16 June 2022
205-22

Call for submissions – Application A1219

Alpha-amylase from GM *Bacillus licheniformis* as a processing aid

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by Danisco New Zealand Ltd to amend the Australia New Zealand Food Standards Code to permit alpha-amylase from a genetically modified *Bacillus licheniformis* containing the alpha-amylase gene from *Cytophaga* species, to be used as a processing aid in brewed beverages, potable alcohol production and starch processing. FSANZ has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at current calls for public comment and how to make a submission.

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published as soon as possible after the end of the submission period.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at information for submitters.

For information on how FSANZ manages personal information when you make a submission, see FSANZ's Privacy Policy.

Submissions should be made in writing; be marked clearly with the word 'Submission'. You also need to include the correct application or proposal number and name. Electronic submissions can be made through the FSANZ website via the link how to make a submission. You can also email your submission to submissions@foodstandards.gov.au. FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 28 July 2022

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making a submission or application and proposal processes can be sent to standards.management@foodstandards.gov.au.

Submissions in hard copy may be sent to the following addresses:

Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604
AUSTRALIA
Tel +61 2 6271 2222

Food Standards Australia New Zealand
PO Box 10559
WELLINGTON 6140
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Supporting document

The following document which informed the assessment of this Application is available on the FSANZ website:

SD Risk and Technical Assessment

Executive summary

Danisco New Zealand Ltd applied to Food Standards Australia New Zealand (FSANZ) to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of the enzyme alpha-amylase (EC 3.2.1.1) from genetically modified (GM) *Bacillus licheniformis* (*B. licheniformis*) as a processing aid for use in brewing, potable alcohol production and starch processing. The alpha-amylase enzyme is produced by submerged fermentation of *B. licheniformis* carrying the alpha-amylase gene from *Cytophaga* species (sp.).

FSANZ has undertaken an assessment to determine whether the enzyme achieves the requested technological purpose in the quantity and form proposed to be used, and to evaluate public health and safety concerns associated with its use.

FSANZ concludes that the proposed use of the alpha-amylase enzyme in the brewing of beverages, production of potable alcohol and starch processing is consistent with its typical function of catalysing the breakdown of starch to sugars. Analysis of the evidence provides adequate assurance that the use of the enzyme, in the form and requested amount (i.e. at a level not higher than necessary to achieve the desired enzyme reaction according to Good Manufacturing Practice (GMP)), is technologically justified and has been demonstrated to be effective in achieving the stated purpose.

Alpha-amylase performs its technological purpose during the production of the nominated foods and is not performing a technological purpose in the final food, therefore functioning as a processing aid for the purposes of the Code. Relevant identity and purity specifications for the enzyme are included in the Code.

No public health and safety concerns were identified in the assessment of alpha-amylase from GM *B. licheniformis* under the proposed conditions of use. A microbiological assessment concluded that *B. licheniformis* has a long history of safe use in food and is neither pathogenic nor toxigenic. A biotechnology assessment confirmed the genetic modification is as described and that the inserted gene has been stably introduced. A toxicological assessment combined with a dietary exposure assessment concluded the enzyme is safe under the proposed conditions of use. In the absence of any identifiable hazard, an acceptable daily intake (ADI) ‘not specified’ is appropriate.

FSANZ has therefore prepared a draft variation to the Code, which if approved, would list the enzyme, alpha-amylase (EC 3.2.1.1) sourced from *B. licheniformis* containing the alpha-amylase gene from a *Cytophaga* species, in the table to subsection S18—9(3) of the Code as a permitted processing aid. The enzyme would be permitted for use in brewing, the production of potable alcohol and starch processing. This permission would be subject to the condition that the maximum permitted level of the enzyme used is an amount consistent with GMP.

FSANZ seeks submissions on the draft variation.

1 Introduction

1.1 The Applicant

The applicant is Danisco New Zealand Ltd (Danisco).

1.2 The Application

The applicant is seeking to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of the enzyme alpha-amylase from genetically modified (GM) *Bacillus licheniformis* (*B. licheniformis*) as a processing aid. The alpha-amylase enzyme is produced by submerged fermentation of *B. licheniformis* carrying the alpha-amylase gene from *Cytophaga* species (sp.). The stated purpose is for use during the processing of brewed beverages, potable alcohol production and starch processing.

The applicant markets different liquid preparations containing this enzyme as the active component, under various names including 'Spezyme SL' and 'GC 126', in other countries where its use is permitted (see Section 2.4.3 of this report).

The applicant has indicated the enzyme is to be used in accordance with Good Manufacturing Practice (GMP) i.e. the minimum amount is used to achieve the technological purpose.

1.3 The current standard

Australian and New Zealand food laws require food for sale to comply with relevant requirements in the Code. The requirements relevant to this application are summarised below.

1.3.1 Permitted use

Enzymes used to process and manufacture food are considered processing aids. Although they may be present in the final food, they no longer provide a technological purpose in the final food.

Paragraph 1.1.1—10(6)(c) provides that food for sale cannot contain, as an ingredient or component, a substance 'used as a processing aid' unless that substance's use as a processing aid is expressly permitted by the Code. Section 1.1.2—13 provides that a substance 'used as a processing aid' in relation to a food is a substance used during the course of processing that meets all of the following conditions:

- it is used to perform a technological purpose during the course of processing
- it does not perform a technological purpose in the food for sale, and
- it is a substance listed in Schedule 18 or identified in section S16—2 as an additive permitted at GMP.

Standard 1.3.3 and Schedule 18 of the Code list the permitted processing aids. Enzymes of microbial origin permitted to be used as processing aids are listed in the table to subsection S18—4(5) or in the table to subsection S18—9(3) of Schedule 18, depending on whether a technological purpose has been specified. Enzymes of microbial origin listed in the table to subsection S18—4(5) are permitted for use as a processing aid to perform any technological purpose if the enzyme is derived from the corresponding source specified in the table. The table to subsection S18—9(3) lists those substances, including enzymes derived from particular sources, that are permitted to be used as processing aids for specific technological purposes in relation to:

- if a food is specified—that food; or
- if no food is specified—any food.

Additionally, paragraph 1.3.3—11(c) specifies that the substance may only be used as a processing aid if it is not present in the food at greater than the maximum permitted level for that substance indicated in the table to section S18—9.

Paragraph 1.1.1—10(6)(g) requires that the presence as an ingredient or component in a food for sale of a food produced using gene technology must be expressly permitted by the Code. Paragraph 1.5.2—3(b) provides that permission in the Code for use as a processing aid also constitutes the permission required by paragraph 1.1.1—10(6)(g).

Alpha-amylase is already permitted to be used as a processing aid by the Code including from plant sources (malted cereals (subsection S18—4(4)), and from various microbial origins including *B. licheniformis* (subsections S18—4(5) and S18—9(3)), however not from *B. licheniformis* carrying the alpha-amylase gene from *Cytophaga* sp. as requested by the applicant.

1.3.2 Identity and purity requirements

Paragraph 1.1.1—15(1)(b) of the Code requires substances used as processing aids to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code.

Subsection S3—2(1) of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications (FAO JECFA Monographs 23 (2019)), and the United States Pharmacopeial Convention (2020) Food chemicals codex (12th edition). These include specifications for enzyme preparations used in food processing.

1.3.3 Labelling requirements

Subsection 1.1.1—10(8) provides that food for sale must comply with all relevant labelling requirements imposed by the Code for that food.

Subsection 1.2.3—4(1) requires certain foods or their derivatives (as listed in the table to section S9—3 of Schedule 9) to be declared when present in a food for sale (unless they are exempt under subsection 1.2.3—4(4)). The food may be present as a substance used as a processing aid or as an ingredient or component of a substance used a processing aid (paragraph 1.2.3—4(5)(c)). Where the food to be declared is a substance used as a processing aid or an ingredient or component of such a substance, subsection 1.2.3—6(2) requires a declaration for the purposes of paragraph 1.2.1—8(1)(d) or subparagraph 1.2.4—5(6)(b)(i) to be made by (among other things) listing in the statement of ingredients of the food for sale the required name[1] of the food to be declared and the words 'processing aid' in conjunction with that required name[2]. If the food is not required to bear a label, the declaration must be displayed in connection with the display of the food or provided to the purchaser on request (subsections 1.2.1—9(6) and (7)).

Paragraphs 1.2.4—3(2)(d) and (e) exempt processing aids from the requirement to be declared in the statement of ingredients, unless other requirements apply.

Section 1.5.2—4 requires processing aids that are foods produced using gene technology to be labelled 'genetically modified' in conjunction with the name of that food, where novel DNA and/or novel protein from the processing aid remains present in the final food. The requirement applies to foods for sale that consist of or have as an ingredient, food that is a *genetically modified food*[3] (GM food). The requirements imposed by section 1.5.2—4 generally apply only to foods for retail sale and to foods sold to a caterer, under subsection 1.2.1—8(1) and 1.2.1—9(3), and section 1.2.1—15 respectively.

1.4 International standards

In developing food regulatory measures, FSANZ must have regard to the promotion of consistency between domestic and international food standards. In terms of food safety, the relevant international standard setting body is the Codex Alimentarius Commission (Codex). In contrast to food additives, there is no Codex Alimentarius 'general standard' for enzymes, however as noted above, there are internationally recognised specifications for enzyme preparations established by JECFA and Food Chemicals Codex.

In addition, there is a Codex guideline, *Guidelines on Substances used as Processing Aids* (CAC/GL 75-2010) which sets out general principles for the safe use of substances used as processing aids, including that substances used as processing aids shall be used under conditions of GMP.

1.5 Reasons for accepting Application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), and
- it related to a matter that warranted the variation of a food regulatory measure.

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[1] ***Required name***, of a particular food, means the name declared by section 1.2.3—5 as the required name for that food for the purposes of Division 3 of Standard 1.2.3 (see subsection 1.1.2—2(3)).

[2] On 25 February 2021 new requirements for the labelling of allergens were introduced in the Code and suppliers have until 25 February 2024 to change over to these new requirements. If a food was packaged and labelled before 25 February 2024 and it complied with the previous allergen labelling requirements, then that food can remain on sale for another two years as long as it complies with the rest of the Code.

[3] Section 1.5.2—4(5) defines ***genetically modified food*** to mean a '*food produced using gene technology that
a) contains novel DNA or novel protein; or
b) is listed in Section S26—3 as subject to the condition that its labelling must comply with this section' (*that being section 1.5.2—4*).

1.6 Procedure for assessment

The application is being assessed under the General Procedure in the FSANZ Act.

2 Summary of the assessment

2.1 Risk assessment

FSANZ has assessed the public health and safety risks associated with alpha-amylase from *Cytophaga* sp. that is produced by GM *B. licheniformis* and its proposed use as a processing aid. A summary of this risk assessment is provided below.

The proposed use of this alpha-amylase as a processing aid in starch processing, brewing of beverages and production of potable alcohol is technologically justified.

No public health and safety concerns were identified in the assessment of alpha-amylase from GM *B. licheniformis* under the proposed conditions of use. A microbiological assessment concluded that *B. licheniformis* has a long history of safe use in food and is neither pathogenic nor toxigenic. A biotechnology assessment confirmed the genetic modification is as described and that the inserted gene has been stably introduced. A toxicological assessment combined with a dietary exposure assessment concluded the enzyme is safe under the proposed conditions of use.

In the absence of any identifiable hazard, an acceptable daily intake (ADI) 'not specified' is appropriate.

For further details on the risk assessment, refer to SD – Risk and Technical Assessment.

2.2 Risk management

The risk management options available to FSANZ after assessment were to either:

- reject the application, or
- prepare a draft variation of the Code.

For the reasons set out in this report, FSANZ decided to prepare a draft variation to the Code (Attachment A) to permit the enzyme, alpha-amylase (EC 3.2.1.1) sourced from a GM *B. licheniformis* containing the alpha amylase gene from a *Cytophaga* species, to be used as a processing aid in brewing, the production of potable alcohol and starch processing. If approved, the proposed permission would be subject to the condition that the maximum permitted level of this enzyme that may be present in the food is consistent with GMP.

The conclusions from the risk and technical assessment were that the proposed use of the enzyme is technically justified and there were no safety concerns associated with its proposed use.

Other risk management considerations for this application are related to the enzyme and source microorganism nomenclature, specifications and labelling. These are discussed below.

2.2.1 Regulatory approval for enzymes

Alpha-amylase performs its technological purpose during brewing, the production of potable alcohol and starch processing, and does not perform a technological purpose in the final food. On that basis, if the draft variation is approved, the enzyme would function as a

processing aid for the purposes of the Code. From the food technology assessment, FSANZ concluded that the proposed use of this alpha-amylase enzyme is consistent with its typical function of catalysing the breakdown of starch to sugars.

The express permission for the enzyme to be used as a processing aid would also provide the permission for its potential presence in the food for sale as a food produced using gene technology. The enzyme is a food produced using gene technology according to the Code as it is derived from 'an organism that has been modified using gene technology' (see subsection 1.1.2—2(3) of the Code)[4].

2.2.2 Enzyme nomenclature, source microorganism nomenclature, and specifications

The International Union of Biochemistry and Molecular Biology (IUBMB) uses the accepted name 'α-amylase'. This is the name used in the proposed draft variation and the name used in existing permissions for alpha-amylase in Schedule 18. The word 'alpha' has been used in this report and was used by the applicant in the application, instead of its symbol.

Nomenclature for the host and gene donor organisms (*Bacillus licheniformis* and *Cytophaga* species, respectively), is in accordance with accepted international norms. The proposed draft variation refers to a *Cytophaga* species rather than a specific species as would normally be included in Schedule 18, because in this case systematic microbiological classification of the species of *Cytophaga* is incomplete (see Section 3.1.2 of the SD).

There are relevant identity and purity specifications for the enzyme in two of the primary sources of specifications listed in Schedule 3 – namely the JECFA Combined Compendium of Food Additive Specifications, and the United States Pharmacopeial Convention Food chemicals codex (refer to Section 1.3.2 above).

2.2.3 Labelling

In general, processing aids are exempt from the requirement to be declared in the statement of ingredients, unless other labelling requirements apply (see Section 1.3.3 above). In the case of foods manufactured using this processing aid, other requirements would apply as detailed in Sections 2.2.3.1 and 2.2.3.2 below.

2.2.3.1 Declaration of certain foods

Section 2.2.1 of SD1 states that wheat and soybeans could be present in the enzyme concentrate. If wheat, gluten or soy is present in a food for sale, including when present as a processing aid or an ingredient or component of a processing aid, they must be declared unless an exemption applies e.g. alcohol distilled from wheat (see subsection 1.2.3—4(4) of Standard 1.2.3 and the table to section S9—3).

2.2.3.2 Labelling requirements for food produced using gene technology

Standard 1.5.2 in effect provides that a substance used as a processing aid that contains novel DNA or novel protein is a GM food. Subsection 1.5.2—4(2) states that the information relating to foods produced using gene technology must include the statement 'genetically modified' in conjunction with the name of the GM food. Subsection 1.5.2—4(3) states that if the GM food is used as a processing aid, the information may be included in the statement of ingredients.

[4] Food produced using gene technology' is defined in subsection 1.1.2—2(3) as meaning 'a food which has been derived or developed from an organism which has been modified by gene technology'.

The requirement for labelling as 'genetically modified' differs depending on whether the GM food is an ingredient of the food for sale or not (section 1.5.2—4(1)). A food for retail sale or sold to a caterer that contains alpha-amylase sourced from *Bacillus licheniformis* as an ingredient (e.g. the enzyme is used in the manufacture of a brewed beverage (e.g. beer) would be required to be labelled with the statement 'genetically modified' in conjunction with the name of the enzyme. FSANZ notes however, if the food made using the enzyme is not the food for sale itself (e.g. is present in the beer used in batter for a battered fish product), the enzyme would not be an ingredient in the food for sale and the labelling requirement would not apply.

2.2.4 Risk management conclusion

The risk management conclusion is to permit the enzyme, alpha-amylase (EC 3.2.1.1) sourced from a GM *B. licheniformis* containing the alpha-amylase gene from a *Cytophaga* species, for use as a food processing aid. If the draft variation is approved, the permission would be listed in the table to subsection S18—9(3) of the Code, which includes enzymes permitted for a specific technological purpose. The technological purpose of this enzyme would be as a processing aid in brewing, the production of potable alcohol and starch processing. The maximum level at which the enzyme may be present in the food would be an amount consistent with GMP. The express permission for the enzyme to be used as a processing aid in Schedule 18 of the Code would also provide the permission for the enzyme's potential presence in the food for sale as a food produced using gene technology.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a standard communication strategy to this application. All calls for submissions are notified via the Food Standards Notification Circular, media release, FSANZ's social media tools and Food Standards News.

The process by which FSANZ approaches standards development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options.

The draft variation will be considered for approval by the FSANZ Board taking into account all public comments received from this call for submissions.

2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members 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.

As noted Section 1.3.4 above, the relevant international standard setting body is the Codex Alimentarius Commission (Codex). As noted, there is no Codex Alimentarius 'general standard' for processing aids, however there are JECFA and Food Chemicals Codex general specifications, and a Codex guideline on processing aids. In addition, under JECFA, enzyme preparations must meet the specifications criteria contained in the individual specification monographs. In the case of this particular alpha-amylase, there is no specific monograph.

Amending the Code to permit the use of alpha-amylase from GM *B. licheniformis* as a processing aid in the foods requested is unlikely to have a significant effect on international

trade. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

When assessing this Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

2.4.1 Section 29

2.4.1.1 Consideration of costs and benefits

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for applications relating to processing aids and GM food (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting new GM foods and new processing aids is deregulatory as their use will be voluntary if the application concerned is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

FSANZ, however, has given consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

The purpose of this consideration is to determine if the community, government and industry as a whole is likely to benefit, on balance, from a move from the status quo. This analysis considers permitting the proposed use of the enzyme alpha-amylase from a GM *B. licheniformis* as a processing aid in brewed beverages, potable alcohol production and starch processing.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures. In fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo by permitting the use of the enzyme produced from the GM *B*. *licheniformis.*

FSANZ's conclusions regarding costs and benefits of the proposed measure are set out below. However, information received from the call for submissions may result in FSANZ arriving at different conclusions.

2.4.1.1.1 Costs and benefits of permitting the use of enzyme alpha-amylase (EC 3.2.1.1) sourced from a GM B. licheniformis as a processing aid

Industry

The enzyme alpha-amylase is already available to industry from other production sources. Due to the voluntary nature of the proposed permission, industry will use alpha-amylase from this additional source, GM *B. licheniformis*, where businesses in the industry believe a net benefit exists for them. An additional source of this enzyme may help industry save on production costs of brewing, production of potable alcohol and starch processing.

The use of this enzyme from this source has GRAS status in USA and approval for various

purposes in France and Denmark. Therefore, the approval of this enzyme in the Code may help some of Australia's and New Zealand's sales in international markets. There may, however, be more competing imports in the domestic market from countries that use this enzyme into the future.

Consumers

Industry may pass cost savings to consumers, where it is cheaper to source alpha-amylase from GM *B. licheniformis* in production processes.

Government

Permitting this additional source of alpha-amylase may result in a small cost to government in terms of adding the permitted source to the current range of processing aids that are monitored for compliance.

Conclusions from cost benefit considerations

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting the proposed use of the enzyme alpha-amylase from a GM *B. licheniformis* as a processing aid in brewed beverages, potable alcohol production and starch processing most likely outweigh the associated costs.

2.4.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the Application.

2.4.1.3 Any relevant New Zealand standards

The relevant standards apply in both Australia and New Zealand. There are no relevant New Zealand only Standards.

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2 Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.4.2.1 Protection of public health and safety

FSANZ undertook a safety assessment (see SD) and concluded there were no public health and safety concerns associated with the proposed use of this enzyme.

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

The labelling requirements for this enzyme are discussed in Section 2.2.3 of this report.

2.4.2.3 The prevention of misleading or deceptive conduct

There are no issues identified with this application relevant to this objective.

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ used the best available scientific evidence to conduct the risk analysis. The applicant submitted a dossier of information and scientific literature as part of its application. This dossier, together with other technical and scientific information, was considered by FSANZ in assessing the application. The risk assessment is provided in SD.

- **the promotion of consistency between domestic and international food standards**

There are relevant international specifications for enzyme preparations, being the JECFA Compendium of Food Additive Specifications and the Food Chemicals Codex specifications for enzymes referred to in Section 1.3 of this report.

- **the desirability of an efficient and internationally competitive food industry**

The applicant advised that the substance is currently approved for use as a processing aid in France and Denmark. Approval for its use would bring Australia and New Zealand into line with other jurisdictions where it is already authorised for use. In this way, Australia and New Zealand would remain competitive with other international markets. This would also help foster continued innovation and improvements in food manufacturing techniques and processes.

The conclusion of the risk assessment is there are no public health and safety concerns associated with the production microorganism or with the proposed use of the enzyme as a food processing aid. It is therefore appropriate that Australian and New Zealand food industries are given the opportunity to benefit from this alternative enzyme for the various applications proposed by the applicant.

Ultimately, the domestic food industry will make their own economic decisions, taking into account the costs and benefits of using the new enzyme, to determine if it is of benefit to their particular business.

- **the promotion of fair trading in food**

No issues were identified for this application relevant to this objective.

- **any written policy guidelines formulated by the Forum on Food Regulation**

The Ministerial Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*[5] includes specific order policy principles for substances added to achieve a solely technological function, such as processing aids. These specific order policy principles state that permission should be granted where:

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the 'stated purpose')
- the addition of the substance to food is safe for human consumption
- the amounts added are consistent with achieving the technological function

[5] Food regulation website

- 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.

FSANZ determined that permitting the proposed use of this enzyme is consistent with these specific order policy principles for 'Technological Function'. All other relevant requirements of the policy guideline are similarly met.

3 Draft variation

The draft variation to the Code is at Attachment A and if approved, is intended to take effect on gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

Attachments

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

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

Food Standards (Application A1219 – Alpha-amylase from GM *Bacillus licheniformis* as a processing aid) Variation

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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 variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[Insert Delegate's name and position title]
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1219 – Alpha-amylase from GM* Bacillus licheniformis *as a processing aid) Variation*.

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

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

3 Commencement

The variation commences on the date of gazettal.

Schedule

Schedule 18—Processing aids

[1] Subsection S18—9(3) (table)

Insert:

α-Amylase (EC 3.2.1.1) sourced from *Bacillus licheniformis* containing the α-Amylase gene from a *Cytophaga* species	For use in: (a) brewing; (b) the production of potable alcohol; and (c) starch processing.	GMP

Attachment B – Draft Explanatory Statement

1. Authority

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

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

The Authority accepted Application A1219 which seeks to amend the Code to permit the enzyme, alpha-amylase from a genetically modified *Bacillus licheniformis* containing the alpha-amylase gene from *Cytophaga* species, to be used as a processing aid in brewed beverages, potable alcohol production and starch processing. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation.

2. Variation will be a legislative instrument

If approved, the draft variation would be a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and be publicly available on the Federal Register of Legislation (www.legislation.gov.au).

If approved, this instrument would not be subject to the disallowance or sunsetting provisions of the *Legislation Act 2003.* Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunsetting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the Food Ministers Meeting (FMM). The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has prepared a draft variation amending the table to subsection S18—9(3) in Schedule 18 of the Code to permit the use of the enzyme, α-Amylase (EC 3.2.1.1) sourced from *Bacillus licheniformis* containing the α-Amylase gene from a *Cytophaga* species, as a processing aid for use in brewing, the production of potable alcohol and starch processing. If approved, this permission would be subject to the condition that the maximum permitted level

or amount of the enzyme that may be present in the food must be consistent with Good Manufacturing Practice (GMP).

4. Documents incorporated by reference

The draft variation does not incorporate any documents by reference.

However, existing provisions of the Code incorporate documents by reference that will prescribe identity and purity specifications for the processing aid to be permitted by the draft variation. Section 1.1.1—15 of the Code requires substances used as processing aids to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code. Section S3—2 of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications (FAO JECFA Monographs 23 (2019)) and the United States Pharmacopeial Convention (2020) Food Chemicals Codex (12th edition). These include specifications for enzyme preparations used in food processing.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1219 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) will be open for a six-week period.

The Office of Best Practice Regulation (OBPR) granted the Authority a standing exemption from the requirement to develop a Regulatory Impact Statement for applications relating to permitting new processing aids and genetically modified food (OBPR correspondence dated 24 November 2010 - reference 12065). This standing exemption was provided as permitting new genetically modified foods and new processing aids is deregulatory as their use will be voluntary if the application concerned is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

6. Statement of compatibility with human rights

If approved, this instrument would be exempt from the requirements for a statement of compatibility with human rights as it would be a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

Item [1] of the Schedule to the draft variation would insert a new entry, in alphabetical order, into the table to subsection S18—9(3) in Schedule 18. The new entry would consist of the following enzyme:

- α-Amylase (EC 3.2.1.1) sourced from *Bacillus licheniformis* containing the α-Amylase gene from a *Cytophaga* species.

The technological purpose for this enzyme would be for use in brewing, the production of potable alcohol and starch processing.

The permission would be subject to the condition that the maximum permitted level or amount of this enzyme that may be present in the food must be consistent with GMP.

If approved, the draft variation would permit the proposed use of α-Amylase (EC 3.2.1.1) sourced from *Bacillus licheniformis* containing the α-Amylase gene from a *Cytophaga* species as a processing aid in accordance with the Code.