28 September 2022

215-22

Approval report – 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 permit the use of a protein engineered variant of the glucoamylase enzyme produced by a genetically modified strain of *Aspergillus niger*.

On 27 May 2022, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received three submissions.

FSANZ approved the draft variation on 14 September 2022. The Food Ministers' Meeting (formerly the Australia and New Zealand Ministerial Forum on Food Regulation) was notified of FSANZ's decision on 28 September 2022.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

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Supporting document

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

SD1 Risk and technical assessment report

Executive summary

Novozymes Australia Pty Ltd submitted an application to Food Standards Australia New Zealand (FSANZ) 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*, as a processing aid in starch processing and the production of distilled alcohol.

There are relevant identity and purity specifications in Schedule 3 of the Code with which the enzyme must comply. The safety assessment included consideration of bioinformatics, toxicity and dietary exposure and identified no public health and safety concerns.

After undertaking its risk and technical assessment, FSANZ concluded that there were no public health and safety concerns with the use of glucoamylase produced from a GM strain of *A. niger,* expressing a protein engineered variant of the glucoamylase gene from *Gloeophyllum trabeum,* under the proposed use conditions.

As glucoamylase performs its technological function during food processing, not in the food for sale, it would function as a processing aid for the purposes of the Code.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation from 27 May 2022 to 8 July 2022. Three submissions were received, all supporting the draft variation.

Based on the information above and other relevant considerations set out in this report, FSANZ has approved a draft variation to the table to subsection S18—9(3) of the Code to permit the use of the enzyme, glucoamylase (EC 3.2.1.3) sourced from a genetically modified strain of *A. niger*, containing a protein engineered variant of the glucoamylase gene from *G*. *trabeum*, as a processing aid in starch processing and the production of distilled alcohol. This permission will 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 Good Manufacturing Practice (GMP). The effect of the approved draft variation is to permit the proposed use of this enzyme as a processing aid in accordance with the Code.

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,* containing a protein engineered variant of the glucoamylase gene from *Gloeophyllum 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. limiting the amount of substance that is added to food to the lowest possible level necessary to accomplish its desired effect.

1.3 The current Standard

Australian and New Zealand food laws require food for sale to 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 general specifications for enzyme preparations used in food processing for identity and purity parameters.

1.3.3 Labelling requirements

Paragraph 1.1.1—10(8) of the Code provides that a 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*[1] (GM food). The requirements imposed by section 1.5.2—4 apply only to foods for sale prescribed by Divisions 2 to 4 of Standard 1.2.1.

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 in Section 1.3.2 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 the 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)
- it related to a matter that warranted the variation of a food regulatory measure.

1.5 Procedure for assessment

The Application was assessed under the General Procedure in the FSANZ Act.

1.6 Decision

For reasons set out in this report, FSANZ decided to approve a draft variation amending the Code to permit the use of this enzyme as a processing aid in starch processing and the production of potable alcohol.

The draft variation as proposed following assessment was approved without change. The variation takes effect on the date of gazettal. The approved draft variation is at Attachment A.

The related 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.

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[1] 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*).

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions on a draft variation to the Code from 27 May 2022 to 8 July 2022. Three submissions were received. All submitters supported permitting the use of a new protein engineered variant of a GM microbial source for the enzyme glucoamylase (EC 3.2.1.3) as a processing aid in distilled alcohol production and starch processing. A summary of submitter comments is provided below in Table 1.

Table 1: Summary of submitter comments

Issue	Raised by	Comment
Supports amending the Code to permit the use of the enzyme We would like to think that sooner rather than later, the assessment and approval process for enzymes and other processing aids might be streamlined so as to reduce the need for repetitive assessment of very similar products.	New Zealand Food and Grocery Council	Support noted. FSANZ's approval processes for enzyme processing aids are regulated by requirements set out in the FSANZ Act. The Australian Government is undertaking a review of the FSANZ Act. Further information regarding the review is available at: https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/Modernisation-of-the-food-regulation-system
Supports amending the Code to permit the use of the enzyme	New Zealand Food Safety	Noted
Supports progression of the application	Victorian Department of Health and Victorian Department of Jobs, Precincts and Regions	Noted

2.2 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.

2.3 Risk management

2.3.1 Regulatory approval for enzymes

After assessing an application, FSANZ must either prepare a written draft measure or reject the application.

As outlined above, FSANZ's assessment concluded that there are no public health and safety concerns relating to the proposed use of this glucoamylase (EC 3.2.1.3) sourced from a GM strain of *A. niger* as a processing aid.

Based on the food technology assessment, FSANZ concluded that use of this enzyme in starch processing and production of potable alcohol is consistent with its typical function of breaking down starch polysaccharides to produce glucose molecules. Analysis of the evidence provided adequate assurance that the enzyme's use in the quantity and form proposed, which must be consistent with GMP controls and processes, is technologically justified. There are relevant identity and purity specifications in Schedule 3 of the Code with which the enzyme must comply.

As glucoamylase performs its technological function during food processing, not in the food for sale, it would function as a processing aid for the purposes of the Code.

FSANZ therefore considered it appropriate to prepare a draft variation amending the Code to permit the proposed use of this enzyme (Attachment A) and called for submissions on the draft variation.

Following the call for submissions and having regard to all submissions received, FSANZ considers it appropriate to approve the draft variation proposed following assessment without change.

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 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]

2.3.2 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).

[2] '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 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.

2.3.3 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 2.3.3.1 below.

2.3.3.1 Labelling requirements for food produced using gene technology

Section 1.5.2—4 of the Code generally requires a food for sale that consists of a GM food or has a GM food as an ingredient to be labelled as 'genetically modified', unless one of the exemptions listed in that subsection apply. If the GM food is present in the food for sale as an ingredient due to its use as a processing aid, the 'genetically modified' statement must be in conjunction with the name of the GM food (subsection 1.5.2—4(2)) and it may be included in the statement of ingredients for the food for sale (subsection 1.5.2—4(3)).

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.

2.3.4 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. The permission will 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 is 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 must be consistent with GMP. The express permission for the enzyme to be used as a processing aid in Schedule 18 of the Code also provides the permission for the enzyme's potential presence in the food for sale as a food produced using gene technology.

2.4 Risk communication

2.4.1 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 were called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application. All comments are valued and contribute to the rigour of our assessment.

The draft variation was considered for approval by the FSANZ Board having regard to all submissions made during the call for submissions period.

2.5 FSANZ Act assessment requirements

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

2.5.1 Section 29

2.5.1.1 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 permitting 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, gave 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 was 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 considered 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.

The consideration of the costs and benefits in this section was 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 sought 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

Using the enzyme preparation from a GM strain of *A. niger* may benefit industry by having additional choice of inputs to their manufacturing process especially if it proves cheaper, is more effective than what is presently available or results in additional competition among suppliers. Due to the voluntary nature of the permission, manufacturers would only use this glucoamylase enzyme where they believe a net benefit exists for them.

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.

Permitting the enzyme to be used as a processing aid 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.

2.5.1.2 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.

2.5.1.3 Any relevant New Zealand standards

The Standards in the Code which are relevant to the permitted use of the enzyme processing aid in question apply in both Australia and New Zealand. There are no relevant New Zealand only Standards.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2 Subsection 18(1)

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

2.5.2.1 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.

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

Existing labelling requirements in the Code related to this enzyme are discussed in Section 2.3.3 above.

2.5.2.3 The prevention of misleading or deceptive conduct

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

2.5.3 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). There are relevant international specifications for enzyme preparations 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. The applicant has advised that 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 proposed use of this enzyme as a 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 Food Ministers' Meeting[3]**

The Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*[4], formulated by the Food Ministers' Meeting, 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')

[3] Formerly known as the Forum on Food Regulation

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

- 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 for use as a processing aid is consistent with these specific order policy principles for 'Technological Function'. All other relevant requirements of the policy guidelines are similarly met.

3 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

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

Attachments

A. Approved draft variation to the Australia New Zealand Food Standards Code

B. Explanatory Statement

Attachment A – Approved 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 – 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 approved a draft variation.

Following consideration by the Food Ministers' Meeting (FMM)[5], section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

2. Variation will be a legislative instrument

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

This instrument is not 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.

[5] Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation.

3. Purpose

The Authority has approved the 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. This permission is subject to the condition that the maximum permitted level or amount of the enzyme that may be present in the food is consistent with Good Manufacturing Practice (GMP).

4. Documents incorporated by reference

The approved 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 approved 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 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. Submissions were called for on 27 May 2022 for a six-week consultation period.

The Office of Best Practice Regulation (OBPR) granted the Authority 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

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

Item [1] of the approved draft variation inserts 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 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 is consistent with GMP.

The above amendment permits 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 approved draft variation repeals the existing Note after the table to subsection S18—9(3), and replaces it with a new Note that includes “Glucoamylase, protein engineered variant” in the list in that table of enzymes 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.