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

15 November 2011
[22-11]

APPLICATION A1057 ENDO–PROTEASE (EC 3.4.21.26) AS A PROCESSING AID (ENZYME) APPROVAL REPORT

Executive Summary

Purpose

The purpose of the Application is to seek permission to use a new enzyme, endo-protease with the Enzyme Commission number EC 3.4.21.26, sourced from a genetically modified (GM) *Aspergillus niger* microorganism, as an approved processing aid. If approved, 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 commenced the assessment on 15 March 2011.

The proposed use of the enzyme preparation is as an alternative cold stabilisation 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 concentration of these proteins available in the final beer. This reduces their interaction with polyphenols and thus the production of 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 it 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 there are no safety concerns with the enzyme or donor/host microorganism and that 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 was demonstrated to be effective.

The 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 specific labelling requirements for this 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. The genetic modification made to the enzyme source microorganism *A. niger* has been to insert identical copies of the endogenous endo-protease gene which does not produce any novel DNA or protein into the enzyme preparation, so therefore the GM labelling requirements are not triggered.

Assessing the Application

The Application was assessed under the General Procedure and included 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.

Decision

To approve the draft variation to the Table to clause 17 of Standard 1.3.3 – Processing Aids, to permit the use of endo-protease (EC 3.4.21.26) sourced from *Aspergillus niger*.

Reasons for Decision

An amendment to the Code approving the use of endo-protease sourced from *A. niger* as a processing aid was approved 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 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 were invited on the Assessment Report, which included a draft variation to the Code, between 18 July 2011 and 29 August 2011. Comments were specifically requested on the scientific aspects of this Application, including the safety assessment and technological function of the enzyme. A total of three submissions were received as a result of this public consultation. All three submissions supported a draft variation to the Code to permit the use of the enzyme as a processing aid. There were no issues raised in the submissions that FSANZ needed to address in the Approval Report. The summary of the submissions are at **Attachment 2**.

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 (Approval)

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 with the Enzyme Commission number EC 3.4.21.26, derived from a genetically modified (GM) strain of *Aspergillus niger* as a source microorganism[1], as a processing aid. FSANZ will use the term endo-protease in the rest of the report to refer to this specific enzyme. 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 was required and must be undertaken and considered before any permission may be granted. This assessment included 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. Background

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.

> **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.

[1] The term source microorganism (or organism) is used to refer to the organism which is used to produce the enzyme using a controlled fermentation process.

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

2.2 International Regulations

The Application states that specific approval for use of this 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* have been self-assessed as generally recognized as safe (GRAS). The relevant GRAS notification is GRN 000089[2]. This US Food and Drug Administration (FDA) GRAS notification does not explicitly refer to endo-protease, the enzyme that is the subject 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, 7th 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 factors for forming beer haze (as noted below). The Application notes that reaction products of using the enzyme to treat proteins produce 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

This endo-protease is proposed by the Applicant as an alternative treatment for brewers to prevent chill haze formation in the final beer. 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 Applicant claims the enzyme hydrolyses the haze-active proteins during the fermentation step of beer production. This reduces the size and also concentration of these proteins available, in the final beer, to interact with polyphenols to produce haze.

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

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. 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.

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 extracted from the more detailed assessment in **SD1**.

RISK ASSESSMENT

5. Risk Assessment Summary

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[3]/kg bw/day), the highest dose level tested.

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

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 not active in the final food. They are usually used at low levels, sufficient to achieve the purpose. Enzymes functioning as processing aids are usually removed or inactivated during further processing of the food. This is the case for endo-protease. 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 information provided by the Applicant, the inactivated enzyme remains inert in the final food at a concentration of 15 mg TOS/L beer.

[3] Total organic solids

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 and thus reduces chill 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.

5.4 Risk Assessment conclusions

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.

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 remain 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 subclause 3(d) 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 paragraph 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 subclause 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 (non-GM) endo-protease gene (this is explained in section 2.3.2 of SD1), no novel DNA or protein will be present in the enzyme preparation and therefore in the final treated 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.

6.3 Consistency with Ministerial Council Policy Guidelines

As noted in Section 3, FSANZ is required to have regard to the relevant Ministerial Council Policy Guidelines when developing or varying food standards. For this Application FSANZ needs to have regard to the Policy Guideline: *Addition to Food of Substances other than Vitamins and Minerals,* which for processing aids are the Specific Order Policy Principles – Technological Function.

The Applicant has clearly articulated the technological function (the stated purpose) for using the enzyme to treat food. FSANZ's assessment has concluded that adding the amounts of the enzyme preparation as proposed by the Applicant is consistent with achieving the technological function. The assessment has also confirmed the use of the enzyme preparation is safe. The Applicant makes no nutrition, health or related claims in regard to the enzyme.

FSANZ notes that the use of the enzyme from both the Application and literature is likely to be in the brewing industry, if approved. However, if enzymes have been assessed as being safe to be used to treat food and also technologically suitable for their stated purpose, even if that is for specific food types, FSANZ permits their use for all foods. This is currently the case for all permitted enzymes in the Tables to clauses 15, 16 and 17 of Standard 1.3.3. There is no good reason to restrict them to the production of certain foods if their use is considered safe. In future, other food industries may want to use the enzyme for different food types.

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 were consequently been identified:

Option 1: Reject the draft variation to the Code

Option 2: Approve a variation to Standard 1.3.3 to permit the use of endo-protease produced from *A. niger*, as a processing aid.

8. Impact Analysis (RIS ID: 12065)

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 Regulation 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 of food with the Code.

8.2 Benefit Cost Analysis

8.2.1 Reject the draft variation to the Code

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 Approve the variation to Standard 1.3.3

This option potentially provides positive benefits to food manufacturers, specifically brewers, who could use this 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

Permitting the use of this endo-protease as a processing aid 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. Therefore, option 2 was the preferred option.

Communication and Consultation Strategy

9. Communication

FSANZ developed and applied a basic communication strategy to this Application. The strategy involved 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 Applicant, individuals, and organisations making submissions on this Application, will be notified at each stage of the Application. The FSANZ Board decision to approve the variation to Standard 1.3.3 has been notified 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

Public submissions were invited on the Assessment Report between 18 July 2011 and 29 August 2011. Comments were specifically requested on the scientific aspects of this Application, including the safety assessment and technological function of the enzyme. Three submissions were received as a result of this public consultation. All three submissions supported preparing a draft variation to the Code to permit the use of the enzyme as a processing aid. There were no issues raised in the submissions that FSANZ needed to address in the Approval Report. The summary of the submissions is at **Attachment 2**.

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 (7th Edition). Therefore, notification to WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreements was not considered necessary.

Primary Legislative Objectives

11. Addressing the Primary Objectives of Section 18 of the FSANZ Act

FSANZ is required by its legislation to meet the section 18 objectives of the FSANZ Act when it is developing or varying a food standard as noted in Section 3 of this report.

The primary objective relevant to consideration of this Application was the protection of public health and safety. The other two objectives have less direct relevance to FSANZ's assessment.

11.1 Risk to public health and safety

FSANZ's risk assessment concluded that approval of the use of this endo-protease enzyme sourced from *A. niger* does not pose any public health and safety concerns.

11.2 Providing adequate information to enable informed consumer choice

For this Application, this objective is taken to relate to labelling of processed foods. As noted in Section 6.2, there are no labelling requirements under the Code for the use of endo-protease as a processing aid to treat food.

11.3 Prevention of misleading and deceptive conduct

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

Conclusion

12. Conclusion and Decision

This Application was assessed against the requirements of section 29 of the FSANZ Act. FSANZ has concluded that the use of the endo-protease enzyme sourced from *A. niger* as a processing aid does not pose any public health and safety risk and is technologically justified.

Therefore the decision, based on the available scientific information, was to approve a 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 Ministerial Council Policy Guidelines relevant for this Application have been addressed in this report. The technological function (the stated purpose) of the enzyme has been articulated and has been assessed as being met. The assessment has concluded that use of the enzyme preparation as proposed by the Applicant is both safe and suitable.

The approved variation is provided in **Attachment 1**.

Decision

To approve the draft variation to the Table to clause 17 of Standard 1.3.3 – Processing Aids, to permit the use of endo-protease (EC 3.4.21.26) sourced from *Aspergillus niger*.

12.1 Reasons for Decision

An amendment to the Code approving the use of endo-protease sourced from *A. niger* as a processing aid was approved 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 draft variation to the Code is consistent with the section 18 objectives of the FSANZ Act.

- There are no relevant New Zealand standards.

13. Implementation and Review

If no review of the Board's decision is requested by the Ministerial Council, the draft variation to the Code will come into effect on gazettal.

ATTACHMENTS

1. Draft variation to the *Australia New Zealand Food Standards Code*
2. Explanatory statement
3. Summary of submissions on the Assessment Report

Attachment 1

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

Food Standards (Application A1057 – Endo-protease (EC 3.4.21.26) as a Processing Aid (Enzyme)) Variation

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

Dated XXXX

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

1 Name

This instrument is the *Food Standards (Application 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*

Attachment 2

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 A1057 which seeks approval of a new enzyme processing aid, an endo-protease (EC 3.4.21.26) sourced from a genetically modified *Aspergillus niger* microorganism, to be used as a processing aid. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft Standard.

Following consideration by Ministerial Council, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the draft 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 for using this endo-protease sourced from a genetically modified *Aspergillus niger* microorganism, to process food. The variation is proposed to address this.

3. Documents incorporated by reference

The variation does not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1057 has included one round of public consultation following an assessment and the preparation of the draft variation. An Assessment Report (which included the draft Standard) was released for consultation on 18 July 2011 for a six-week consultation period.

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

5. Variations

5.1 Item [1]

This item inserts a permission in the Table to clause 17 of Standard 1.3.3 to permit the use of endo-protease (EC 3.4.21.26) sourced from *Aspergillus niger* as an enzyme processing aid from microbial sources able to be used in the manufacture of any food.

Attachment 3

Summary of submissions on the Assessment Report

Three submissions were received during the public consultation period on the Assessment Report. The summary of these submissions is provided in the Table below. All submissions supported option 2, for FSANZ to progress the Application and to prepare a draft variation to the Code to permit the use of the enzyme as a processing aid.

Submitter	Group	Comments
Food Technology Association of Australia	Professional organisation	Supports option 2
Ministry of Agriculture and Forestry, New Zealand	Government	Supports option 2 Satisfied that the proposed use of the enzyme was technologically justified and that no public health or safety concerns had been identified.
Queensland Health	Government	Supports option 2 It noted: • The use of the enzyme did not raise any public health and safety concerns. • The use of the enzyme, in the form and amounts used, was technologically justified and had been demonstrated to be effective in achieving its stated purpose. • The use of the enzyme would provide economic and process time benefits to brewers and would not impose significant costs to government agencies, consumers or manufacturers. • The microorganism was removed from the enzyme preparation prior to use and the enzyme was inactivated by heat during the manufacture of beer so no method of analysis for the enzyme in the final food was necessary.