27 May 2022

202-22

Call for submissions – Application A1248

Glucoamylase from GM *Aspergillus niger* (gene donor: *Gloeophyllum trabeum*) as a processing aid

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by Novozymes Pty Ltd to amend the Australia New Zealand Food Standards Code to permit the use of a protein engineered variant of the glucoamylase enzyme produced by a genetically modified strain of *Aspergillus niger*. FSANZ has subsequently 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) 8 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:

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PO Box 5423
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PO Box 10559
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Supporting document

The following document which informed the assessment of this application are available on the FSANZ website:

SD1 Risk and technical assessment report

Executive summary

The application seeks to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of a protein engineered variant of the glucoamylase enzyme (EC 3.2.1.3) from a new genetically modified (GM) strain of *Aspergillus niger* (*A. niger*), as a processing aid in starch processing and the production of distilled alcohol[1]. Glucoamylases from other sources are permitted in the Code.

Glucoamylase breaks down starch polysaccharides to release glucose and other fermentable sugars. The resulting glucose molecules can then be used to produce potable alcohol and starch hydrolysates such as glucose syrup.

This glucoamylase is produced from a GM strain of *A. niger* containing a protein engineered variant of the glucoamylase gene from *Gloeophyllum trabeum* (*G. trabeum*). *A. niger* is neither toxigenic nor pathogenic and has a long history of safe use as a source of enzyme processing aids, including several already permitted in the Code. Analysis of the production strain confirmed the presence and stability of the inserted DNA.

After undertaking a risk assessment, FSANZ concludes there are no public health and safety concerns associated with the proposed use of this glucoamylase enzyme. In the absence of any identifiable hazard, an acceptable daily intake (ADI) of 'not specified' is appropriate.

The application clearly states the technological purpose of the enzyme. It contains adequate evidence that the proposed use of the enzyme in the recommended form and quantity is technologically justified and has been demonstrated to be effective in achieving its stated purpose. The enzyme meets international purity specifications.

FSANZ has therefore prepared a draft variation to the Code, which if approved, would list the enzyme glucoamylase derived from a GM strain of *A. niger*, containing a protein engineered variant of the glucoamylase gene from *G. trabeum*, in the table to subsection S18—9(3) as a permitted processing aid for use in starch processing and production of potable alcohol. 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.

FSANZ now seeks submissions to assist consideration of the draft variation to the Code.

[1] The term 'potable alcohol' is used in this report. See section 1.2 for further information.

1 Introduction

1.1 The Applicant

Novozymes Australia Pty Ltd is a biotechnology company that manufactures enzymes for food and industrial uses.

1.2 The Application

The application seeks to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of a new protein engineered variant of a genetically-modified (GM) microbial source for the enzyme glucoamylase (EC 3.2.1.3) as a processing aid in distilled alcohol production and starch processing. Although the application refers to 'distilled alcohol', the term 'potable alcohol' has been used in this report. The permissions already in S18—9(3) for similar enzymes refer to 'potable alcohol' rather than distilled alcohol, which reflects that the terms are used interchangeably in the beverage industry. The applicant confirmed that 'potable alcohol' is appropriate in this case.

Other glucoamylases are permitted for use as processing aids in the manufacture of starch-based products such as syrups, bakery products, fruit products and potable alcohol. The glucoamylase in this application is produced from a new GM strain of *Aspergillus niger* (*A. niger*), containing a protein engineered variant of the glucoamylase gene from *Gloeophyllum trabeum* (*G. trabeum*). If permission is granted, this glucoamylase will provide an additional option for starch processors and manufacturers of potable alcohol.

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 must comply with relevant requirements in the Code. The relevant requirements for 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).

There are currently permissions for glucoamylase (EC 3.2.1.3) from other source organisms including *A. niger* within the table to subsection S18—4(5), to be used in the manufacture of all foods. Glucoamylase from *A. niger* with other gene donors is also permitted in S18—9(3) to hydrolyse starch in brewing, the manufacture of bakery products, syrups, beverages, cereal-based products, fruit products and vegetable products; and for use in starch processing and the production of potable alcohol. However, glucoamylase from the particular microbial source and gene donor that is the subject of this application is not currently permitted.

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) of the Code provides that food for sale must comply with all relevant labelling requirements imposed by the Code for that food.

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, or have as ingredients, 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*[2] (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 subsections 1.2.1—8(1) and 1.2.1—9(3), and section 1.2.1—15 respectively.

[2] 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*).

1.3.4 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). 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.

The applicant advised that the substance is currently approved for use as a processing aid in France and Denmark.

1.4 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 At 1991* (FSANZ Act)
- it related to a matter that warranted the variation of a food regulatory measure.

1.5 Procedure for assessment

The Application is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Risk assessment

FSANZ has assessed the public health and safety risks associated with glucoamylase produced using a GM strain of *A. niger,* containing a protein engineered variant of the glucoamylase gene from *G. trabeum*, and its proposed use (see SD1). A summary of this risk assessment is provided below.

The proposed use of this protein engineered variant of glucoamylase produced from GM *A. niger* as a processing aid in starch processing and the production of potable alcohol, is technologically justified.

No public health and safety concerns were identified in the assessment of this protein engineered glucoamylase, under the proposed conditions of use. A microbiological assessment concluded that the host strain is neither pathogenic nor toxigenic. The GM production strain was confirmed to contain the inserted DNA and the glucoamylase gene was shown to be expressed over multiple generations and is stable.

A toxicological assessment combined with a dietary exposure assessment concluded the enzyme is safe under the proposed conditions of use. The toxicological assessment noted a degree of similarity between the enzyme and a respiratory allergen. However, respiratory allergens are usually not food allergens and there is no evidence of allergic reactions following oral exposure to this glucoamylase.

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

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 listed in this report, FSANZ decided to prepare a draft variation to the Code permitting the use of glucoamylase produced using a GM strain of *A. niger,* containing a protein engineered variant of the glucoamylase gene from *G. trabeum*, as a processing aid in starch processing and production of potable alcohol. If approved, this permission would be subject to the condition that the maximum permitted level or amount of enzyme used in the food must be consistent with GMP.

The Risk and technical assessment report concluded that there are no safety concerns relating to using Novozymes' glucoamylase for its proposed purpose. Further details are provided below.

If permitted, this enzyme preparation will provide the food industry with an alternative source of glucoamylase.

2.2.1 Regulatory approval for enzymes

As stated above, FSANZ has prepared a draft variation to permit the use of the enzyme as a processing aid for its stated purpose. The express permission for the enzyme to be used as a processing aid will 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 for Code purposes as it is derived from 'an organism that has been modified using gene technology' (see subsection 1.1.2—2(3) of the Code).

2.2.2 Enzyme and source microorganism nomenclature

FSANZ noted that the International Union of Biochemistry and Molecular Biology (IUBMB), the internationally recognised authority for enzyme nomenclature, recognises the name "glucoamylase" for the enzyme with an EC number of EC 3.2.1.3 (IUBMB 2018).

The nomenclature of the gene donor and production microorganisms were checked and confirmed as being appropriate as listed in the application. The host organism *A. niger* is a commonly listed microorganism within Schedule 18 of the Code.

2.2.3 Labelling requirements

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 apply as detailed in section 2.2.3.1 below.

2.2.3.1 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.

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 glucoamylase from GM *A. niger* as an ingredient (e.g. the enzyme is used in the manufacture of glucose syrup) would be required to be labelled '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 glucose syrup used as a sweetener in confectionery), the enzyme would not be an ingredient in the food for sale and the labelling requirement would not apply.

FSANZ notes an intended use of the enzyme is in the production of potable alcohol. Potable alcohol is manufactured using a distillation process. If a distillation process is used, novel DNA and novel protein would be removed and the requirement to label glucoamylase as 'genetically modified' would not apply.

2.2.4 Risk management conclusion

The risk management conclusion is to permit the enzyme glucoamylase (EC 3.2.1.3) sourced from *A. niger,* containing a protein engineered variant of the glucoamylase gene from *G. trabeum*, for use as a food processing aid. If 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 used in starch processing and the production of potable alcohol. The maximum permitted level or amount of the enzyme that may be present in the food would have to be 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 basic 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 considers 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 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.

There are no relevant international standards and amending the Code to permit a new microbial source for a currently permitted enzyme is unlikely to have a significant effect on international trade as enzymes used as processing aids are not regulated by Codex Alimentarius. 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 permitting new processing aids and GM foods (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting new processing aids and GM foods 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 away from the status quo (i.e. approving the application). This analysis considers permitting the use of a protein engineered glucoamylase enzyme derived from a GM strain of *A. niger,* as a processing aid in starch processing and the production of potable alcohol. FSANZ is of the view that no other realistic food regulatory measures exist, however information received during public consultation may result in FSANZ arriving at a different outcome.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, 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.

Costs and benefits of permitting the use of a protein engineered glucoamylase enzyme derived from a GM strain of A. niger as a processing aid

Industry

Due to the voluntary nature of the permission, industry will use this glucoamylase enzyme where they believe a net benefit exists. There are other enzymes available to industry that perform similar functions and it would be of benefit to industry to have additional choice available to them, especially where the enzyme is more effective or cheaper than other enzymes currently available.

Novozymes' enzyme is permitted for use in Denmark and France. The international permissions for this enzyme may be a business opportunity for Australian and New Zealand industries, although there may also be competing imports from these countries into the domestic market.

Consumers

Industry may pass some of the possible cost savings from using this enzyme onto consumers. Consumers may also benefit from better and/or more consistent product quality.

Government

Permitting this enzyme may result in a small cost to government in terms of adding the enzyme 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 use of this enzyme as a processing aid for the proposed technological purpose 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 and 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 (SD1) 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 considerations for this enzyme are discussed in Section 2.2.3 above.

2.4.2.3 The prevention of misleading or deceptive conduct

There were 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 has used the best available scientific evidence to conduct the risk analysis, which is provided in SD1. The applicant submitted a dossier of scientific studies as part of the application. This dossier, together with other technical information including scientific literature, was used in assessing the application.

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

There is no Codex Alimentarius general standard for processing aids (in contrast to the Codex General Standard for Food Additives). However, the enzyme processing aid meets the general specifications for enzymes set out in the JECFA Combined Compendium of Food Additive Specifications and the Food Chemicals Codex specifications for enzymes referred to in Section 1.3 of this report. This enzyme is permitted for use in Denmark and France.

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

As mentioned above, the use of this enzyme is already permitted in Denmark and France. Therefore, the approval for use of this enzyme would bring Australia and New Zealand into line with these other countries where it is already authorised for use. In this way, Australia and New Zealand will remain competitive with other international markets. This will 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 using this 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, participants in the domestic food industry will make their own economic decisions, taking into account the costs and benefits of using this new enzyme, to determine if it is suitable for 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*[3] 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
- 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 this enzyme is consistent with these specific order policy principles for 'Technological Function'. All other requirements of the policy guidelines 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.

4 References

IUBMB (2018). EC 3.2.1.3 https://iubmb.qmul.ac.uk/enzyme/EC3/2/1/3.html Accessed 11 March 2022

JECFA (2017) Combined compendium of food additive specifications (FAO JECFA Monograph 1) http://www.fao.org/docrep/009/a0691e/A0691E03.htm

[3] https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Substances-other-than-Vitamins-and-Minerals

USPC (2018) Food Chemicals Codex 11th Edition, United States Pharmacopeial Convention, Rockville, MD. http://publications.usp.org/

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 A1248 – Glucoamylase from GM *Aspergillus niger* (gene donor: *Gloeophyllum trabeum*) 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]

[Delegate's name and position]

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 A1248 – Glucoamylase from GM* Aspergillus niger *(gene donor:* Gloeophyllum trabeum*) 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:

Glucoamylase, protein engineered variant, (EC 3.2.1.3) sourced from *Aspergillus niger* containing the glucoamylase gene from *Gloeophyllum trabeum*	For use in starch processing and the production of potable alcohol	GMP

[2] Subsection S18—9(3) (note after table)

Repeal the note, substitute:

Note Some enzyme sources identified in this table are protein engineered. If such an enzyme is used as a processing aid, the resulting food may have as an ingredient a food produced using gene technology, and the requirements relating to foods produced using gene technology will apply—see Standard 1.2.1 and Standard 1.5.2. The relevant enzymes are the following:

- Endo-1,4-ß-xylanase, protein engineered variant;
- Glucoamylase, protein engineered variant;
- Maltogenic α-Amylase, protein engineered variant;
- Protein engineered enzymes used in the manufacture of various steviol glycosides.

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 A1248 which seeks to amend the Code to permit the use of a protein engineered glucoamylase enzyme (EC 3.2.1.3) produced by a new genetically modified strain of *Aspergillus niger* as a processing aid in starch processing and potable alcohol production. 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) of the Code to permit the use of glucoamylase (EC 3.2.1.3) sourced from *Aspergillus niger* containing a protein engineered variant of the glucoamylase gene from *Gloeophyllum trabeum,* as a processing aid in starch processing and potable alcohol production. 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 would 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) Compendium of Food Additive Specifications (FAO/WHO 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 A1248 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 occur for a six-week consultation period.

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from needing to develop a Regulatory Impact Statement for proposed variations of the Code to permit additional processing aids and genetically modified food (OBPR correspondence dated 24 November 2010 - reference 12065). This standing exemption was provided as permitting new processing aids and genetically modified food is deregulatory as their use will be voluntary if the application concerned is approved. This standing exemption relates to the introduction of a food product 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 draft variation would insert a new entry, in alphabetical order, into the table to subsection S18—9(3) of the Code. The new entry consists of the following enzyme:

"Glucoamylase, protein engineered variant, (EC 3.2.1.3) sourced from *Aspergillus niger* containing the glucoamylase gene from *Gloeophyllum trabeum*"

The permitted technological purpose for this enzyme would be use as a processing aid in starch processing and the production of potable alcohol.

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, **item [1]** of the draft variation would permit the proposed use of the enzyme, glucoamylase (EC 3.2.1.3) sourced from a genetically modified strain of *Aspergillus niger*, containing a protein engineered variant of the glucoamylase gene from *Gloeophyllum trabeum* in accordance with the Code.

Item [2] of the draft variation would repeal the existing Note after the table to subsection S18—9(3), and replace it with a new Note that includes "Glucoamylase, protein engineered variant" in the list of enzymes in that table, which have protein engineered sources.

The Note explains that:

- some enzyme sources identified in the table to subsection S18—9(3) are protein engineered; and
- if such an enzyme is used as a processing aid, the resulting food may have as an ingredient a food produced using gene technology, and the requirements relating to foods produced using gene technology will apply (see Standard 1.2.1 and Standard 1.5.2).

The Note then lists the relevant enzymes.