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

7 April 2010
[9-10]

APPLICATION A1036
LIPASE DERIVED FROM *ASPERGILLUS NIGER* AS A PROCESSING AID (ENZYME)
ASSESSMENT REPORT

Executive Summary

Food Standards Australia New Zealand (FSANZ) received an Application from DSM Food Specialties on 5 October 2009 seeking approval to permit a protein engineered lipase produced from *Aspergillus niger* expressing a gene based on the pre-pro-lipase encoding gene sequences of various *Fusarium* species. The engineered lipase gene derived from *Fusarium culmorum* contains the lipase gene sequences of several *Fusarium* species, as well as several changes unique to the current lipase.

Lipase (EC 3.1.1.3) hydrolyses ester bonds of triacylglycerol to release free fatty acids from the glycerol backbone. It belongs to the subclass of carboxylic ester hydrolases. The proposed use of this lipase is in bakery applications where its technological function is to enhance the gas holding capacity of the dough. This leads to increased stability of the dough upon proofing, increasing loaf volume and improving loaf shape and oven spring post baking. Further claimed effects are improved crumb structure and softness.

A pre-market assessment of the safety of the enzyme, including the source and donor organisms, as well as assessment of the technological suitability, is required prior to any approval being granted. Processing aids used in food manufacture are regulated under Standard 1.3.3 which currently lists approvals for lipase from a number of other sources.

Use of this lipase has already been approved in both Denmark and Russia, whilst the French Food Safety Authority (Agence Française de Sécurité Sanitaire des Aliments; AFSSA) have endorsed the safety of the enzyme preparation with marketing authorization expected during 2010. Further, in response to a submission for assessment of self-GRAS determination (GRN: 296) in the United States, a 'no-questions' letter was received.

The lipase enzyme preparation complies with relevant international specifications for enzyme preparations prepared by the FAO/WHO Expert Committee on Food Additives (JECFA) (2006) and specifications of the Food Chemicals Codex (FCC), 6th Ed, 2008.

The Application is being assessed under the General Procedure.

Risk Assessment

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

Key findings of the evaluation are:

- The use of *A. niger* as the host organism, is a well-characterised expression system for the production of enzymes, and has a long history of safe use.
- Enzymes from *Fusarium* species are generally considered to be safe, and several other *Fusarium* lipases have been approved for use by FSANZ.
- The evidence shows that this recombinant lipase is likely to be proteolytically degraded in the human gastrointestinal tract.
- There is no evidence of toxicity at any of the high doses tested in a 90-day repeat dose study. The No Observable Adverse Effect Level (NOAEL) was 2135 mg/kg bw/day, the highest dose tested. There was also no evidence of genotoxicity.
- Based on the reviewed toxicological data it was concluded that in the absence of any identifiable hazard an ADI (Acceptable Daily Intake) does not need to be specified.
- The ADI for enzyme preparations produced by *A. niger* is 'not specified' by JECFA.
- There is no evidence of any mycotoxins associated with the enzyme preparation.
- Based on the available evidence, lipase produced in *A. niger* is considered safe for use in foods for human consumption.
- The stated purpose for this lipase is to improve the gas holding capacity of dough for bread making. When used in the form and amounts prescribed, lipase is technologically justified and achieves its stated purpose.
- The lipase enzyme produced from the genetically modified *A. niger* described in this Application meets international specifications for identity and purity.

Labelling

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 paragraph 4(1)(d) of Standard 1.5.2, labelling requirements do apply where novel DNA and/or novel protein from the processing aid remains present in the final food.

If approved, food produced using this lipase 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.

Lipase produced by a genetically modified strain of A*. niger* is not considered to be allergenic. However, its use is in bakery products and wheat flour is used in production of the commercial product. Accordingly, foods produced using this enzyme preparation require labelling in accordance with the provisions set out in 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 Standard 1.3.3 to permit the use of a protein-engineered variant of lipase produced by a genetically modified *Aspergillus niger* as a processing aid.

Reasons for Preferred Approach

An amendment to the Code approving the use of the lipase 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, *A. niger,* has an established safe history of use in the production of food enzymes.
- Use of the lipase 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 lipase produced by a genetically modified strain of *A. niger* 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 considered in developing the Approval Report.

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) 19 May 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

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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/applicationa1036lipa4582.cfm

SD1: Risk Assessment Report

Introduction

Food Standards Australia New Zealand (FSANZ) received an Application from DSM Food Specialties on 5 October 2009 seeking approval to permit a protein engineered lipase produced from *A. niger* expressing a gene based on the pre-pro-lipase encoding gene sequences of various *Fusarium* species. The protein engineered lipase shows approximately 82% homology to the wild-type lipase of *F. culmorum,* as well as containing lipase gene sequences of several *Fusarium* species, and several unique changes. The marketing name for this enzyme preparation is Panamore Golden.

Lipase (EC 3.1.1.3) hydrolyses ester bonds of triacylglycerol to release free fatty acids from the glycerol backbone. It belongs to the subclass of carboxylic ester hydrolases. The proposed use of this lipase is in bakery applications where its technological function is to enhance the gas holding capacity of the dough. This leads to increased stability of the dough upon proofing, increasing loaf volume and improving loaf shape and oven spring post baking. Further claimed effects are improved crumb structure and softness.

1. The Issue / Problem

The Applicant proposes the use of a protein engineered lipase produced from a genetically modified strain of *A. niger* as a processing aid to enhance the gas holding capacity of bread dough, leading to increased dough stability upon proofing.

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 claimed 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 produced.

Lipase, triacylglycerol (EC 3.1.1.3) is already a permitted processing aid from a number of other microbial and animal sources as listed in Standard 1.3.3.

2.2 International regulations

Use of this lipase has already been approved in both Denmark and Russia, whilst the French Food Safety Authority (Agence Française de Sécurité Sanitaire des Aliments; AFSSA) have endorsed the safety of the enzyme preparation with marketing authorization expected during 2010. Further, in response to a submission for assessment of self-GRAS determination (GRN: 296) in the United States, a 'no-questions' letter was received.

Identity and purity specifications written for the lipase enzyme preparation comply with the relevant international specifications prepared by the Joint Expert Committee on Food Additives (JECFA) (2006) and specifications of the Food Chemicals Codex, 6th Ed, 2008.

2.3 Nature of the Enzyme and Source of Organism

Lipase, triacylglycerol (EC 3.1.1.3) is a hydrolase enzyme belonging to the subclass of carboxylic ester hydrolases. Lipase hydrolyses ester bonds of triacylglycerol to release free fatty acids from the glycerol backbone.

The lipase described in this Application hydrolyses the following reaction:

Triacylglycerol + H_2O → diacylglycerol + a carboxylate

The source organism used to produce this lipase is a genetically modified (GM) strain of *A. niger* with a history of safe use in the production of food enzymes. The modified *A. niger* expresses a gene based on the lipase encoding gene sequences of various *Fusarium* species. The protein engineered lipase shows approximately 82% homology to the wild-type lipase of *F. culmorum,* as well as containing lipase gene sequences of several *Fusarium* species, and several unique changes.

2.4 Technological purpose

The enzyme preparation is proposed to be used in bread products to enhance the gas holding capacity of the dough resulting in increased stability of the dough upon proofing. This then correlates to an increased loaf volume, improved loaf shape and oven spring post baking. Further effects are improved crumb structure and softness. Reduced reliance on flour/bread improvers to deal with seasonal variations of flour is also a claimed benefit.

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 engineered lipase enzyme from a genetically modified *A. niger* 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 following:

- 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
- 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
- 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 risk assessment questions:

- Is the enzyme safe for the proposed use?
  - Are the donor and source organisms safe for producing this lipase?
  - Are there any potential allergenicity concerns with any components associated with the production process?
  - Does the lipase share homology with known allergens?
- Does the enzyme achieve its stated technological purpose?
  - Is the quantity and form proposed for addition, consistent with proposed use?

RISK ASSESSMENT

A detailed assessment of the safety and functionality of the lipase 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 materials including published scientific literature and general technical information were used in this assessment.

5. Risk Assessment Summary

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

Based on the available 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 lipase undergoing normal proteolytic digestion in the gastrointestinal tract.

It was further concluded that the Application clearly articulates the stated purpose for this lipase, namely to improve the gas holding capacity of the dough and the evidence submitted in support of the Application provides adequate assurance that the lipase, in the form and amounts added, is technologically justified and has been demonstrated to be effective in achieving its stated purpose.

The available data are considered sufficient to provide an acceptable level of confidence in the conclusions of this risk assessment in regard to the safety and suitability of this lipase for its stated purpose.

5.1 Safety Assessment

The safety assessment of lipase from a GM *A. niger*, concluded:

- There is no evidence of any toxicity in a 13-week oral toxicity study in rats.
- The NOAEL was 2135 mg/kg bw (1008 mg Total Organic Solids (TOS) or 20389 DSM Lipase Units (DLU)) in males and 2250 mg/kg bw/day (1062 mg TOS or 21487 DLU) in females.
- There is no evidence of genotoxicity.
- There is no evidence of any mycotoxin production associated with the enzyme preparation.

Based on the available 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 lipase undergoing normal proteolytic digestion in the gastrointestinal tract.

In 1990 the JECFA reviewed its initial numerical Acceptable Daily Limit (ADI) decision to set an ADI of *A. niger* enzyme preparations as ‘not specified’ (JECFA, 1990).

5.2 Dietary Exposure Assessment

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.

The Applicant has provided estimated daily intake (EDI) data for the lipase based on residual enzyme level data from their inactivation trials and 90th percentile food intake data from The Netherlands and USA (Section G4 in the Application). The EDI was determined to be between 0.041-0.675 DLU/kg bw based on The Netherlands data and 0.039-0.65 DLU/kg bw using the US data.

This lipase is expected to be 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.

FSANZ has reviewed and accepts the submitted dietary exposure evidence and this together with the allocated ADI supports the determination that further dietary exposure assessment is unnecessary.

5.3 Technological Justification

Apart from the reaction described in Section 2.3, the lipase can also act on ester bonds of other lipid substrates, including (polar) diacyl lipids, phospholipids and glycolipids, such as galactolipids. Depending on the lipids present in the application, one of the above activities will be more prevalent than the other.

The lipase's technological effect in bakery applications is to enhance the gas holding capacity of the dough leading to increased stability of the dough upon proofing. This results in an increased loaf volume, improved loaf shape and oven spring post baking. Further effects are improved crumb structure and softness. Reduction in manufacturer's reliance on flour/bread improvers to deal with seasonal variations of flour is also a proposed benefit of the enzyme's use.

The mechanisms underlying these technological effects are mainly based on the generation of polar lipids from the lipids naturally present in the dough. The natural content of lipids in wheat flour is approximately 2.5% (w/w), comprising both polar and apolar lipids. The gas holding capacity of dough is highly influenced by the lipid composition of the flour. The higher the content of highly polar monoacyl lipids, the better the gas-holding capacity and thus the baking performance will be.

The baking trial and inactivation evidence presented provides adequate assurance that the enzyme is technologically justified and has been demonstrated to be effective in achieving its stated purpose. Adequate assurance is also provided that the enzyme in the form and amounts prescribed are consistent with achieving its technological function.

5.4 Production of the enzyme

The lipase is produced by a submerged fermentation process using appropriate substrates and nutrients followed by several filtration and purification steps. The fermentation process consists of two steps: inoculum fermentation and main fermentation. Biosynthesis and excretion of the lipase by the production organism occurs during the main fermentation phase. Once fermentation is stopped, the production organism is killed off using a validated procedure. The cell material is separated from the lipase by means of a simple filtration process (broth filtration, followed by polish filtration and a germ reduction filtration). The lipase content in the fermentation broth is then concentrated by ultrafiltration. The ultrafiltered (UF) concentrate is then spray dried in the presence of wheat flour and subsequently blended with granulated wheat flour to the desired lipase activity.

The fermentation process is carried out using Good Manufacturing Practice.

Specifications for identity and purity written for the enzyme preparation comply with the international specifications relevant for enzymes prepared by (JECFA, 2006). These specifications are primary reference sources listed in clause 2 of Standard 1.3.4: Identity and Purity, of the Code.

The expression organism for the lipase is a genetically modified *A. niger* strain. *A. niger* has a history over several decades of safe use as a production organism for food enzymes. A number of enzymes produced in *A. niger* have been evaluated for safety by the FAO/WHO Joint Expert Committee on Food Additives (JECFA) and are considered to be non-toxic. The acceptable daily intake (ADI) for these enzymes has been determined to be 'not specified' on account of its low toxicity. It is also a permitted source of a number of enzymes in the Code.

The modified lipase is encoded by a novel gene sequence derived from a number of lipase genes from the fungal genus *Fusarium*. The primary homology is to the lipase gene of *F. culmorum* (approximately 82% amino acid identity). Enzymes from *Fusarium* species are generally considered to be safe, and several other *Fusarium* lipases have been approved for use by FSANZ.

5.5 Allergenicity

The Applicant presented the results of a bioinformatic assessment of the lipase protein. These data were also presented to the USFDA for their GRAS assessment. In the analysis, the lipase sequence was compared with the Allermatch database to identify sequences of 35% or greater homology with known allergens. No significant matches were found between this lipase and known allergens.

Wheat flour is used to formulate the commercial enzyme preparation, hence the product triggers labelling provisions set forth in Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations, for the declaration of cereals containing gluten.

Risk Management

6. Issues raised

6.1 Risk Management Strategy

The risk assessment concludes that use of a protein engineered lipase sourced from genetically modified *A. niger* as a processing aid does not pose a public health and safety risk and that its proposed use is technologically justified.

The engineered lipase gene derived from *F. culmorum* contains the lipase gene sequences of several *Fusarium* species, as well as several changes unique to the current lipase. The lipase gene from *F. culmorum* has been optimised for performance in bakery applications using specific mutations.

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

The commercial enzyme product triggers labelling provisions set forth in Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations, for the declaration of cereals containing gluten, as wheat flour is used to standardise the product.

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 lipase 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 necessary.

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: To prepare a draft variation to amend Standard 1.3.3 to permit the use of lipase produced by a genetically modified *A. niger* 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: 11031) 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 this lipase as a processing aid
- consumers of food products in which lipase 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: Approve the Application

- allows food industry choice

- manufacturers may benefit as improvements to product quality may improve market share

- there may be benefits for manufacturers through use of different processing techniques and potential cost savings associated with reduced reliance on bread/dough improvers to deal with seasonal variations in raw ingredients

- consumers may benefit from foods produced using lipase through accessibility to products of consistent high 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 bread.

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 possible reductions in processing costs. Potential benefits may exist for both industry and consumers in the provision of products with consistent high quality.

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 lipase 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 lipase 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 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.

The Assessment Report concludes that use of a protein engineered lipase produced by genetically modified *A. niger* 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 this lipase 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 Standard 1.3.3 to permit the use of a protein-engineered variant of lipase produced by a genetically modified *Aspergillus niger* as a processing aid.

11.1 Reasons for Preferred Approach

An amendment to the Code approving the use of this lipase 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, *A. niger* is regarded as non-toxigenic and has a safe history of use in production of food enzymes.
- Use of lipase produced from a GM *A. niger* 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 –

Lipase, triacylglycerol, protein engineered variant EC 3.1.1.3	Aspergillus niger, containing the gene for lipase, triacylglycerol isolated from *Fusarium culmorum*