11 February 2020
[112 - 20]

Call for submissions – Application A1184

Glucoamylase from GM *Aspergillus niger* (donor *Trametes cingulata*)

FSANZ has assessed an application made by Novozymes Australia Pty Ltd to permit the use of glucoamylase from a genetically modified strain of *Aspergillus niger* containing the glucoamylase gene from *Trametes cingulata* as a processing aid in starch processing and the production of potable alcohol. 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 information for submitters.

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

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.

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient to receive submissions electronically through the FSANZ website via the link on documents for public comment. You can also email your submission directly to submissions@foodstandards.gov.au.

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) 24 March 2020

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 submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

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Supporting document

The following document[1] which informed the assessment of this application is available on the FSANZ website:

SD1 Risk and Technical Assessment Report

[1] http://www.foodstandards.gov.au/code/applications/Pages/A1184.aspx

Executive summary

Novozymes Australia Pty Ltd is seeking permission to use the enzyme glucoamylase (EC 3.2.1.3), from a genetically modified (GM) strain of *Aspergillus niger (A. niger*), as a processing aid in starch processing and the production of potable alcohol.

Glucoamylase breaks down starch polysaccharides to release glucose and other fermentable sugars. The benefits of using this enzyme during starch processing and alcohol production, as claimed by the applicant, is that it leads to an increased glucose yield and is able to perform its technological function at high operating temperatures and a low operating pH.

The glucoamylase in this application is derived from a GM strain of *A. niger* expressing a glucoamylase gene from *Trametes cingulata (T. cingulata)*. *A. niger* is neither toxigenic or 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. Glucoamylase from GM *A. niger* was not genotoxic *in vitro*, and did not cause adverse effects in short-term toxicity studies in rats.

Bioinformatic analyses indicated that the enzyme has no significant homology with any known toxins or food allergens, and is unlikely to pose an allergenicity or toxicity concern. Soy and possibly wheat are used in the fermentation medium, however due to washing and filtration processes they are not expected to be present in the final enzyme preparation. It is unlikely but the presence of allergens in the final enzyme treated food products would require standard allegen labelling as required by the Australia New Zealand Food Standards Code (the Code).

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

The stated technological purpose of this enzyme is clearly articulated in the application. The evidence presented to support the proposed use of the enzyme provides adequate assurance that the enzyme, in the recommended form and amounts 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 to permit the enzyme glucoamylase derived from a GM strain of *A. niger*, containing the glucoamylase gene from *T. cingulata*, as a processing aid in starch processing and the production of potable alcohol, subject to the condition that the amount of enzyme used must be consistent with good manufacturing practice (GMP).

1 Introduction

1.1 The applicant

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

1.2 The application

The purpose of the application is to seek permission to use the enzyme glucoamylase (EC 3.2.1.3) from a genetically modified (GM) strain of *A. niger* as a processing aid in starch processing and the production of potable alcohol.

Glucoamylase hydrolyses 1,4-alpha-D-glucosidic linkages in starch polysaccharides successively from the non-reducing ends to release beta-D-glucose and other fermentable sugars. Most forms of the enzymes can hydrolyse 1,6-alpha-D-glucosidic linkages when the next bond in the polysaccharide sequence is 1,4.

In starch processing, glucoamylase degrades polysaccharides into glucose, to produce syrups. In the production of alcohol, glucoamylase is used to degrade gelatinised starch and dextrins into glucose and other fermentable sugars. The use of this enzyme leads to a higher glucose yield.

The enzyme preparation will be used as a processing aid where the enzyme is not present or or else present in negligible amounts, with no technological function in the final food.

The enzyme is sourced from a GM strain of *A. niger,* expressing a glucoamylase gene from the fungus *T. cingulata* and will provide food processors with an alternative enzyme preparation in starch processing and alcohol production, which has the benefit of being able to be used at high operating temperatures and low operating pH.

The glucoamylase is produced by submerged fed-batch pure culture fermentation, which involves the growth of the microorganism and production of the enzyme. Subsequent steps involve the separation of the enzyme from the microbial biomass, purification, concentration and formulation of the enzyme preparation.

1.3 The current standard

Australian and New Zealand food laws require food for sale must comply with the Australia New Zealand Food Standards Code (the Code). The requirements relevant to this application are summarised below.

Permitted use

Enzymes used to process and manufacture food are considered processing aids. Paragraph 1.1.1—10(6)(c) of the Code provides that a food for sale must not contain, as an ingredient or a component, a substance that is used as a processing aid, unless expressly permitted by the Code.

Section 1.1.2—13 of the Code provides a definition of ‘used as a processing aid’. That definition imposes certain conditions on substances permitted by Standard 1.3.3 and Schedule 18 to be used as a processing aid, such that it does not perform a technological function in the final food for sale.

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.

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) of Standard 1.5.2 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).

Identity and purity requirements

Subsection 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.

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.

Subsection 1.2.3—4(1) requires certain foods and substances to be declared when present in a food for sale. Paragraph 1.2.3—4(2)(c) states the food or substance may be present as a substance or food used as a processing aid, or an ingredient or component of such a substance or 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 prevail.

Section 1.5.2—4 requires processing aids that are foods produced using gene technology to be labelled ‘genetically modified’, 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. 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 section 1.2.1—15 respectively.

1.3.1 International standards

The Codex Alimentarius does not establish standards for processing aids or for enzymes. Individual countries regulate the use of enzymes differently to the Code. However, there are internationally recognised specifications for enzymes. These enzyme specifications are established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) (FAO/WHO 2017) and the Food Chemicals Codex (Food Chemicals Codex 2018).

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 FSANZ Act; and
- it related to a matter that might be developed as 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

There are no public health and safety concerns associated with the proposed use of glucoamylase from *A. niger* as a food processing aid.

The host organism *A. niger,* has a long history of safe use as a source of enzyme processing aids, including several already permitted in the Code and is neither toxigenic or pathogenic. Molecular characterisation of the production strain confirmed that the gene insert was as expected and would encode the glucoamylase as specified. The insert was also shown to be genetically stable and heritable.

The glucoamylase showed no evidence of genotoxicity in a bacterial reverse mutation assay or a micronucleus assay in human lymphocytes. The enzyme did not cause any adverse effects in a sub-chronic toxicity study in rats. The no observed adverse effect level (NOAEL) was the highest dose tested, 10 mL/kg bw/day or 1135 mg/kg bw/day on a total organic solids (TOS) basis. The applicant's estimated theoretical maximal daily intake (TMDI) of glucoamylase is 0.31 mg kg bw/day TOS, resulting in a Margin of Exposure (MoE) of more than 3000 between the NOAEL and TMDI.

Bioinformatic analyses did not identify any significant homology with any known toxins or food allergens, and the enzyme is unlikely to pose an allergenicity or toxicity concern. Soy and possibly wheat are used in the fermentation medium, however due to washing and filtration processes they are not expected to be present in the final product.

Based on the reviewed toxicological data, it is concluded that in the absence of any identifiable hazard an Acceptable Daily Intake (ADI) 'not specified' is appropriate. A dietary exposure assessment was therefore not required.

The evidence presented to support the proposed use of the enzyme provides adequate assurance that the enzyme, in its recommended form and amounts, is technologically justified and has been demonstrated to be effective in achieving its stated purpose. The enzyme meets international purity specifications.

For further details on the risk assessment, refer to the Risk and Technical Assessment Report (SD1).

2.2 Risk management

The Risk and Technical Assessment Report concluded that there are no safety concerns from using this enzyme for its stated purpose, in the form and quantities consistent with GMP. As processing aids require permissions in the Code, the main risk management option available to FSANZ is to approve or reject the request to amend the Code and, if approved, to impose any conditions that may be appropriate. Other risk management considerations for this application are related to enzyme nomenclature and labelling, which are discussed below. The regulatory options analysed in section 2.4.1.1 take account of the safety of the enzyme.

If permitted, the food industry will have access to an alternative source of glucoamylase for starch processing and alcohol production.

2.2.1 Regulatory approval for enzymes

The risk assessment concluded that there are no public health and safety concerns

associated with the use of this enzyme. Therefore, FSANZ 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 the enzyme's 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'. 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) of Standard 1.5.2 provides that permission for use as a processing aid also constitutes the permission required by paragraph 1.1.1—10(6)(g).

2.2.2 Microorganism and enzyme nomenclature

FSANZ noted that the International Union of Biochemistry and Molecular Biology (IUBMB), the internationally recognised authority for enzyme nomenclature, uses the 'accepted' name 'glucan 1,4-α-glucosidase' for the enzyme with an EC number of EC 3.2.1.3 (IUBMB 2018). 'Other' names for this enzyme include 'glucoamylase', which is the name used throughout the application, this document, and Supporting Document 1. 'Glucoamylase' (with the number EC 3.2.1.3) is the name that will be used in the proposed draft variation to the Code for this enzyme.

The nomenclature of the gene donor and production microorganisms were checked and confirmed as being appropriate as listed in the application (see section 3.1 of SD1). The source organism *A. niger* is already permitted as a production microorganism for numerous enzymes within Schedule 18.

2.2.3 Labelling requirements

The risk assessment concluded that the use of the enzyme poses no public health and safety concerns and that it performs its technological purpose as a processing aid. Therefore, the generic exemption from declaration of processing aids in the statement of ingredients will apply to foods containing this processing aid and no new labelling requirements are proposed.

2.2.3.1 Labelling requirements for food produced using gene technology

The requirements for labelling as 'genetically modified' differ depending on whether the GM food is an ingredient of the food for sale or not, as follows.

If a food is for retail sale or sold to a caterer, and contains the enzyme glucoamylase sourced from the GM strain of *A. nige*r (for example, the enzyme is used in the manufacture of potable alcohol), that food would be required to be labelled 'genetically modified' in conjunction with the name of the GM food, if novel DNA or novel protein from the GM strain of *A. nige*r remains in that food for sale (see paragraph 1.5.2—4(1)(b)).

However, FSANZ also notes the enzyme is used in starch processing, to produce syrups. If the syrup is not a food for sale itself but is used as an ingredient in a food for retail sale or in food sold to a caterer, the enzyme would not be an ingredient in the food for sale containing the syrup. The requirement to label as 'genetically modified' would not apply to that food for sale because the labelling requirements only apply to food that consists of, or has as an ingredient, a GM food (section 1.5.2—4(1)).

2.2.3.2 Declaration of certain substances

The risk assessment (section 2.1) has identified that soy and possibly wheat (as a source of starch) are used as ingredients in the fermentation medium for the enzyme preparation, but they are not expected to be present in the final product. If however soy or wheat is present, including when present as a processing aid or an ingredient or component of a processing aid, these must be declared in accordance with section 1.2.3—4 of Standard 1.2.3 (Information requirements – warning statements, advisory statements and declarations). If the food is not required to bear a label, the allergen information must be displayed in connection with the display of the food or provided to the purchaser on request (section 1.2.1—9 of Standard 1.2.1).

Certain products are exempt from the requirement to declare wheat. In the case where the enzyme is used in the manufacture of glucose syrups made from wheat starch, the glucose syrups would be exempt from declaring wheat if they have been subject to a refining process that has removed gluten protein content to the lowest level that is reasonably achievable, and they have a gluten protein content that does not exceed 20 mg/kg (subparagraph 1.2.3—4(1)(b)(i)(B)). Beer, spirits, and alcohol distilled from wheat are also exempt from declaring wheat (and any other cereals containing gluten) (subparagraph 1.2.3—4(1)(b)(i)).

Certain products are exempt from the requirement to declare soy, but these exemptions do not apply to soy protein, which is the specific ingredient used during the production of this enzyme.

2.2.4 Risk management conclusion

The risk management conclusion is to add the permission for glucoamylase derived from a GM strain of *A. niger*, expressing a glucoamylase gene from *T. cingulata,* as a processing aid into the table to S18—9(3), which includes enzymes permitted for a specific technological purpose. The technological purpose is for starch processing and the production of potable alcohol. The maximum permitted level is an amount consistent with GMP.

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 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.

There are no relevant international standards (i.e. Codex Alimentarius Standards) and amending the Code to approve the enzyme as a processing aid is unlikely to have a significant effect on international trade. The enzyme is authorised for use in Denmark and France.

Furthermore, this enzyme is consistent with specifications in the latest edition of the JECFA General Specifications and Considerations for Enzyme Preparations Used in Food Processing (FAO/WHO 2017) and the Food Chemicals Codex specifications for enzymes (Food Chemicals Codex 11th edition (2018)).

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 (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting processing aids is machinery in nature and their use is voluntary. 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 (i.e. rejecting the application). This analysis considers permitting the use of glucoamylase as a processing aid from the source of GM *Aspergillus niger* (the enzyme).

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.

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.

Costs and benefits of permitting the use of enzyme glucoamylase (EC 3.2.1.3) from a GM strain of A. niger *as a processing aid (the enzyme)*

Using the enzyme from this new permitted production source may be an option for the food and beverage industry to reduce costs or increase efficiency of producing syrups,

fermentable sugars, and higher alcohol yields with less use of raw materials.

Due to the voluntary nature of the permission, manufacturers will only use the enzyme where they believe a net benefit exists. There are other permitted methods of producing glucoamylase. Part of any cost savings to industry may be passed onto consumers.

Permitting the enzyme may result in a small cost to government in terms of adding these to the current range of food additives and 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 the enzyme in question 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

Standards 1.1.1, 1.1.2 and 1.3.3 and Schedule 18 apply in both Australia and New Zealand and there are no other 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 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 the enzyme processing aid are discussed in section 2.2.3.

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 used the best available scientific evidence to conduct the risk analysis, which is provided in SD1 – the Risk and Technical Assessment Report. The applicant submitted a dossier of information and scientific literature as part of its application. Other technical and

scientific information was also used by FSANZ in assessing the application.

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

There are no Codex Alimentarius Standards for processing aids or enzymes. However, it meets the general specifications for enzymes set out in the JECFA Compendium of Food Additive Specifications and the Food Chemicals Codex specifications for enzymes.

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

The enzyme is already authorised for use in several countries (being Denmark and France). Therefore, the approval for use of this enzyme would bring Australia and New Zealand into line with these jurisdictions. In this way, Australia and New Zealand will remain competitive with international markets.

The conclusion of the risk assessment is there are no public health and safety concerns associated with the production microorganism or with using 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 preparation for starch processing and alcohol production.

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**

FSANZ identified no issues relevant to this objective. As mentioned above, FSANZ's risk assessment is that there are no public health and safety concerns associated with the production microorganism or enzyme.

- **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*[2] 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'.

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

3 Draft variation

The draft variation to the Code is at Attachment A and 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

FAO/WHO (2017) General specifications and considerations for enzyme preparations used in food processing. http://www.fao.org/docrep/009/a0691e/A0691E03.htm

IUBMB (2017) EC 3.2.1.3. https://www.qmul.ac.uk/sbcs/iubmb/enzyme/EC3/2/1/3.html

The United States Pharmacopeia (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 A1184 – Glucoamylase from GM *Aspergillus niger* (donor *Trametes cingulata*)) 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 variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by Delegate]

[Insert Delegate's name and 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 A1184 – Glucoamylase from GM* Aspergillus niger *(donor* Trametes cingulata*)) 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

[1] Schedule 18 is varied by inserting in the table to subsection S18—9(3), in alphabetical order

Glucoamylase (EC 3.2.1.3) sourced from *Aspergillus niger* containing the glucoamylase gene from *Trametes cingulata*	For use in starch processing and the production of potable alcohol	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 A1184 which seeks permission to use the enzyme glucoamylase (EC 3.2.1.3) from a genetically modified (GM) strain of *Aspergillus niger* (*A. niger*) as a processing aid in starch processing and the production of potable alcohol. The Authority considered the application in accordance with Division 1 of Part 3 and has prepared a draft variation to the Code.

The Authority noted that the IUBMB uses the 'accepted' name 'glucan 1,4-α-glucosidase' for this enzyme (IUBMB 2017). 'Other' names for this enzyme include 'glucoamylase', which is the name used throughout the application and, as such, this document. 'Glucoamylase' is the name that has been used in the proposed draft variation to the Code for this enzyme with the number EC 3.2.1.3.

2. 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 glucoamylase (EC 3.2.1.3) from a GM strain of *A. niger* as a processing aid in starch processing and the production of potable alcohol.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

Existing provisions of the Code incorporate a document 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) Compendium of Food Additive Specifications (FAO/WHO 2017) and the United States Pharmacopeial Convention (2018) Food Chemicals Codex (11th edition). These include specifications for enzyme preparations used in food processing.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1184 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 (OBPR correspondence dated 24 November 2010 - reference 12065). This standing exemption was provided as permitting additional processing aids is likely to have only a minor impact on business and individuals. It is a minor, deregulatory change that allows for the introduction of a food product to the food supply that has been determined to be safe. The use of the approved processing aid is also voluntary.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

Item [1] of the variation inserts in the table to subsection S18—9(3) in Schedule 18 in alphabetical order, a new entry for “Glucoamylase (EC 3.2.1.3) sourced from *Aspergillus niger* containing the glucoamylase gene from *Trametes cingulata*” into column 1, and “For use in starch processing and the production of potable alcohol” into column 2, and “GMP” into column 3.

The new entry will, in effect, permit the use of the enzyme, glucoamylase (EC number 3.2.1.3), sourced from a particular GM strain of *A. niger (A. niger* containing the glucoamylase gene from *Trametes cingulata*), as a processing aid for a specific technological purpose.

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

The permission is 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 good manufacturing practice.