FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

8 November 2024
315-24

Approval report – Application A1291

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

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 glucoamylase (EC 3.2.1.3) from a genetically modified strain of *Aspergillus niger* containing a gene from *Gloeophyllum sepiarium.* This glucoamylase would be used as a processing aid in baking, brewing, distilled alcohol production, and starch processing for the production of glucose syrups and other starch hydrolysates.

FSANZ sought submissions on a draft variation between 27 August and 24 September 2024 and published an associated report. FSANZ received two submissions.

FSANZ approved the draft variation on 30 October 2024. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 8 November 2024.

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

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

Table of contents

Supporting document

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

SD Risk and technical assessment

Executive summary

Novozymes Australia Pty Ltd has applied 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) to be used as a processing aid in baking, brewing, distilled alcohol production, and starch processing for the production of glucose syrups and other starch hydrolysates. The enzyme is sourced from a genetically modified (GM) strain of *Aspergillus niger* containing the glucoamylase gene from *Gloeophyllum sepiarium.*

FSANZ has undertaken an assessment to determine whether the enzyme achieves its technological purpose in the quantity and form proposed, and to evaluate public health and safety concerns that may arise from the proposed use of this enzyme.

The proposed technological purpose is consistent with the typical function of glucoamylase, and the enzyme is not performing the 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 the enzyme in the Code with which this enzyme would have to comply.

No public health and safety concerns were identified in the assessment of the protein engineered variant of glucoamylase (EC 3.2.1.3) produced by this GM *A. niger* under the proposed use. *A. niger* has a long history of safe use as a production microorganism of enzyme processing aids, including several that are already permitted in the Code. The production organism is neither pathogenic nor toxigenic. Analysis of the GM production strain confirmed the presence and stability of the inserted DNA. Bioinformatics analysis indicated that the produced glucoamylase does not have substantial homology with known toxins or food allergens.

A toxicological assessment combined with a dietary exposure assessment concluded the enzyme is safe for the proposed uses. In the absence of any identifiable hazard, an acceptable daily intake (ADI) of 'not specified' is appropriate.

Following assessment and the preparation of the draft variation, FSANZ called for submissions regarding the draft variation. FSANZ received two submissions, both of which supported the draft variation.

Based on the information above, and for the reasons set out in this report, FSANZ has approved a draft variation to permit a protein engineered variant of glucoamylase (EC 3.2.1.3) produced from a GM strain of *A. niger* containing the glucoamylase gene from *G. sepiarium* to be used as a processing aid in baking, brewing, distilled alcohol production, and starch processing for the production of glucose syrups and other starch hydrolysates.

The approved draft variation will amend the table to subsection S18—9(3) of the Code by listing this enzyme and its associated technological purposes in that table. The table lists substances (including enzymes) permitted as processing aids for specific technological purposes.

The effect of the approved draft variation will be to permit the proposed use of this protein engineered enzyme glucoamylase (EC 3.2.1.3) as a processing aid in accordance with the Code. The permission will be subject to the condition that the maximum permitted level or amount of the enzyme that may be present in the food must be an amount consistent with Good Manufacturing Practice.

1. Introduction

1.1 The applicant

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

1.2 The application

The purpose of the application was 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) as a processing aid for specific technological purposes. This enzyme is sourced from a genetically modified (GM) strain of *Aspergillus niger* containing the glucoamylase gene from *Gloeophyllum sepiarium*. The production strain of *A. niger* used by the applicant was developed from the BO-1 cell lineage.

The enzyme is intended to be used as a processing aid in baking, brewing, distilled alcohol production, and starch processing for the production of glucose syrups and other starch hydrolysates. Glucoamylase degrades starch into D-glucose. The enzyme will be used in accordance with the principles of Good Manufacturing Practice (GMP[2]), at the minimum level required to achieve the 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 requirements relevant to this application are summarised below.

1.3.1 Permitted use

Paragraph 1.1.1—10(6)(c) provides that a food for sale must not have, as an ingredient or a component, a substance that is 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 processing that meets all the following conditions:

- it is used to perform a technological purpose during 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 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), depending on whether a technological purpose has been specified.

An enzyme of microbial origin listed in the table to subsection S18—4(5) is 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.

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[2] GMP is defined in the Standard 1.1.2—2 of the Code as follows: *with respect to the addition of substances used as food additives and substances used as processing aids to food, means the practice of:*
(a) limiting the amount of substance that is added to food to the lowest possible level necessary to accomplish its desired effect; and
(b) to the extent reasonably possible, reducing the amount of the substance or its derivatives that:
*(i) remains as a *component of the food as a result of its use in the manufacture, processing, or packaging; and*
(ii) is not intended to accomplish any physical or other technical effect in the food itself;
(c) preparing and handling the substance in the same way as a food ingredient.

The table to subsection S18—9(3) lists those substances, including enzymes derived from microbial sources, which 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 a level 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 of a food produced using gene technology as an ingredient or component in a food for sale 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 variants of glucoamylase (EC 3.2.1.3) from several microbial sources (including *A. niger)* in the table to subsection S18—4(5). Glucoamylase from *A. niger* as the donor organism (including protein engineered variants) with other gene donors is also permitted in the table to subsection S18—9(3). However, glucoamylase from a GM strain of *A. niger* containing a protein engineered variant of the glucoamylase gene from *G. sepiarium* is not currently permitted in the Code.

1.3.2 Identity and purity requirements

Paragraph 1.1.1—15(1)(b) 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) incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Compendium of Food Additive Specifications (FAO JECFA Monographs 26, 2021[3]), which explicitly contains the specification for enzyme preparations in the earlier FAO/WHO (2006)[4]. Subsection S3—2(1) also incorporates by reference the United States Pharmacopeial Convention (2022)[5] Food chemicals codex 13th edition. These include general specifications for enzyme preparations used in food processing for identity and purity parameters.

1.3.3 Labelling requirements

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

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[6] 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 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.

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[3] FAO/WHO (2021) Evaluation of certain food additives: eighty-ninth report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series, No. 1027.
[4] FAO/WHO (2006) Compendium of Food Additive Specifications, FAO JECFA Monographs 3
[5] FCC (2022) Food Chemicals Codex, 13th edition. Rockville (MD): United States Pharmacopeial Convention, http://publications.usp.org/
[6] ***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*[7] (GM food) or has a GM food as an ingredient to be labelled as 'genetically modified', unless an exemption applies. The 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. The requirements imposed by section 1.5.2—4 apply 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, Food Standards Australia New Zealand (FSANZ) must have regard to the promotion of consistency between domestic and international food standards. In terms of food safety, the relevant international standard setting body is the Codex Alimentarius Commission (Codex). In contrast to food additives, there is no Codex Alimentarius 'general standard' for enzymes, however as noted in section 1.3.2 above, there are internationally recognised specifications for enzyme preparations established by JECFA and Food Chemicals Codex.

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

1.5 Reasons for accepting application

The application was accepted for assessment because:

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

1.6 Procedure for assessment

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

1.7 Decision

For the reasons outlined in this report, FSANZ decided to approve a draft variation amending the Code to permit the use of a protein engineered variant of the enzyme glucoamylase (EC 3.2.1.3) from a GM strain of *A. niger* containing the glucoamylase gene from *G. sepiarium* as a processing aid in baking, brewing, distilled alcohol production, and starch processing for the production of glucose syrups and other starch hydrolysates.

The draft variation as proposed following assessment was approved after FSANZ had regard to submissions. FSANZ made a minor amendment to the drafting to correct a formatting error. The approved variation takes effect on gazettal and is at Attachment A.

The related explanatory statement is in Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

FSANZ also made minor editorial changes to the *Supporting Document Risk and Technical Assessment – A1291* which was published with the A1291 call for submissions.

[7] Subsection 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 the draft variation to the Code between 27 August and 24 September 2024. Two submissions were received during that submission period from New Zealand Food Safety (NZFS) and Distilled Spirits Aotearoa (DSA). Both submissions supported the draft variation.

DSA supports the use of any enzymes to be used as a processing aid in brewing of beer and in distilled alcohol production. However, DSA does not support the use of any enzymes in the production of spirits labelled as *New Zealand Single Malt Whisky* based on product authenticity/brand identity.

DSA advised that in New Zealand, members of DSA and the New Zealand Whiskey Association have developed an industry standard for whisky producers and distillers in New Zealand. This standard specifies that whisky labelled *New Zealand Single Malt Whisky* may not have any enzymes added or used beyond what is already naturally occurring in the grain. This approach is similar to the UK Government standard for Scotch Whisky.

FSANZ thanks DSA for raising this issue in its submission. FSANZ considers the issue to be outside the scope of the current application based on the voluntary nature of the proposed use of glucoamylase and that FSANZ's risk assessment did not identify any public health and safety concerns with its proposed use in all foods requested in the application. Food businesses will be able to choose whether to use glucoamylase as processing aid to suit their needs, including not using it, to be consistent with an industry standard.

2.2 Food technology assessment

FSANZ undertook a food technology assessment to determine whether the enzyme achieves its technological purpose in the quantity and form proposed (see the document titled *Supporting Document Risk and Technical Assessment – A1291* and accompanying this report) (SD).

The proposed use of glucoamylase (EC 3.2.1.3) as an enzyme processing aid in the quantity and form proposed is consistent with its typical function of breaking down starch into glucose. The enzyme performs its technological purpose during the production of the nominated foods and is not performing a technological purpose in the food for sale. It is therefore functioning as a processing aid for the purposes of the Code.

2.3 Safety assessment

FSANZ also undertook a safety assessment (see SD).

FSANZ has assessed the public health and safety concerns associated with a protein engineered variant of glucoamylase from a GM strain of *A. niger* and its proposed use as a processing aid (see SD). A summary of this risk assessment is provided below.

There were no safety concerns from the use of glucoamylase from a GM strain of *A. niger* containing the glucoamylase gene from *G. sepiarium*. Glucoamylase from other sources has a long history of safe use in food. The production organism is neither pathogenic nor toxigenic. Analysis of the GM production strain confirmed the presence and stability of the inserted DNA.

A No Observed Adverse Effect Level (NOAEL) of 1070.2 mg total organic solids (TOS)/kg bw/day was identified in a 13-week oral toxicity study in rats. The theoretical maximum daily intake (TMDI) of the glucoamylase from *A. niger* was calculated to be 6.15 mg TOS/kg bw. A comparison of the NOAEL and the TMDI results in a Margin of Exposure (MOE) of

approximately 200.

Based on the reviewed data it is concluded that, in the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) 'not specified' is appropriate. FSANZ concludes that there are no public health and safety concerns.

2.4 Risk management

Following assessment, FSANZ prepared a draft variation and called for submissions on that draft variation between 27 August and 24 September 2024.

The risk management options available to FSANZ following the call for submissions were to either:

- approve the draft variation proposed following assessment, or
- approve that draft variation subject to such amendments as FSANZ considers necessary, or
- reject that draft variation.

Having regard to the submissions received, and for the reasons set out in this report, FSANZ approved the draft variation as proposed following assessment with a minor amendment to correct a formatting error. (Attachment A).

The conclusions from the risk and technical 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.

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

2.4.1 Regulatory approval for processing aids

As stated above, FSANZ approved the amended draft variation to permit the proposed use of this enzyme as a processing aid.

The express permission for the enzyme to be used as a processing aid also provides the permission for its potential presence in food for sale as a food produced using gene technology (see section 1.3.1 of this report above). The enzyme is a food produced using gene technology for Code purposes as it is derived from an organism which has been modified by gene technology (see subsection 1.1.2—2(3) of the Code)[8].

2.4.2 Enzyme nomenclature, source microorganism nomenclature and specifications

2.4.2.1 Enzyme and microorganisms

The International Union of Biochemistry and Molecular Biology (IUBMB) uses the accepted name glucoamylase. This is the name used in the approved draft variation and the name used in existing permissions for the enzyme in Schedule 18.

Nomenclature for the host and gene donor organisms – *A. niger* and *G. sepiarium* respectively – is in accordance with accepted international norms for fungal taxonomy.

2.4.2.2 Specifications

There are relevant identity and purity specifications in primary sources of specifications listed in Schedule 3 for enzyme preparations used in food processing (refer to section 1.3.2 above), with which this enzyme would have to comply.

[8] 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'.

2.4.3 Labelling

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.

2.4.4 Risk management conclusion

The risk management conclusion is to permit the enzyme, a protein engineered variant of glucoamylase (EC 3.2.1.3) sourced from *A. niger*, containing the glucoamylase gene from *G. sepiarium* for use as a processing aid in baking, brewing, distilled alcohol production, and starch processing for the production of glucose syrups and other starch hydrolysates.

The enzyme and its associated technological purpose 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 the enzyme will be as a processing aid in baking, brewing, distilled alcohol production, and starch processing for the production of glucose syrups and other starch hydrolysates.

The maximum permitted level or amount of the enzyme that may be present in the food will have to be an amount consistent with GMP. The express permission for the enzyme to be used as a processing aid in Schedule 18 of the Code will also provide the permission for the enzyme's potential presence in the food for sale as a food produced using gene technology.

2.5 Risk communication

2.5.1 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 channels and Food Standards News.

The process by which FSANZ considers standards development matters is open, accountable, consultative and transparent. Public submissions were called to assist consideration of the draft variation to the Code.

FSANZ acknowledges the time taken to make submissions on this application.

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

2.6 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:

2.6.1 Section 29

2.6.1.1 Consideration of costs and benefits

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)[9]. Impact analysis is no longer required to be finalised with the OIA. Prior to these changes, the OIA advised FSANZ that a Regulatory Impact Statement (RIS) was not needed for the applications relating to processing aids and GM food. This is because applications relating to permitting the use of processing aids and GM food that have been determined to be safe are minor and deregulatory in nature, as their use will be voluntary if the draft variation concerned is approved. Under this approach, FSANZ's assessment was that a RIS is not needed for this application.

[9] Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis (pmc.gov.au)

FSANZ, however, considered 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 decide if the community, government, and industry is likely to benefit, on balance, from a move from the *status quo* (where the status quo is rejecting the application). This analysis considered permitting the proposed use of this protein engineered variant of glucoamylase from *A. niger* as a processing aid in baking, brewing, distilled alcohol production, and starch processing for the production of glucose syrups and other starch hydrolysates.

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 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 approving the proposed variation to the Code.

FSANZ's conclusions regarding the costs and benefits of the proposed measure are set out below. No further information was received during the consultation process that changed that assessment.

Costs and benefits of permitting the proposed use of this enzyme

Industry may benefit from several improvements and efficiencies from the use of this processing aid in baking, brewing, distilled alcohol production, and starch processing for the production of glucose syrups and other starch hydrolysates.

Due to the voluntary nature of the permission, industry will only use the enzyme as proposed where they believe a net benefit exists for them.

If industry were to experience cost savings because of using this enzyme, industry may pass on some of the cost savings to consumers.

Permitting the proposed use of this enzyme may result in a small, inconsequential cost to government in terms of an addition to the current range of processing aids that are already monitored for compliance.

Conclusions from cost benefit considerations

FSANZ's assessment at the call for submissions was that the direct and indirect benefits that would arise from permitting the proposed use of the protein engineered variant of glucoamylase from *A. niger* outweigh the associated costs. No further information was received during the consultation process that changed that assessment.

2.6.1.2 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 because of the application.

2.6.1.3 Any relevant New Zealand standards

There are no relevant New Zealand only 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.

2.6.1.4 Any other relevant matters

Other relevant matters are considered below.

2.6.2 Subsection 18(1)

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

2.6.2.1 Protection of public health and safety

FSANZ undertook a safety assessment (see SD) and concluded there are no public health and safety concerns associated with permitting the proposed use of this protein engineered variant of glucoamylase from *A. niger*.

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

Existing labelling requirements will apply to this glucoamylase in accordance with the Code to enable consumers to make informed choices (see sections 1.3.3 and 2.4.3).

2.6.2.3 The prevention of misleading or deceptive conduct

There were no issues for this application relevant to this objective.

2.6.3 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. The risk assessment is provided in the SD. The applicant submitted a dossier of scientific studies as part of the application.

This dossier, together with other technical information including scientific literature, was considered by FSANZ in assessing the application.

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

There are relevant international specifications for enzyme preparations as referred to in section 1.3.2 of this report, with which this enzyme would have to comply.

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

Glucoamylase (EC 3.2.1.3) is used as processing aid in a range of countries where there are no restrictions on the use of enzyme processing aids or where the enzyme is covered by a country positive list or specific approval.

Approval for a wider variety of sources of this enzyme would bring Australia and New Zealand into line with other jurisdictions. 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 that there are no public health and safety concerns associated with the proposed use of this enzyme as a food processing aid. It is therefore appropriate that Australian and New Zealand food industries are given the opportunity to benefit from the use of this enzyme for the various applications proposed by Novozymes Australia Pty Ltd.

The domestic food industry will make their own economic decisions, considering the costs and benefits of using the new enzyme, to determine if it is of benefit to their 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 Ministerial Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*[10] 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 regarding the substance.

FSANZ determined that permitting the proposed 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.

Attachments

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

B. Explanatory Statement

C. Draft variation to the Australia New Zealand Food Standards Code proposed at the call for submissions

[10] Available on the Food regulation website.

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

Food Standards (Application A1291 – Glucoamylase from GM *Aspergillus niger* 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]

[Name and position of Delegate]

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 A1291 – Glucoamylase from GM* Aspergillus niger *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 sepiarium*	For use in: (a) baking; (b) brewing; (c) the production of distilled alcohol; and (d) starch processing for the production of glucose syrups and other starch hydrolysates.	GMP

Attachment B – Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1291 – Glucoamylase from GM* Aspergillus niger *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 A1291 which sought to amend the Code to permit the use of a protein engineered variant of the enzyme glucoamylase (EC 3.2.1.3) from a genetically modified *Aspergillus niger* containing the glucoamylase gene from *Gloeophyllum sepiarium* as a processing aid for use in: baking; brewing; distilled alcohol production; and starch processing to produce glucose syrups and other starch hydrolysates. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation: the *Food Standards (Application A1291 – Glucoamylase from GM* Aspergillus niger *as a processing aid) Variation* (the approved draft variation).

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

2. Variation is 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 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 to amend the table to subsection S18—9(3) of the Code to permit the use of a protein engineered variant of the enzyme glucoamylase (EC 3.2.1.3) produced by a genetically modified *Aspergillus niger* containing the glucoamylase gene from *Gloeophyllum sepiarium* as a processing aid for use in: baking; brewing; distilled alcohol production; and starch processing to produce glucose syrups and other starch hydrolysates.

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 would 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 2021) and the United States Pharmacopeial Convention (2022) Food Chemicals Codex (13th edition). These include general specifications for the identity and purity parameters of 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 A1291 included one round of public consultation following an assessment, and the preparation of a draft variation to the Code and associated assessment summary. FSANZ called for submissions on the draft variation between 27 August and 24 September 2024.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA).[11]. Impact analysis is no longer required to be finalised with the OIA. Prior to these changes, the OIA advised FSANZ that a Regulatory Impact Statement (RIS) was not needed for applications relating to processing aids and genetically modified food. This is because applications relating to permitting the use of processing aids and genetically modified food that have been determined to be safe are minor and deregulatory in nature, as their use will be voluntary if the draft variation concerned is approved.

Under this approach, FSANZ's assessment is that a RIS is not needed for this application.

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*.

[11] Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis (pmc.gov.au)

7. Variation

References to 'the variation' in this section are references to the approved draft variation.

Clause 1 provides that the name of the variation is the *Food Standards (Application A1291 – Glucoamylase from GM* Aspergillus niger *as a processing aid) Variation.*

Clause 2 provides that the Code is amended by the Schedule to the variation.

Clause 3 provides that the variation commences on the date of gazettal of the instrument.

Schedule to the variation

Item [1] of the Schedule to the variation inserts a new entry, in alphabetical order, into column 1 of 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 sepiarium.'*

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

- baking;
- brewing;
- the production of distilled alcohol; and
- starch processing for the production of glucose syrups and other starch hydrolysates.

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 item [1] is to permit the use of the protein engineered variant of the enzyme glucoamylase (EC 3.2.1.3) sourced from genetically modified *Aspergillus niger* containing the glucoamylase gene from *Gloeophyllum sepiarium* as a processing aid in accordance with the Code.

The Note after the table to subsection S18—9(3) relates to protein engineered variants of enzymes, which are listed in that table as processing aids permitted to be used for specific technological purposes. The Note explains to the reader that 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 in the Code will apply (see Standards 1.2.1 and 1.5.2). The Note then lists the relevant enzymes.

'Glucoamylase, protein engineered variant' is already listed in that Note.

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

Food Standards (Application A1291 – Glucoamylase from GM *Aspergillus niger* 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 name and position of Delegate]

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 A1291 – Glucoamylase from GM* Aspergillus niger *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 sepiarium*	For use in: (a) baking; (b) brewing; (c) the production of distilled alcohol; and (d) starch processing for the production of glucose syrups and other starch hydrolysates.	GMP