26 March 2012
[7-12]

Approval Report– Application A1061

Amylomaltase as a Processing Aid (Enzyme)

Food Standards Australia New Zealand (FSANZ) has assessed an application made by DSM Food Specialties (DSM) 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, as an approved food processing aid.

On 31 October 2011, FSANZ sought submissions on a draft standard and published an Assessment Report. FSANZ received four submissions.

FSANZ approved the draft variation to the Standard on 8 March 2012. The COAG Legislative and Governance Forum on Food Regulation[1] (the Forum) was notified of FSANZ's decision on 23 March 2012.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

[1] Previously known as the Australia and New Zealand Food Regulation Ministerial Council

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Supporting documents

The following documents used to prepare this Report are available on the FSANZ website at http://www.foodstandards.gov.au/foodstandards/applications/applicationa1061amyl5193.cfm.

SD1 Risk Assessment Report

1. Executive summary

The Application sought permission to use the enzyme amylomaltase EC 2.4.1.25 sourced from genetically modified (GM) *Bacillus amyloliquefaciens,* containing the gene for amylomaltase derived from *Thermus thermophilus,* as a processing aid (in the production of modified potato starch for use as an ingredient in food). The Application was assessed under the General Procedure which included one round of public consultation.

As part of its assessment and the subsequent development of a food regulatory measure, FSANZ has had regard to section 29 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). FSANZ has also addressed the objectives set out in section 18 of the FSANZ Act.

FSANZ assessed the potential hazards of the production microorganism and amylomaltase protein, and the technological suitability of amylomaltase as a food processing aid. No food safety concerns were identified with the use of amylomaltase sourced from GM *B. amyloliquefaciens* as a processing aid. It was determined that amylomaltase fulfils its intended technological function. That is, it is effective as a processing aid in the production of modified potato starch.

FSANZ also determined that the production of modified potato starch using amylomaltase is consistent with the specific order policy principles for 'Technological Function' under the Addition to Food of Substances other than Vitamins and Minerals Policy Guideline ".

Therefore, the draft variation to Standard 1.3.3 to permit the use of amylomaltase sourced from GM *B. amyloliquefaciens* was approved without change. The approved variation is at Attachment A.

2. Introduction

2.1 The Applicant

The Applicant is DSM Food Specialties (DSM), a Netherlands-based company which develops, produces and sells a broad spectrum of ingredients for the food industry.

2.2 The Application

The Application sought 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 food processing aid. The enzyme is sourced from a genetically modified (GM) strain of *B. amyloliquefaciens* carrying the amylomaltase gene from *T. thermophilus.*

2.3 The 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:

> ***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, amylomaltase is not permitted as a processing aid and is therefore not listed in the Table to clause 17. Before permission may be granted, FSANZ must assess the potential hazards of the production microorganism and amylomaltase protein, and the technological suitability of amylomaltase as a food processing aid.

2.4 Reasons for accepting the Application

The Application was accepted for assessment on the basis that:

- it complied with the procedural requirements under subsection 22(2);
- it related to a matter that warranted the variation of a food regulatory measure.

2.5 Procedure for assessment

The Application was assessed under the General Procedure.

2.6 Decision

The draft variation to Standard 1.3.3 as proposed following assessment was approved without change. The approved variation is at Attachment A. An Explanatory Statement is at Attachment B.

3. Summary of the findings

3.1 Risk assessment

A safety assessment of the enzyme, including the production microorganism, and an assessment of the technological justification for use of the enzyme was 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. That is, it is effective as a processing aid in the production of modified potato starch.

The specific findings of the risk assessment were:

- *B. amyloliquefaciens* has a history of safe use in the production of enzyme processing aids.
- The source microorganism, including any residues, is removed from the final enzyme preparation, so it is not likely to be present in the final food.
- Any residual enzyme that may be present in the final food would be at very low levels, inactive and as susceptible to digestion as the vast majority of dietary proteins.
- Bioinformatic analysis concluded that amylomaltase has no biologically relevant homology to known protein allergens or toxins.
- There was no evidence of toxicity due to 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’ was appropriate.
- The amylomaltase preparation meets international specifications for enzyme preparations used in the production of food.

3.2 Risk management

Drawing on the conclusion from the risk assessment, the following sections discuss other issues requiring consideration in developing regulations for use of amylomaltase from GM *B. amyloliquefaciens* as a processing aid.

3.2.1 Risk to public health and safety

There are no specific safety risks to manage given the risk assessment conclusion in 3.1.

3.2.2 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.

Under current requirements in the Code, processing aids are, in most cases, exempt from the requirement to be declared in the statement of ingredients (paragraph 3(d) of Standard 1.2.4 – Labelling of Ingredients). Paragraph 4(1)(d) of Standard 1.5.2 – Food produced using Gene Technology overrides this exemption when 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'.

FSANZ has determined that, consistent with labelling requirements for processing aids, amylomaltase would be exempt from labelling. This is because the gene and protein derived from it are not considered to be novel under the definition of novel DNA and/or novel protein in subclause 4(1) of Standard 1.5.2, because the gene has not been protein engineered. Therefore, Standard 1.5.2 does not apply.

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.

In response to the release of Assessment Report and draft variation to the Code for public comment, one submitter stated that the reasons FSANZ gave for exempting amylomaltase from GM labelling are not consistent with Standard 1.5.2. FSANZ does not support this view. Section 2.3 of the Assessment Report and this Report explain that the amylomaltase gene from *T. thermophilus* was only modified to optimise its expression in *B. amyloliquefaciens.* However, the amylomaltase gene expressed by the GM *B. amyloliquefaciens* is identical to that expressed by *T. thermophilus*.

Furthermore, the Applicant stated that the GM source microorganism *B. amyloliquefaciens*, including any residues, is removed from the final enzyme preparation. Therefore, it is not likely to be present in the final food.

Given that amylomaltase does not contain novel DNA and/or novel protein or the GM source microorganism (or any residues of it), any food produced using this processing aid would not meet the definition of a genetically modified food. FSANZ considers the approach to exempt amylomaltase from GM labelling is consistent with existing requirements in Standard 1.5.2.

3.2.3 Specifications for amylomaltase

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 – Identity and Purity, so no separate specifications for the enzyme need to be written.

3.2.4 Method of Analysis

The production microorganism is killed 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 enzyme is inactivated. Therefore, methods of analysis for the presence of the enzyme or source organism in food containing modified potato starch are unnecessary.

3.2.5 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 (OBPR), in a letter dated 24 November 2010 (reference 12065), provided a standing exemption from the need to assess if a Regulation Impact Statement is required for applications relating to processing aids as they are machinery in nature.

3.2.6 Summary of submissions

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application.

Every submission on an application or proposal is reviewed by FSANZ staff who examine the issues identified and prepare a response to those issues. While not all submissions can be taken on board during the process, they are valued and all contribute to the rigour of our assessment.

Submissions were received from the Food Technology Association of Australia, Queensland Government, Ministry of Agriculture and Forestry New Zealand and New South Wales Food Authority.

All four submitters supported the proposed variation to Standard 1.3.3 to permit the use of amylomaltase sourced from GM *B. amyloliquefaciens*, as a processing aid. However, two of the submitters raised issues that needed clarification as discussed in Table 1.

Table 1: Summary of issues raised in submissions

Issue	Raised by	FSANZ Response
The Dossier claims "As can be seen in the 3 Certificates of Analysis given in Annex II.A.5-1, the amylomaltase preparations do not contain antibiotic activity". Our examination of Annex II.A.5-1 did not find this result	Ministry of Agriculture and Forestry New Zealand	The Applicant has provided revised Certificates of Analysis showing the results for antibiotic activity and the following response: *Since our enzymes comply to the JECFA specifications antibiotic activity is being monitored. Erroneously the analytical result referring to the antibiotic activity was not mentioned on the earlier issued Certificates.* FSANZ considers the revised certificates of analysis adequately address the issue raised in the submission. The revised Certificates of Analysis are available at http://www.foodstandards.gov.au/foodstandards/applications/applicationa1061amyl5193.cfm.

Issue	Raised by	FSANZ Response
Would like the following reconsidered: i. Reasons for exempting modified potato starch from GM labelling not consistent with Standard 1.5.2. i. Paragraph 2 of SD1 Section 3.3 is not consistent with material submitted by Applicant. 1.5-5.5% is the usage rate for modified potato starch in certain foods.	New South Wales Food Authority	i. FSANZ considers the exemption is consistent with Standard 1.5.2. Amylomaltase does not contain any novel DNA and/or novel protein, or any of the GM source organism or its residues. Food produced using the amylomaltase processing aid would not meet the definition of genetically modified food (see Section 3.2.2 for details). ii. SD1 has been amended to align with the information submitted by the Applicant.

3.3 Risk communication

FSANZ applied a basic communication strategy to this Application. This involved using the media, website and Facebook and Twitter sites to encourage people to comment. Email alerts were sent to more than 4500 subscribers to the FSANZ Notification Circular and to interested parties, including the Applicant.

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 were evaluated and addressed in this Report.

The Applicant and organisations who made submissions on this Application were notified at each stage of the Application. The FSANZ Board's decision has been notified to the Forum. If no request for a review of the decision is made by the Forum, 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.

4. Reasons for Decision

The draft variation to Standard 1.3.3, as proposed following assessment, was approved without change on the basis of the available evidence for the following reasons:

- 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 proposed 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 is consistent with the requirements of sections 18 and 29 of the FSANZ Act as described below.

4.1 Section 29

FSANZ had regard to the following matters under section 29 of the FSANZ Act:

- whether costs that would arise from a food regulatory measure developed or varied as a result of the Application outweighed the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure
- there were no other measures that would be more cost-effective than a variation to Standard 1.3.3 that could achieve the same end
- any relevant New Zealand standards
- any other relevant matters.

FSANZ concluded that:

- There are no relevant New Zealand standards that would impact on our decision to amend the Code.
- There are no other measures other than a variation to Standard 1.3.3 that could achieve the same end.
- Based on the results of the qualitative cost benefit analysis below, permitting use of the enzyme would not impose significant costs for government agencies, consumers or manufacturers.

4.1.1 Cost Benefit Analysis

Medium to significant competitive impacts or compliance costs are unlikely for this Application, so FSANZ did not seek specific advice from the Office of Best Practice Regulation (OBPR) to estimate compliance costs of regulatory options. However, FSANZ performed a qualitative assessment of the costs and benefits for the two regulatory options.

Option 1: Approve the draft variation

Sector	Costs or benefits to sector
Consumers	Because modified potato starch may be used as a replacement for ingredients such as gelatine, it may be beneficial to those consumers who do not eat ingredients of animal origin.
Industry	This option is potentially beneficial 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. Substitution of gelatine with modified potato starch may allow access to kosher, halal and vegetarian markets.
Government	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 host organism or enzyme in food.

Option 1: Reject the draft variation

Sector	Costs or benefits to sector
Consumers	There are no costs or benefits to consumers from this option.
Industry	This option could disadvantage those members of the food industry who may wish to use modified potato starch as an ingredient in food.
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.

4.2 Addressing FSANZ's objectives for standards-setting

FSANZ has considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment of this Application as follows.

4.2.1 Protection of public health and safety

There are no specific safety risks to manage given the risk assessment conclusion in 3.1.

4.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

There will be no novel DNA or protein present in the final food which would require labelling. Therefore no specific additional information requirements were proposed.

4.2.3 The prevention of misleading or deceptive conduct

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

4.2.4 Subsection 18(2) considerations

FSANZ has also had regard to the objectives set out in subsection 18(2) as follows:

- *the need for standards to be based on risk analysis using the best available scientific evidence*
  This Application was assessed using the best available scientific evidence. The Applicant submitted a dossier of scientific studies in support of their Application. Other resource material including published scientific literature and general technical information was also used in assessing this Application.

- *the promotion of consistency between domestic and international food standards:*
  The proposed variation is consistent with international food standards. Amylomaltase is currently used in The Netherlands to produce modified potato starch which is sold worldwide.

- *the desirability of an efficient and internationally competitive food industry:*
  The proposed variation is not expected to have any negative impact on competitiveness of the food industry. Use of modified potato starch in place of ingredients of animal origin such as gelatine may allow Australian and New Zealand food industries to access previously unavailable markets e.g. vegetarian and kosher.

- *the promotion of fair trading in food:*
  The proposed variation is not expected to have any negative impact on fair trading in food.

- *any written policy guidelines formulated by the Ministerial Council:*
  The 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.

FSANZ determined that permitting the use of amylomaltase from GM *B. amyloliquefaciens* to produce modified potato starch is consistent with the specific order policy principles for 'Technological Function'.

4.3 Implementation

The variation will come into effect on gazettal.

5. 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

A. Approved variation to the *Australia New Zealand Food Standards Code*
B. Explanatory Statement

Attachment A – Approved variation to the *Australia New Zealand Food Standards Code*

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

[Signature to be inserted]

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 B – 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 thermophilus* (for use to produce modified potato starch as an ingredient in food). The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation of a standard.

Following consideration by the COAG Legislative and Governance Forum on Food Regulation[2] (the Forum), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunsetting under the *Legislative Instruments Act 2003*.

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 Authority has approved the 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 *B. amyloliquefaciens* containing the *T. thermophilus* gene for amylomaltase.

3. Documents incorporated by reference

The variations to food regulatory measures do 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 has included one round of public consultation following an assessment and the preparation of a draft Standard. An Assessment Report (which included the draft Standard) was released for consultation on 31 October 2011 for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variation to Standard 1.3.3 is likely to have a minor impact on business and individuals.

[2] Previously known as the Australia and New Zealand Food Regulation Ministerial Council

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

Item [1] inserts an entry into 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*.