EC 2.4.1.25 sourced from *Bacillus amyloliquefaciens* containing the *Thermus thermophilus* gene for amylomaltase.

Reasons for Preferred Approach

An amendment to the Code approving the use of amylomaltase sourced from GM *B. amyloliquefaciens* as a processing aid is proposed on the basis of the available evidence for the following reasons:

- A safety assessment has concluded that the use of the enzyme as a processing aid for food manufacture does not raise any public health and safety concerns.
- Amylomaltase fulfils its proposed technological function. It is effective as a processing aid in the production of modified potato starch.
- 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 safety assessment and technological function of the enzyme.

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 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 Changing the Code 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) 14 December 2011

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 6143
NEW ZEALAND
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SUPPORTING DOCUMENT

The following material, which was used in the preparation of this Assessment Report, is available on the FSANZ website at
http://www.foodstandards.gov.au/foodstandards/applications/applicationa1061amyl5193.cfm

SD1 Risk Assessment Report

Introduction

Food Standards Australia New Zealand (FSANZ) received an Application from DSM Food Specialties (DSM) on 21 April 2011. DSM is a Netherlands-based company which develops, produces and sells a broad spectrum of ingredients for the food industry.

The Application seeks to amend Standard 1.3.3 – Processing Aids in the *Australia New Zealand Food Standards Code* (the Code) to permit the use of a new enzyme, amylomaltase, as a processing aid in food. The enzyme is sourced from a genetically modified strain of *Bacillus amyloliquefaciens* carrying the amylomaltase gene from *Thermus thermophilus.* The Applicant states the purpose and technological function of amylomaltase will be to produce modified potato starch. The Applicant claims the modified potato starch has excellent thermo-reversible gelling properties and may be used as a replacement for fat and casein and other fat and casein substitutes in food.

1. The Issue / Problem

A pre-market assessment and approval is required before any new processing aid is permitted to be used to process food sold in Australia and New Zealand. Enzymes are regulated as processing aids in the Code.

Therefore, a safety assessment of amylomaltase is required. This assessment includes the safety of the source organism, the production of the enzyme preparation, as well as an assessment of the technological function of the enzyme for its proposed use.

2. Current Standard

2.1 Background

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.

> **processing aid** means a substance listed in clauses 3 to 19, 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.

The Table to clause 17 (Permitted enzymes of microbial origin) contains a list of permitted enzymes and the microbial source from which they can be derived.

Currently there is no permission for amylomaltase to be used as an enzyme to manufacture food. FSANZ has previously assessed the source organism, *B. amyloliquefaciens,* as a safe production organism for a number of food-grade enzymes.

2.2 International Regulations

The Applicant states that amylomaltase is currently used only in The Netherlands to produce modified potato starch and that this modified starch is used worldwide.

The Applicant further states that carbohydrase preparations from *Bacillus subtilis* characterised by the presence of α-amylase and β-glucanase, as well as carbohydrase and protease enzyme preparations derived from *B. amyloliquefaciens* have GRAS (generally regarded as safe) status in the United States of America[1]. The Applicant claims that the modified potato starch with help of amylomaltase can be considered GRAS in the USA based on GRAS self-affirmation prepared by DSM that was confirmed by an independent expert panel.

The Applicant also claims that the amylomaltase enzyme preparation complies with the international enzyme preparation specifications of the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 2006) and the Food Chemicals Codex, 7th Edition (see section 2.3 in SD1).

2.3 Nature of the Enzyme and Source Organism

Amylomaltase catalyses the cleavage of α-1,4 linkages between glucose molecules in starch, and in a second step, catalyses the formation of another α-1,4 linkage (Tafazoli et al 2009). According to the Applicant, this results in the breakdown of amylose and changes in the length and distribution of the amylopectin side chains.

The source organism for amylomaltase is a GM strain of *B. amyloliquefaciens* (production strain MAS-3) which expresses a modified form of the amylomaltase gene (*malQ,* designated *masQ*) from *Thermus thermophilus* HB8 (ATTC27634). The *malQ* gene was modified to optimise its expression in Bacillus. This involved a modification to the overall G+C% content and codon usage. The Applicant stated that the *masQ* gene encodes the same primary amino acid sequence as that encoded by the wild-type *malQ* gene in *T. thermophilus*.

FSANZ has previously assessed *B. amyloliquefaciens* as a safe production organism for a number of food-grade enzymes. Standard 1.3.3 permits the use of the following enzymes sourced from *B. amyloliquefaciens* as food processing aids: α-acetolactate, α-amylase, β-amylase, β-glucanase, hemicellulose endo-1,4-xylanase, hemicellulose multicomponent enzyme, metalloproteinase, pullulanase and serine proteinase.

The safety of the source organism and the derivation of the host strain have been assessed as part of the risk assessment (see Section 3 in **SD1**).

2.4 Technological Function of the Enzyme

The technological function proposed by the Applicant is to use amylomaltase for the production of modified potato starch for use as a food ingredient. The enzyme modifies potato starch by converting amylose to amylopectin. The Applicant states that modified potato starch has excellent thermo-reversible gelling properties which enable it to mimic fat. The Applicant states that at ambient temperature, the modified potato starch is a gel, and at higher temperatures it behaves more like a liquid.

The Applicant therefore argues that modified potato starch can be used as a replacement for fat and casein and other fat and casein substitutes in foods such as yoghurts, curds, mousses, ice creams, cheese analogues and low fat spreads.

[1] See http://edocket.access.gpo.gov/cfr_2001/aprqtr/pdf/21cfr184.1148.pdf

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 amylomaltase sourced from *B. amyloliquefaciens*, 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 specific order policy principles for substances added to achieve a solely technological function, such as processing aids. These specific order policy principles state that permission 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'); and
- the addition of the substance to food is safe for human consumption; and
- the amounts added are consistent with achieving the technological function; and
- 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.

The main objective which applies to the assessment of this Application is protection of public health and safety.

4. Questions to be answered

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

-
- Does the enzyme preparation present any food safety issues?

- Does the enzyme achieve its stated technological purpose?

Risk assessment

5. Risk Assessment Summary

This risk assessment has considered the technological suitability of amylomaltase as a food processing aid and the potential hazards of the production microorganism and amylomaltase protein. This assessment is described in detail in Supporting Document 1.

5.1 Hazard assessment

No food safety concerns were identified by FSANZ with the use of amylomaltase as a food processing aid on the basis of the following considerations:

- *B. amyloliquefaciens* has a history of safe use in the production of enzyme processing aids.

- Any low levels of residual, inactive enzyme that may be present in the final food would be susceptible to digestion as any other dietary protein.

- Bioinformatic analysis indicated that amylomaltase contains no biologically relevant homology to known protein allergens or toxins.

- There was no evidence of toxicity from the enzyme preparation at the highest doses tested in 14- and 90-day toxicity studies in rats. The No-Observed-Adverse-Effect-Level (NOAEL) in both studies was 1000 mg total organic solids (TOS)/kg bw per day, the highest dose tested.

- The enzyme preparation was not genotoxic *in vitro*.

Based on the reviewed toxicological data, it was concluded that in the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) 'not specified' is appropriate.

5.2 Dietary Exposure

Processing aids perform their technological function during the manufacture of food and do not perform a technological function in the final food.. They are used at levels sufficient to achieve the purpose. Information contained in this application on the use of amylomaltase and subsequent food processing steps, indicated that very small amounts of denatured enzyme may be present in the final food. Any traces of residual inactive enzyme would undergo normal proteolytic digestion in the gastrointestinal tract.

A dietary exposure assessment is considered unnecessary given the low level of hazard presented by amylomaltase derived from GM *B. amyloliquefaciens*.

5.3 Technological justification

Based on the information supplied by the Applicant, including scientific literature available in the public domain, FSANZ concludes that amylomaltase fulfils its intended technological function. It is effective as a processing aid in the production of modified potato starch.

The amylomaltase preparation meets international specifications for enzyme preparations used in the production of food.

5.3 Risk assessment conclusions

The risk and technical assessment concludes that use of amylomaltase sourced from GM *B. amyloliquefaciens* as a processing aid in food production does not raise any public health and safety risks, and its use is technologically justified for its proposed purpose.

Risk Management

6. Risk Management Issues

FSANZ's regulatory approach differs depending on the nature of the risks identified and there are a number of approaches used to manage identified risks. These may include prescribing specifications for the identity and purity of the substance, compositional and/or labelling requirements, and where necessary, restriction or prohibition. Drawing on the conclusions from the risk assessment, the following sections discuss other broader issues requiring consideration in the development of regulations for use of amylomaltase from GM *B. amyloliquefaciens* as a processing aid.

6.1 Risk to public health and safety

There are no specific safety risks to manage given the risk assessment conclusions in 5.3 above.

6.2 Consistency with Policy Guidelines

FSANZ is required to have regard to the Policy Guideline on the Addition of Substances other than Vitamins and Minerals to foods. Since the purpose for addition of amylomaltase to food falls under 'Technological Function', regard has been given particularly to the specific order policy principles for 'Technological Function'.

It has been determined that the Applicant provided a clear stated purpose, there are no health and safety concerns from the use of amylomaltase as a processing aid, the enzyme has a clear technological function and it is added in a quantity and form which is consistent with delivering the stated purpose. There are no proposed nutrition, health or related claims to be made in regard to amylomaltase or modified potato starch. Therefore, FSANZ concludes that the production of modified potato starch using amylomaltase is consistent with the specific order policy principles for 'Technological Function'.

6.3 Labelling

In this Application labelling addresses the objective set out in paragraph 18(1)(b) of the FSANZ Act; the provision of adequate information relating to food to enable consumers to make informed choices.

Although processing aids are not normally subject to labelling on the final food (paragraph 3(d) of Standard 1.2.4 – Labelling of Ingredients), 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. In such cases, the name of the processing aid must be declared in the list of ingredients in conjunction with the statement 'genetically modified'.

In the case of amylomaltase, the gene and protein derived from it are not considered to be novel under the definition in Standard 1.5.2 because the gene has not been protein engineered. Furthermore, the Applicant has stated that the genetically modified source microorganism *B. amyloliquefaciens* including any residues is removed from the final enzyme preparation, so it will not be present in the final food.

Additionally, the enzyme preparation does not contain any substances that require mandatory declaration, under clause 4 of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations.

6.4 Specifications for amylomaltase

Standard 1.3.4 – Identity and Purity adopts specifications for food additives (and other substances in foods) by reference to specific sources, including specifications established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). The purpose of Standard 1.3.4 is to regulate the identity and purity of substances.

Based on the analytical results provided by the Applicant, FSANZ considers the amylomaltase enzyme preparation complies with the international enzyme preparation specifications of the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 2006) and the Food Chemicals Codex, 7th Edition (see section 2.3 in SD1). Both these sources of specifications are primary sources in clause 2 of Standard 1.3.4, so no separate specifications for the enzyme need to be written.

6.5 Method of Analysis

The production microorganism is killed off at the end of the fermentation stage so that the final enzyme preparation does not contain viable *B. amyloliquefaciens.*

During production of modified potato starch, the reaction mixture is processed to 120°C which inactivates the enzyme. Therefore, a method of analysis for the presence of the enzyme or source organism in food containing modified potato starch is unnecessary.

6.6 Prevention of misleading and deceptive conduct

FSANZ has considered this objective and concludes there are no misleading or deceptive conduct aspects to this assessment.

6.7 Risk Management Strategy

FSANZ proposes to permit the use of amylomaltase sourced from the GM *B. amyloliquefaciens* as a processing aid for producing modified potato starch at Good Manufacturing Practice (GMP) levels. This is based on the consideration that no public health or safety issues were identified from such use of amylomaltase.

7. Options

Processing aids require pre-market approval under Standard 1.3.3; therefore it is not appropriate to consider non-regulatory options for this Application. Two regulatory options have consequently been identified:

Option 1: Reject the Application

Option 2: To prepare a draft variation to Standard 1.3.3 to permit the use of amylomaltase produced from GM *B. amyloliquefaciens*, 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 Office of Best Practice Regulation in a letter dated 24 November 2010 (reference 12065) provided a standing exemption from the need to assess if a Regulatory Impact Statement is required for applications relating to processing aids as they are machinery in nature.

However, the benefits and costs associated with the proposed amendments to the Code have been analysed using regulatory impact principles. The level of analysis is commensurate to the nature of the Application and significance of the impacts. In accordance with the Best Practice Regulation Guidelines, completion of a preliminary assessment for this Application indicated a low or negligible impact.

8.1 Affected Parties

The affected parties for this Application include:

- Australian and New Zealand food importers
- those sectors of the Australian and New Zealand food manufacturing industry, such as industries making consumer dairy products, who may wish to use modified potato starch produced using amylomaltase sourced from GM *B. amyloliquefaciens*, as an ingredient in food sold in Australia and New Zealand
- Australian and New Zealand consumers of food containing the modified potato starch as an ingredient
- Australian, State, Territory and New Zealand Government agencies with responsibility for ensuring compliance of food with the Code.

8.2 Benefit Cost Analysis

As medium to significant competitive impacts or compliance costs are unlikely for this Application, FSANZ has not sought specific advice from the Office of Best Practice Regulation (OBPR) to estimate compliance costs of regulatory options. However FSANZ has performed a qualitative assessment of the benefits and costs for the two options outlined above.

8.2.1 Option 1

8.2.1.1 Consumers

There are no costs or benefits to consumers from this Option.

8.2.1.2 Industry

This option would disadvantage those members of the food industry who wish to use modified potato starch during manufacture of food.

In particular it could disadvantage manufacturers of consumer dairy products and other food producers who may wish to use modified potato starch as an alternative to fat and casein and other fat and casein substitutes in products such as yoghurts, curds, mousses and ice creams.

8.2.1.3 Government

There are no benefits to Governments in prohibiting the use of amylomaltase from GM *B. amyloliquefaciens* as there are no public health or safety issues or perceived costs on jurisdictions that enforce the food regulations. Lack of approval may be regarded as unnecessarily trade restrictive.

8.2.2 Option 2

8.2.2.1 Consumers

As well as use as an alternative to fat and casein in consumer dairy products, modified potato starch may be used as a replacement for ingredients such as gelatine. This may be of benefit to those consumers who do not eat ingredients of animal origin.

8.2.2.2 Industry

This option potentially provides positive benefits to manufacturers of foods such as dairy products, who could use modified potato starch as an alternative to fat and casein and other fat and casein substitutes. This may have economic and process time advantages. Substitution of gelatine with modified potato starch may allow access to kosher, halal and vegetarian markets.

8.2.2.3 Government

FSANZ considers there will be no additional cost to Government agencies that enforce the regulations since they will not need to analyse for the presence of the enzyme in treated food. Also as the ADI is 'not specified' the level of amylomaltase in the final food is not a safety matter.

There should also be no added costs to consumers.

8.3 Comparison of Options

Option 2 was the preferred option on the basis that:

- approving the use of amylomaltase from GM *B. amyloliquefaciens* as a processing aid would not impose a financial burden on consumers, industry or enforcement agencies
- the food industry could benefit from increased choice of alternatives
- consumers who do not take products of animal origin such as gelatine will have increased choice

- there are no public health and safety issues from the use of amylomaltase as a processing aid.

Communication and Consultation Strategy

9. Communication

FSANZ has developed and will apply a basic communication strategy to this Application. The strategy involves notifying subscribers and any interested parties about the availability of the assessment reports for public comment 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.

Issues raised in public submissions will be taken into account by the FSANZ Board.

The Applicant, individuals, and organisations making submissions on this Application, will be notified at each stage of the assessment of the Application. If the FSANZ Board approves the draft variation to the Code, FSANZ will notify its decision to the Ministerial Council. If no review of the Board's decision is requested by the Ministerial Council, the draft variation to the Code is expected to come into effect on gazettal. 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 about the scientific aspects of the Application, including any safety aspects and technological function of using amylomaltase sourced from GM *B. amyloliquefaciens* as a processing aid to produce modified potato starch for use in food as well as information about any potential costs or benefits associated with using amylomaltase from GM *B. amyloliquefaciens* 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 amylomaltase sourced from GM *B. amyloliquefaciens* as a permitted processing aid (enzyme) is unlikely to have a significant effect on international trade as the enzyme preparation complies with international specifications for food enzymes written by JECFA and the Food Chemicals Codex (7th Edition). Therefore, notification to WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures 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. FSANZ is required to consider the three primary objectives set out in section 18 of the FSANZ Act as described below.

11.1 Protection of public health and safety

The Assessment Report concludes that the use of the enzyme amylomaltase sourced from GM *B. amyloliquefaciens* as a processing aid does not pose any public health and safety risk and is technologically justified.

11.2 Provision of adequate information relating to food

FSANZ has considered whether specific additional information requirements are needed to enable consumers to make informed choices and concluded that there will be no novel DNA or protein present in the final food which would require labelling. Therefore no specific additional information requirements are proposed.

11.3 Prevention of misleading or deceptive conduct.

FSANZ has concluded there are no misleading or deceptive conduct aspects to this assessment.

11.4 Ministerial Council Policy Guidelines

The relevant Ministerial Council Policy Guideline has been addressed in this assessment. The technological function of using the additive has been articulated and assessed as being met. Its use as proposed has been assessed as being safe and suitable.

11.5 Preferred option

Based on the available scientific information and assessment of impacts to stakeholders, the preferred option is to prepare a draft variation to the Code giving permission to use amylomaltase sourced from GM *B. amyloliquefaciens*, as a processing aid to produce food sold in Australia and New Zealand.

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 amylomaltase EC 2.4.1.25 sourced from *Bacillus amyloliquefaciens* containing the *Thermus thermophilus* gene for amylomaltase.

11.2 Reasons for Preferred Approach

An amendment to the Code approving the use of amylomaltase sourced from GM *B. amyloliquefaciens* as a processing aid is proposed on the basis of the available evidence for

the following reasons:

- The safety assessment has concluded that the use of the enzyme as a processing aid for food manufacture does not raise any public health and safety concerns.

- Use of the enzyme as a processing aid in the production of modified potato starch is technologically justified and may provide benefits to manufacturers of foods such as dairy products. Substitution of gelatine with modified potato starch may allow access to kosher, halal and vegetarian markets.

- 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 that would impact on our decision to amend the code.

- There are no other measures than variations to Standard 1.3.3 that could achieve the same end.

12. Implementation and Review

The draft variation to the Code is proposed to come into effect on gazettal.

13. References

Food Chemicals Codex 2010 (7th Edition), Enzyme preparations published by United States Pharmacopeial Convention.

JECFA (2006) Compendium of Food Additive Specifications - General specifications and considerations for enzymes used in food processing. Joint FAO/WHO Expert Committee on Food Additives. FAO JECFA Monograph 3, 67th meeting 63-67, FAO, Rome 2006. http://www.fao.org/docrep/009/a0691e/A0691E03.htm

Tafazoli, S., Wong, A.W., Akiyama, T., Kajiura, H., Tomioka, E., Kojima, I., Takata, H. and Kuriki, T. (2010). Safety evaluation of amylomaltase from *Thermus aquaticus*. Regulatory Toxicology & Pharmacology **57**: 62-69.

ATTACHMENTS

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

Attachment 1

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

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

Food Standards (Application A1061 – Amylomaltase as a Processing Aid (Enzyme)) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated XXXX

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

1 Name

This instrument is the *Food Standards (Application A1061 – Amylomaltase as a Processing Aid (Enzyme)) Variation*.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies the Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

This variation commences **on the date of gazettal**.

SCHEDULE

[1] ***Standard 1.3.3*** *is varied by inserting in alphabetical order in the* Table to clause 17 –

Amylomaltase EC 2.4.1.25	*Bacillus amyloliquefaciens*, containing the gene for amylomaltase derived from *Thermus thermophilus*

Attachment 2

Draft Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted Application A1061 which seeks to approve the use of a new enzyme processing aid, amylomaltase sourced from *Bacillus amyloliquefaciens* containing the gene for amylomaltase derived from *Thermus thermophilis* (for use to produce modified starch products as an ingredient in dairy products). The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft Standard.

2. Purpose and operation

Currently there is no permission in the Code for the use of amylomaltase sourced from genetically modified *B. amyloliquefaciens* as a processing aid. The draft variation is proposed to address this.

The amylomaltase enzyme preparation complies with the international enzyme preparation specifications of the Joint FAO/WHO Expert Committee on Food Additives and the Food Chemicals Codex, 7th Edition. Both these sources of specifications are primary sources in clause 2 of Standard 1.3.4 – Identity and Purity, so no separate specifications for amylomaltase need to be written.

3. Documents incorporated by reference

The variation does not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1061 will include one round of public consultation following an assessment and the preparation of a draft variation. A Report (which includes the draft Standard) will be released for a six-week consultation period.

A Regulation Impact Statement (RIS) was not required because the proposed variations to Standards 1.3.3 is likely to have a minor impact on business and individuals.

5. Variations

5.1 Item [1]

This item inserts a permission in the Table to clause 17 of Standard 1.3.3 to permit the use of amylomaltase from genetically modified *B. amyloliquefaciens* in the course of manufacture of any food sold in Australia and New Zealand provided the amylomaltase gene is derived from *T. thermophilus*.