16 February 2023
[231-23]

Approval report – Application A1252

Glucoamylase from GM *Aspergillus niger* (gene donor: *Penicillium oxalicum)* as a processing aid

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by Novozymes Australia Pty Ltd to amend the Australia New Zealand Food Standards Code to permit the use of a protein engineered variant of the enzyme glucoamylase (EC 3.2.1.3), sourced from a genetically modified (GM) strain of *Aspergillus niger*, as a processing aid in the manufacture of bakery products; brewing; and starch processing for the production of starch hydrolysates, including glucose syrups.

On 28 September 2022, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received three submissions.

FSANZ approved the draft variation on 1 February 2023. The Food Ministers' Meeting was notified of FSANZ's decision on 16 February 2023.

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

SD1 Risk and Technical Assessment - Application A1252

[1] A1252 - Glucoamylase from GM Aspergillus niger (gene donor: Penicillium oxalicum) as a processing aid (foodstandards.gov.au)

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 enzyme glucoamylase (EC 3.2.1.3), sourced from a genetically modified (GM) strain of *Aspergillus niger (A. niger),* as a processing aid in baking processes; brewing; and starch processing for the production of starch hydrolysates, including glucose syrups. This glucoamylase is sourced from *A. niger*, containing the glucoamylase gene from *Penicillium oxalicum* (*P. oxalicum*).

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

FSANZ concluded that the proposed use of the glucoamylase enzyme is consistent with its typical function of breaking down starch by hydrolysing the terminal (1->4)-linked alpha-D-glucose residues from non-reducing ends of carbohydrate chains. This assist in its technological function for use in the manufacture of bakery products; brewing; and starch processing for the production of starch hydrolysates, including glucose syrups. Analysis of the evidence provides adequate assurance that the proposed use of the enzyme in the quantity and form is technologically justified.

Glucoamylase performs its technological purpose during food processing and production and does not perform a technological purpose in the food for sale, therefore functioning as a processing aid for the purposes of the Code. There are relevant identity and purity specifications for enzyme preparations included in the Code, with which the enzyme must comply.

No public health and safety concerns were identified in the assessment of this protein engineered variant of the glucoamylase enzyme from *A. niger* under the proposed conditions of use. A microbiological safety assessment concluded that *A. niger* has a long history of safe use in food and is neither pathogenic nor toxigenic. A biotechnology assessment confirmed the presence and stability of the inserted DNA. A toxicology assessment combined with a dietary exposure assessment concluded the enzyme is safe under the proposed conditions of use. In the absence of any identifiable hazard, an acceptable daily intake (ADI) 'not specified' is appropriate.

The applicant has advised that wheat flour is used as the carrier and that wheat protein is present in the final enzyme preparation. This only applies to the granulated preparation, which is used in baking processes. Therefore, declaration requirements for wheat and gluten as required names will apply if they are present in a food for sale that is manufactured using this processing aid.

Following assessment and the preparation of a draft variation to the Code, FSANZ called for submissions regarding the draft variation from 28 September 2022 to 10 November 2022. FSANZ received three submissions – two from government agencies and one from an industry stakeholder - which all supported the draft variation.

Based on the information above and on 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 this glucoamylase enzyme as a processing aid. The enzyme will be permitted for use in the manufacture of bakery products; brewing; and starch processing for the production of starch hydrolysates, including glucose syrups. 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 GMP. The effect of the approved draft variation will be 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 manufacturer of enzymes, microorganisms and precision proteins.

1.2 The application

The purpose of the application is to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of a protein engineered variant of the enzyme glucoamylase (EC 3.2.1.3), sourced from a genetically modified (GM) strain of *A. niger*, as a processing aid. This organism is sourced from the glucoamylase gene from *P. oxalicum*. Novozymes is requesting the approval of this glucoamylase to perform the technological function of hydrolysis of the terminal (1->4)-linked alpha-D-glucose residues from non-reducing ends of carbohydrate chains. This then assists in the manufacture of bakery products; brewing; and starch processing for the production of starch hydrolysates, including glucose syrups.

The applicant markets both a liquid and a granular preparation containing this enzyme as the active constituent. The applicant has indicated the enzyme is to be used at minimum levels necessary to achieve the desired effect, in accordance with Good Manufacturing Practice (GMP).

1.3 The current standard

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

1.3.1 Permitted use

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

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

- it is used to perform a technological purpose during the course of processing
- it does not perform a technological purpose in the food for sale
- 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).

Glucoamylase from other sources is already permitted to be used as a processing aid in the table to subsection S18—4(5). However glucoamylase from *A. niger*, containing the glucoamylase gene from *P. oxalicum* as requested in 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 in food 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 Food Chemicals Codex (12th edition, 2020). 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.

Division 3 of Standard 1.2.3 requires declarations of certain foods (e.g. allergens) on the label of food for sale, unless an exemption applies. If the declaration relates to a processing aid, it must be made in the statement of ingredients and must include the required name[2] for the food which is to be declared in conjunction with the words 'processing aid'. If the requirement for a statement of ingredients does not apply, the required name must be declared on the label of the food for sale. If a food for retail sale is not required to bear a label, the required name must be displayed in connection with the display of the food or provided to the purchaser on request. If food sold to a caterer is not required to bear a label, the required name must be provided to the caterer with the food.

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

Section 1.5.2—4 of the Code requires a food for sale that consists of a *genetically modified food*[3] (GM food) or has a GM food as an ingredient to be labelled as 'genetically modified', unless an exemption applies. The label statement 'genetically modified' must be made in conjunction with the name of the GM food. If the GM food is used as a processing aid, this statement may be included in the statement of ingredients. In these circumstances, the requirements imposed by section 1.5.2—4 apply only to foods for retail sale and to foods sold to a caterer in accordance with Standard 1.2.1.

1.4 International standards

In developing food regulatory measures, FSANZ must have regard to the promotion of consistency between domestic and international food standards. In terms of food safety, the relevant international standard setting body is the Codex Alimentarius Commissions (Codex).

In contrast to food additives, there is no Codex 'general standard' for processing aids or for enzymes. However, there are internationally recognised specifications for enzymes established by JECFA and Food Chemicals Codex, as outlined in Section 1.3.2.

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

The applicant has advised that the enzyme is permitted for use in Denmark.

1.5 Reasons for accepting Application

The application was accepted for assessment because:

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

1.6 Procedure for assessment

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

1.7 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 the manufacture of bakery products; brewing; and starch processing for the production of starch hydrolysates, including glucose syrups.

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

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 28 September 2022 to 10 November 2022. Three submissions were received from two government agencies and one industry stakeholder. All supported the application and draft variation (see Table 1).

Table 1: Summary of submitters comments

Submitter	Matter raised	FSANZ response
New Zealand Food Safety	Supports amending the Code to permit use of the enzyme.	Noted
Victorian Department of Health and the Victorian Department of Jobs, Precincts and Regions	Supports progression of the application.	Noted
New Zealand Food and Grocery Council	Agree that the processing aid should be included in the Code and agree with the draft variation. Request that the assessment and approval process for enzymes and other processing aids be streamlined to reduce need for repetitive assessments.	Support noted FSANZ's approval processes for enzyme processing aids are regulated by requirements set out in the FSANZ Act. The Australian Government is completing a review of the Act. Further information on the review is available on the Food Regulation website.

2.2 Risk assessment

FSANZ has assessed the public health and safety risks associated with the protein engineered variant of the glucoamylase enzyme from *P. oxalicum* that is produced by GM *A. niger* and its proposed use as a processing aid. A summary of this risk assessment is provided below.

The proposed use of this protein engineered variant of the glucoamylase enzyme as a processing aid in the manufacture of baking products;, brewing; and starch for the production of starch hydrolysates, including glucose syrups is technologically justified.

No public health and safety concerns were identified in the assessment of this protein engineered variant of the glucoamylase enzyme from GM *A. niger* under the proposed conditions of use. A microbiological assessment concluded that *A*. *niger* has a long history of safe use in food and is neither pathogenic nor toxigenic. A biotechnological assessment confirmed the presence and stability of the inserted DNA. A toxicological assessment combined with a dietary exposure assessment concluded that the enzyme is safe under the proposed conditions of use.

The applicant has advised that wheat flour is used as the carrier and that wheat protein is present in the final enzyme preparation. This only applies to the granulated preparation, which is used in baking processes. Therefore, declaration requirements for wheat and gluten as required names will apply if they are present in a food for sale that is manufactured using this processing aid.

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

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

2.3 Risk management

The risk management options available to FSANZ following assessment were either to prepare a draft food regulatory measure or reject the application.

The conclusions from the assessment were that the proposed use of the enzyme is technologically justified and there are no public health and safety concerns associated with its proposed use a processing aid at levels of GMP.

FSANZ therefore considered it appropriate to prepare a draft variation amending the Code to permit the proposed use of this enzyme for use in the manufacture of bakery products; brewing; and starch processing for the production of starch hydrolysates, including glucose syrups, 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 (see Attachment A).

Risk management considerations for this application relating to the enzyme and source microorganism nomenclature, specifications and labelling are discussed below.

2.3.1 Regulatory approval for enzymes

FSANZ's food technology assessment concluded that use of this enzyme in the manufacture of bakery products; brewing; and starch processing for the production of starch hydrolysates, including glucose syrups, is consistent with its typical function of hydrolysis of the terminal (1->4)-linked alpha-D-glucose residues from non-reducing ends of carbohydrate chains. 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 for the enzyme in Schedule 3 of the Code with which the enzyme must comply.

Glucoamylase performs its primary technological purpose during food processing and does not perform a technological purpose in the food for sale, therefore functioning as a processing aid as defined in the Code.

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).[4]

2.3.2 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 'glucoamylase' for the enzyme (see 2.1.1 of SD1). This is consistent with how it the enzyme

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

is already permitted for use in the Code.

2.3.3 Labelling requirements

The labelling provisions in the Code will apply to foods for sale that are manufactured using this processing aid (see Section 1.3.3 above).

Section 2.2.1 of SD1 notes that wheat flour is used as a carrier in the granulated form of the enzyme preparation, and wheat protein is present in the final enzyme preparation. Declaration requirements for wheat and gluten as required names will apply if they are present in a food for sale that is manufactured using this processing aid.

2.3.4 Risk management conclusion

The risk management conclusion is to permit glucoamylase (E.C. 3.2.1.3) sourced from a GM strain of *A. niger* as a processing aid for use in the manufacture of bakery products; brewing; and starch processing for the production of starch hydrolysates, including glucose syrups. This organism contains the glucoamylase gene from *P. oxalicum*. The enzyme 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 will be to use as a processing aid in the manufacture of bakery products; brewing; and starch processing for the production of starch hydrolysates, including glucose syrups. The maximum permitted level or amount of the enzyme that may be present in the food will 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 will also provide the permission for the enzyme's potential presence in the food for sale as a food produced using gene technology.

2.4 Risk communication

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 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.

The draft variation was considered for approval by FSANZ having regard to all submissions made during the call for submission 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 Impact Analysis (OIA)[5] granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for applications relating to permitting processing aids and GM food (OIA correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting new GM foods and new processing aids is deregulatory as their use will be voluntary if the application concerned is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

FSANZ, however, 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 from the status quo. This analysis considered permitting the use of the enzyme glucoamylase from GM *A. niger* containing the glucoamylase gene from *P. oxalicum* as a processing aid in the manufacture of bakery products; brewing; and starch processing for the production of starch hydrolysates, including glucose syrups.

The consideration of the costs and benefits in this section was not intended to be an exhaustive, quantitative economic analysis of the proposed measure. 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 enzyme glucoamylase (EC 3.2.1.3) sourced from a GM strain of A. niger as a processing aid

The enzyme glucoamylase (not protein engineered) is already available to industry from other production sources. Due to the voluntary nature of the proposed permission, industry will use this glucoamylase where businesses believe a net benefit exists for them. An additional source of this enzyme may help industry save on costs of manufacturing bakery products; brewing; and starch processing for the production of starch hydrolysates, including glucose syrups.

The applicant has advised that the enzyme is permitted for use in Denmark. Therefore, the approval of this source of glucoamylase in the Code may help some of Australia's and New Zealand's sales in international markets. There may, however, be more competing imports in the domestic market in future from countries that use the GM strain of *A. niger* as a source for this glucoamylase enzyme.

Consumers

Industry may pass cost savings to consumers, where it is cheaper to source glucoamylase enzyme from this GM strain of *A. niger* (gene donor: *Penicillium oxalicum*) in production processes.

[5] Formerly known as the Office of Best Practice Regulation (OBPR).

Government

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

Conclusions from cost benefit considerations

FSANZ's assessment at the call for submissions stage was 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 would most likely outweigh the associated costs. No further information was received during the consultation process that changed that assessment.

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 relevant standards 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 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 (see SD1) and concluded that there were no public health and safety concerns relating to the proposed use of the enzyme.

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

The labelling requirements for this enzyme are discussed in Section 2.3.3 of the report 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 also had regard to:

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

FSANZ used the best available scientific evidence to conduct the risk analysis. The applicant submitted a dossier of information and scientific literature as part of its application. This

dossier, together with other technical and scientific information, was considered by FSANZ in assessing the application. The risk assessment is provided in SD1.

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

There are relevant international specifications for enzyme preparations, being the JECFA Compendium of Food additive Specifications and the Food chemicals codex specifications for enzymes referred to in Section 1.3 with which the enzyme must comply. The applicant has advised that the enzyme from this source is already permitted in Denmark.

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

As stated above, the applicant has advised that the enzyme is permitted for use in Denmark. Therefore, the approval for use of this enzyme would bring Australia and New Zealand into line with the 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 support continued innovation and improvements in food manufacturing techniques and processes.

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

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

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

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

- **any written policy guidelines formulated by the Food Ministers' Meeting**

The Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*[6] 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')
- 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 has determined that permitting the use of this enzyme as a processing aid is consistent with the specific order policy principles for 'technological function'. All other relevant requirements of the policy guideline are similarly met.

[6] Available on the Food regulation website.

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 A1252 – Glucoamylase from GM *Aspergillus niger* (gene donor: *Penicillium oxalicum*) as a processing aid) Variation

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

Dated [To be completed by the Delegate]

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

Note:

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

1 Name

This instrument is the *Food Standards (Application A1252 – Glucoamylase from GM* Aspergillus niger *(gene donor:* Penicillium oxalicum*) 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 *Penicillium oxalicum*	For use in: (a) the manufacture of bakery products; (b) brewing; and (c) starch processing for the production of starch hydrolysates, including glucose syrups.	GMP

Attachment B

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1252 – Glucoamylase from GM* Aspergillus niger *(gene donor:* Penicillium oxalicum*) as a processing aid) Variation

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 A1252 Glucoamylase from GM *Aspergillus niger* (gene donor: *Penicillium oxalicum*) as a processing aid which sought to amend the Code to permit the use of a protein engineered glucoamylase enzyme (EC 3.2.1.3) from a new genetically modified (GM) strain of *Aspergillus niger* as a processing aid in the manufacture of bakery products; brewing; and starch processing for the production of starch hydrolysates, including glucose syrups. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation - *Food Standards (Application A1252 – Glucoamylase from GM* Aspergillus niger *(gene donor:* Penicillium oxalicum*) as a processing aid) Variation.*
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Following consideration by the Food Ministers' Meeting (FMM), 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 is a legislative instrument

The approved draft variation, Food Standards (Application A1252 – Glucoamylase from GM *Aspergillus niger* (gene donor: *Penicillium oxalicum*) as a processing aid) 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 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 approved 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) sourced from a GM strain of *Aspergillus niger,* containing a protein engineered variant of the glucoamylase gene from *Penicillium oxalicum*, as a processing aid in the manufacture of bakery products; brewing; and starch processing for the production of starch hydrolysates, including glucose syrups. This permission is 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 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 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) Combined Compendium of Food Additive Specifications (FAO JECFA Monographs 23 (2019)) and the United States Pharmacopeial Convention Food Chemicals Codex (12th edition, 2020). 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 A1252 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 28 September 2022 for a six-week period.

The Office of Impact Analysis[7] (OIA) granted the Authority a standing exemption from the requirement to develop a Regulatory Impact Statement for applications relating to 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.

6. Statement of compatibility with human rights

[7] Formerly known as the Office of Best Practice Regulation (OBPR)

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 Schedule to the approved draft variation inserts a new entry in alphabetical order, into the table to subsection S18—9(3) in Schedule 18. The new entry will consist of the following enzyme in column 1 of the table:

- 'Glucoamylase, protein engineered variant, (EC 3.2.1.3) sourced from *Aspergillus niger* containing the glucoamylase gene from *Penicillium oxalicum*'.

The permitted technological purpose for this enzyme prescribed in column 2 of the table is for use as a processing aid in:

- the manufacture of bakery products;
- brewing; and
- starch processing for the production of starch hydrolysates, including glucose syrups.

The permission is subject to the condition, as prescribed in column 3 of the table, that the maximum permitted level or amount of this enzyme that may be present in the food must be consistent with GMP.

The effect of the approved draft variation is to permit the proposed use of the enzyme, glucoamylase (EC 3.2.1.3) sourced from *Aspergillus niger* containing a protein engineered variant of the glucoamylase gene from *Penicillium oxalicum* as a processing aid in accordance with the Code.