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

18 July 2011
[14-11]

APPLICATION A1057
ENDO-PROTEASE AS A PROCESSING AID (ENZYME)
ASSESSMENT REPORT

Executive Summary

Purpose

The purpose of the Application is to seek permission to use a new enzyme, endo-protease, sourced from a genetically modified (GM) *Aspergillus niger* microorganism, as an approved processing aid used to process food. This request would require an amendment to Standard 1.3.3 – Processing Aids of the *Australia New Zealand Food Standards Code* (the Code).

Food Standards Australia New Zealand (FSANZ) received this Application from DSM Food Specialties on 31 January 2011, and after an administrative assessment commenced the assessment on 15 March 2011.

The proposed use of the enzyme preparation is as an alternative treatment to reduce the formation of haze, so called chill haze, in final packaged beer during cold storage. The Applicant claims the enzyme hydrolyses (by cleaving off parts of the protein) the haze-active proteins found in beer during the fermentation step in beer production. Hydrolysing the haze-active proteins reduces the size and also concentration of these proteins available in the final beer to reduce their interaction with polyphenols to produce haze when the beer is chilled.

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 Assessment

A safety assessment of the enzyme, including the donor/host microorganism, and an assessment of the technological justification for use of the enzyme, are required as part of the assessment.

The risk assessment has considered the technological suitability, the potential hazard of the donor/host microorganism and the potential hazard of the endo-protease enzyme preparation. The evidence presented was sufficient to determine that no safety concerns with the enzyme or donor/host microorganism exist and endo-protease is unlikely to pose any health risk when used as a food processing aid.

It was further concluded that the proposed use of the enzyme, namely as a processing aid to prevent haze formation in beer during cold storage, was technologically justified in the form and prescribed amounts, and demonstrated to be effective.

The specific findings of the risk assessment are:

- *Aspergillus niger,* the host organism, is a well-characterised expression system for the production of enzymes, and has a long history of safe use.

- There was no evidence of systemic toxicity associated with the enzyme preparation following repeat dose (sub-acute and sub-chronic) testing in rats. The No Observed Adverse Effect Level (NOAEL) was 20000 mg/kg bw/day (5040 mg Total Organic Solids /kg bw/day), the highest dose level tested.

- There was 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) 'not specified' is appropriate.

- Based on the available evidence, endo-protease produced in *A. niger* is considered safe for use in foods for human consumption.

- The stated purpose for this endo-protease is to reduce haze formation in beer during cold storage. When used in the form and amounts prescribed, the enzyme is technologically justified and achieves its stated purpose.

- The enzyme meets international purity specifications for enzymes used for food processing.

Labelling

There are no labelling requirements for endo-protease, 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 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.

- There are 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.

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 endo-protease sourced from *Aspergillus niger*.

Reasons for Preferred Approach

An amendment to the Code approving the use of endo-protease sourced from *A. niger* as a processing aid 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 as a processing aid for food manufacture does not raise any public health and safety concerns.

- Use of the enzyme as a processing aid is technologically justified as an alternative cold stabilisation treatment to reduce haze formation in chilled packaged beers (chill haze), which may provide economic and process time benefits to brewers.

- 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. 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) 29 August 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
Tel (04) 978 5636

CONTENTS

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/applicationa1057endo5114.cfm

SD1 Risk Assessment Report

Introduction

Food Standards Australia New Zealand (FSANZ) received an Application from DSM Food Specialties on 31 January 2011 to amend the *Australia New Zealand Food Standards Code* (the Code) to permit a new enzyme, endo-protease sourced from a genetically modified (GM) strain of *Aspergillus niger,* as a processing aid. The Application requests an amendment to the Table to clause 17 of Standard 1.3.3 – Processing Aids to permit the use of this enzyme to process food sold in Australia and New Zealand.

FSANZ accepted the Application after completing an administrative assessment. The Applicant sought to expedite FSANZ's consideration of their Application. FSANZ commenced its assessment of the Application on 15 March 2011.

The Applicant states the purpose and technological function of endo-protease will be to reduce haze formation during beer production, which is advantageous to brewers by decreasing processing costs and times. Specifically, the Applicant claims that treating beer during production with the enzyme reduces the formation of haze formed in the final packaged beer with cold storage, so called chill haze.

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.

A safety assessment of the new enzyme is required and must be undertaken and considered before any permission may be granted. 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 from.

Currently there is no permission for endo-protease to be used as an enzyme to manufacture food.

2.2 International Regulations

The Application states that specific approval for use of endo-protease sourced from *A. niger* has been obtained from French, Russian, Danish and Chinese authorities. In the USA, enzyme preparations obtained from *A. niger*, including protease, have been self-assessed as generally recognized as safe (GRAS). The relevant GRAS notification is GRN 000089[1]. This US FDA GRAS notification does not explicitly refer to endo-protease, the enzyme of this Application.

The Application provides information confirming that the endo-protease enzyme preparation complies with the international enzyme preparation specifications of both the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Food Chemicals Codex, 6th Edition (see section 2.4.2 in the Risk Assessment Report, **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.

2.3 Nature of the Enzyme and Source Organism

Endo-protease (EC 3.4.21.26) sourced from a variant of the microorganism *A. niger* hydrolyses peptides at the carboxyl site of proline residues. Proteins containing proline amino acids are often called haze-active proteins and their presence in high concentrations in beer are important for forming beer haze (as noted below). The reaction products are smaller peptides with a proline residue at the C-terminus of one of the smaller peptides (or a peptide plus the amino acid proline) and amino acids.

A. niger is a common, well characterised and safe microbial source of many permitted enzymes in the Code. In the present Application, the source organism has been genetically modified to contain additional copies of an endogenous endo-protease gene *A. niger* is thus the host as well as the donor of the introduced gene. The safety of the source organism and the derivation of the host strain have been assessed as part of the risk assessment (see Section 2.3.2 in **SD1**).

2.4 Technological Function

Endo-protease is proposed by the Applicant as an alternative treatment for brewers to prevent haze formation in the final beer that often forms during cold storage of the final packaged beer (commonly called chill haze). Use of the enzyme would be as an alternative, or an additional treatment, to various cold stabilisation treatments brewers currently use. This haze is produced due to the interactions and binding of haze-active proteins and polyphenols naturally present in beer as components of the ingredients (malted barley and hop products) used to produce beer. Complexes of haze-active protein and polyphenols produce larger compounds that can form visible haze particles that precipitate out when beer is chilled.

The enzyme is claimed by the Applicant to hydrolyse the haze-active proteins during the fermentation step of beer production. Hydrolysing the haze-active proteins reduces the size and also concentration of these proteins available in the final beer to interact with polyphenols to produce haze.

Brewers usually undertake a separate cold stabilisation step to reduce the formation of haze. This cold stabilisation step typically involves chilling and storing the fermented beer at very low temperatures to assist in forming the haze precipitates which are then removed from the beer by filtration.

[1] http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/ucm154613.htm

Likewise, brewers can also reduce the concentration of haze-active proteins by treating with silica gel which adsorbs the protein which is then removed by filtration. Brewers can also reduce the concentrations of polyphenols in beer by treating with PVPP (polyvinyl polypyrrolidone). Using hydrolysis by endo-protease as an alternative process to stabilise the final beer is claimed to save brewers processing time and capital expenditure. It is also possible that using the enzyme during beer production could be an added stabilisation treatment to current steps undertaken, or could allow some reduction in the current practices.

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 endo-protease sourced from *A. niger*, 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 permitted 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 the primary objective of protection of public health and safety. This objective has been met by conducting a risk assessment. This risk assessment has also investigated the technological function and justification for using the enzyme as a processing aid, to address the Ministerial Council Policy Guideline: *Addition to Food of Substances other than Vitamins and Minerals.*

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?

The answers to these questions are provided in the Risk Assessment Summary taken from the more detailed assessment in **SD1**.

RISK ASSESSMENT

5. Risk Assessment Summary

The risk assessment has considered the technological suitability of the enzyme, the potential hazard of the donor/host microorganism and the potential hazard of the endo-protease enzyme preparation.

Based on the available data, no food safety concerns have been identified with the enzyme, or with the microorganism used to produce the enzyme, which would preclude permitting its use as a food processing aid. The absence of any identified hazards is consistent with the enzyme undergoing normal proteolytic digestion in the gastrointestinal tract. The Application provides adequate information to demonstrate that the enzyme is technologically justified and effective in achieving its stated purpose.

The available data are sufficient to provide confidence in the safety and suitability of the enzyme.

5.1 Hazard assessment

A. niger strain ISO-508 was modified using recombinant DNA techniques to contain additional copies of an endo-protease gene derived from *A. niger*.

The hazard assessment concluded that:

- *A. niger* is a well-characterised expression system for the production of enzymes and has a long history of safe use.
- There is no evidence of systemic toxicity associated with the enzyme preparation following repeat dose (sub-acute and sub-chronic) testing in rats. The NOAEL is 20000 mg/kg bw/day (5040 mg TOS[2]/kg bw/day), the highest dose level tested.
- The enzyme preparation is not genotoxic *in vitro*.

[2] Total organic solids

Based on the absence of toxicity of the endo-protease preparation, as well as the absence of toxigenic potential of the host organism, an ADI 'not specified' is considered appropriate.

5.2 Dietary Exposure

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. No endo-protease activity can be detected following pasteurisation of the beer. Given the absence of any detectable enzyme activity, any residual enzyme would be expected to be present as denatured protein and would undergo normal proteolytic digestion in the gastrointestinal tract.

Based on calculations provided by the Applicant, the inactivated enzyme remains inert in the final food at a concentration of 15 mg TOS/L beer. Based on beer consumption data for the Netherlands, the Applicant calculated that a 60 kg person consuming beer at the 90th percentile would have an estimated daily intake of inactivated enzyme of 1.25 mg TOS/kg bw/day. The NOAEL of 5040 mg TOS/kg bw/day therefore provides a very large margin of safety. This large margin of safety, which would also be expected based on an Australian/New Zealand diet, combined with the allocation of an ADI "not specified" indicate that further dietary exposure assessment is unnecessary.

5.3 Technological justification

The Application clearly articulates the stated purpose for the enzyme, namely for the hydrolysis of haze-active proteins in beer which effectively prevents complex formation with polyphenols, thus reducing haze formation. The evidence submitted in support of the Application provides adequate assurance that the endo-protease, in the form and amounts added, is technologically justified and achieves its stated purpose.

Risk Management

6. Risk Management Issues

The risk assessment concludes that use of endo-protease sourced from *A. niger* as a processing aid used to produce food does not raise any public health and safety risks, and its use is technologically justified for its proposed purpose. There are therefore no specific safety risks to manage.

6.1 Method of Analysis

A method of analysis for the presence of the enzyme or source organism in treated food is unnecessary. This is because the enzyme is inactivated during the heating step in the brewing process, and there are no residues of the source organism in the enzyme preparation, so none will be remaining in the final food.

6.2 Labelling

Substances used as processing aids, including enzymes, in accordance with Standard 1.3.3 are not subject to ingredient labelling in the final food, under clause 3 of Standard 1.2.4 – Labelling of Ingredients.

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.

Standard 1.5.2 – Food produced using Gene Technology outlines provisions for labelling of GM foods. 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". As *A. niger* has been genetically modified to contain identical copies of an endogenous endo-protease gene, no novel DNA or protein will be present in the final food. Labelling under Standard 1.5.2 therefore does not apply.

Additionally, the enzyme preparation does not contain any residual microorganism due to the purification steps undertaken during production so no GM organism would remain in the final treated food.

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 endo-protease produced from *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 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. The Office of Best Practice Regulation has advised that as the Application appears to be of a minor or machinery nature and any approval would be voluntary a Regulatory Impact Statement (RIS) is not required.

8.1 Affected Parties

The affected parties for this Application may include:

- those sectors of the food manufacturing industry, in particular the brewing industry, who wish to use endo-protease sourced from *A. niger*, as a processing aid
- consumers of food produced using the enzyme as a processing aid
- Government agencies with responsibility for ensuring compliance with the Code.

8.2 Benefit Cost Analysis

8.2.1 Reject the Application

This option is the status quo, where no changes are made to the Code.

This option would disadvantage those members of the food industry who wish to use the enzyme during manufacture of food. In particular it would disadvantage breweries who wish to use the enzyme as an alternative or additional cold stabilisation treatment that could have both economic and process time advantages over current processes.

There are no advantages to stakeholders with this option.

8.2.2 Prepare a draft variation to Standard 1.3.3

This option potentially provides positive benefits to food manufacturers, specifically brewers, who could use endo-protease as an alternative or additional haze stabilisation treatment which may have economic and process time advantages.

There should be no compliance costs for government agencies since they will not need to analyse for the presence of the enzyme in treated food.

There should also be no added costs to consumers.

8.3 Comparison of Options

Given that acceptance of this Application would impose no financial burden on any sector of the community, there may be economic benefits to the food industry and there are no public health and safety issues, option 2 is the preferred option.

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 of 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.

The issues raised in the public submissions will be evaluated and addressed in the subsequent Approval Report.

The Applicant, individuals, and organisations making submissions on this Application, will be notified at each stage of the Application. If the FSANZ Board subsequently 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 the scientific aspects of the Application, including any safety aspects and technological function of using endo-protease sourced from *A. niger* as a processing aid to produce food. Comments are also sought on the proposed draft variation (**Attachment 1**) to the Code.

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.

There are no relevant international standards for enzymes used to process food. Amending the Code to allow endo-protease sourced from *A. niger* 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 (6th 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.

The Assessment Report concludes that the use of the enzyme endo-protease sourced from *A. niger* as a processing aid does not pose any public health and safety risk and is technologically justified.

Therefore the preferred option, based on the available scientific information, is to prepare a draft variation to the Code giving permission to use endo-protease sourced from *A. niger*, 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 endo-protease sourced from *Aspergillus niger*.

11.1 Reasons for Preferred Approach

An amendment to the Code approving the use of endo-protease sourced from *A. niger* as a processing aid 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 as a processing aid for food manufacture does not raise any public health and safety concerns.

- Use of the enzyme as a processing aid is technologically justified as an alternative cold stabilisation treatment to reduce haze formation in chilled package beers, which may provide economic and process time benefits to brewers.

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

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

- There are no relevant New Zealand standards.

12. Implementation and Review

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

ATTACHMENT

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

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 A1057 – Endo-protease 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 A1057 – Endo-protease 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 –

Endo-protease EC 3.4.21.26	*Aspergillus niger*