28 September 2022
215-22

Call for submissions – Application A1252

Glucoamylase from GM *Aspergillus niger* (gene donor: *Penicillium oxalicum*) 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 a protein engineered variant of the glucoamylase enzyme produced from a genetically modified strain (GM) of *Aspergillus niger.* The enzyme will be used in baking processes, brewing processes and starch processing for the production of starch hydrolysates, including glucose syrups. FSANZ has subsequently prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at current calls for public comment and how to make a submission.

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published as soon as possible after the end of the submission period.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at information for submitters.

For information on how FSANZ manages personal information when you make a submission, see FSANZ's Privacy Policy.

Submissions should be made in writing; be marked clearly with the word 'Submission'. You also need to include the correct application or proposal number and name. Electronic submissions can be made through the FSANZ website via the link how to make a submission. You can also email your submission to submissions@foodstandards.gov.au. FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 10 November 2022

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making a submission or application and proposal processes can be sent to standards.management@foodstandards.gov.au.

Submissions in hard copy may be sent to the following addresses:

Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604
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PO Box 10559
WELLINGTON 6140
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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

[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 glucoamylase enzyme (EC 3.2.1.3), sourced from genetically modified (GM) *Aspergillus niger (A. niger),* containing the glucoamylase gene from *Penicillium oxalicum (P. oxalicum).* The enzyme is proposed to be used as new processing aid in baking processes, brewing processes and starch processing for the production of starch hydrolysates, including glucose syrups.

Glucoamylase breaks down starch (saccharification) to release glucose to produce various products such as alcohol (ethanol) and amino and organic acids. End products can be further processed to produce glucose syrups and other starch hydrolysates (Kumar and Satyanarayana 2009).

FSANZ identified no public health and safety concerns in the assessment of the protein engineered glucoamylase (EC 3.2.1.3) from a genetically modified (GM) strain of *A. niger* under the proposed use conditions. The *A*. *niger* host is neither pathogenic nor toxigenic. Analysis of the modified production strain confirmed the presence and stability of the inserted DNA.

Glucoamylase does not show any sequence homology with known toxins. The enzyme was not genotoxic *in vitro*, and no treatment-related adverse effects were observed and no treatment-related adverse effects were observed in a 13-week oral toxicity study in rats. The no observed adverse effect level (NOAEL) was the highest dose tested, 1360 mg total organic solids (TOS)/kg bw/day. No significant homology to known food allergens was identified. Based on the available evidence the enzyme is unlikely to pose a food allergenicity concern.

The applicant has advised that wheat flour is used as the carrier and that wheat protein is present in the final enzyme preparation[3]. This only applies to the granulated preparation, which is used in baking processes. If wheat is present in a food for sale, including when present as a processing aid or an ingredient or component of a processing aid, it must be declared unless an exemption applies.

FSANZ has therefore prepared a draft variation to the Code which, if approved, would list the enzyme glucoamylase derived from GM *A. niger*, containing a protein engineered variant of the glucoamylase gene from *P. oxalicum*, in the table to subsection S18—9(3) as a permitted processing aid for use in baking processes, brewing processes and starch processing for the production of starch hydrolysates, including glucose syrups. This permission would be subject to the condition that the maximum permitted level or amount of the enzyme that may be present in the food must be consistent with Good Manufacturing Practice.

FSANZ invites submissions on the draft variation.

1 Introduction

1.1 The Applicant

Novozymes Australia Pty Ltd is a manufacturer of enzymes, microorganisms and precision proteins based in Sydney, Australia.

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 new protein engineered variant of glucoamylase (EC 3.2.1.3), sourced from genetically modified (GM) *Aspergillus niger (A. niger)*, as a processing aid for use in baking processes, brewing processes and starch processing for the production of starch hydrolysates, including glucose syrups. This organism contains the glucoamylase gene from *Penicillium oxalicum (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.

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.

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 Good Manufacturing Practice (GMP).

Standard 1.3.3 and Schedule 18 of the Code list 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.

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 Food Chemicals Codex (12th edition, 2020). These include specifications for enzyme preparations used in food processing.

Labelling requirements

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

Subsection 1.2.3—4(1) requires certain foods or their derivatives (as listed in the table to section S9—3 of Schedule 9) to be declared when present in a food for sale (unless they are exempt under subsection 1.2.3—4(4)). The food may be present as a substance used as a processing aid or as an ingredient or component of a substance used a processing aid (paragraph 1.2.3—4(5)(c)). Subsection 1.2.3—6(2) requires a declaration to be made[2] by (among other things) listing in the statement of ingredients the required name[3] of the food and the words 'processing aid' in conjunction with that required name[4]. If the food is not required to bear a label, the declaration must be displayed in connection with the display of the food or provided to the purchaser on request (subsections 1.2.1—9(6) and (7)).

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

[2] For the purposes of paragraph 1.2.1—8(1)(d) or subparagraph 1.2.4—5(6)(b)(i).
[3] ***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.
[4] If a food was packaged and labelled before 25 February 2024, that food may continue to be sold until 24 February 2026 if the food complies with either the previous Code requirements as in force before 25 February 2021, or the amended Code requirements that came into force on 25 February 2021.

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*[5] (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.

1.3.1 International standards

In developing food regulatory measures, FSANZ must have regard to the promotion of consistency between domestic and international food standards. In terms of food safety, the relevant international standard setting body is the Codex Alimentarius Commission (Codex). There is no Codex Alimentarius 'general standard' for enzymes, however as noted above there are internationally recognised specifications for enzyme preparations established by JECFA and Food Chemicals Codex. The applicant has advised that the enzyme is permitted for use in Denmark.

1.4 Reasons for accepting Application

The application was accepted for assessment because:

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

1.5 Procedure for assessment

The application is being assessed under the General Procedure of the FSANZ Act.

2 Summary of the assessment

2.1 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 baking processes, brewing processes and starch processing 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 the *A*. *niger* has a long history of safe use in food and is neither pathogenic nor toxigenic. A biotechnological assessment confirmed the genetic modification is as described and that the inserted gene has been stably introduced. A toxicological assessment combined with a dietary exposure assessment concluded that the enzyme is safe under the proposed conditions of use. Based

[5] 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*).

on the available evidence the enzyme is unlikely to pose a food allergenicity concern.

The applicant has advised that wheat flour is used as the carrier and that wheat protein is present in the final enzyme preparation3. This only applies to the granulated preparation, which is used in baking processes. If wheat is present in a food for sale, including when present as a processing aid or an ingredient or component of a processing aid, it must be declared unless an exemption applies.

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 SD – Risk and Technical Assessment.

2.2 Risk management

The risk management options available to FSANZ after assessment, were to either:

- reject the application, or
- prepare a draft variation of the Code.

For the reasons listed in this report, FSANZ decided to prepare a draft variation to the Code permitting the protein engineered variant of the enzyme, glucoamylase (EC 3.2.1.3) sourced from *A. niger* containing the glucoamylase gene from *P. oxalicum*, to be used as a processing aid in baking processes, brewing processes and starch processing for the production of starch hydrolysates, including glucose syrups, subject to the condition that the amount of enzyme used must be consistent with GMP.

The Risk and Technical Assessment report concluded that there are no safety concerns relating to using this protein engineered variant of glucoamylase for its proposed purpose. Further details are provided below.

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

2.2.1 Regulatory approval for enzymes

As stated above, FSANZ has prepared a draft variation to permit the use of this enzyme as a processing aid in baking processes, brewing processes and starch processing for the production of starch hydrolysates, including glucose syrups. 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)[6].

2.2.2 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 with an EC number of EC 3.2.1.3 (IUBMB 2018). This is consistent with how it is already permitted for use in the Code.

[6] 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'.

2.2.3 Labelling

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 above). In the case of foods manufactured using this processing aid, other requirements apply as detailed in sections 2.2.3.1 and 2.2.3.2 below.

2.2.3.1 Declaration of certain foods

Wheat flour is used in the granulate enzyme preparation for baking applications as discussed in Section 2.2.1 of SD1. If wheat is present in a food for sale, including when present as a processing aid or an ingredient or component of a processing aid, it must be declared unless an exemption applies (Division 3 of Standard 1.2.3).

FSANZ notes that one of the intended uses of glucoamylase is in the manufacture of bakery products. If these bakery products are made with wheat-derived ingredients (e.g. wheat flour, wheat bran), then they will be required to declare 'wheat' and 'gluten' in accordance with requirements in Division 3 of Standard 1.2.3. Wheat-free bakery products that are manufactured using glucoamylase will also be subject to 'wheat' and 'gluten' declarations if wheat and gluten from the enzyme remain in the food for sale.

The applicant has also mentioned that another potential use of the proposed glucoamylase preparation is in starch processing for glucose syrups. There are existing exemptions for glucose syrups from the requirement to declare wheat, providing the glucose syrup meets certain conditions that are detailed in subsection 1.2.3—4(4) of the Code.

2.2.3.2 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 the intended use of the enzyme is to manufacture brewed beverages such as potable alcohol but also to be used as a processing aid in baking processes and starch processing for the production of starch hydrolysates, including glucose syrups. 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 sourced from *A. niger* as 'genetically modified' would not apply.

2.2.4 Risk management conclusion

The risk management conclusion is to permit the enzyme glucoamylase (EC 3.2.1.3) sourced from a GM strain of *A. niger,* containing a protein engineered variant of the glucoamylase gene from *P. oxalicum*, for use as a food processing aid. If the draft variation is approved, the permission would be listed in the table to subsection S18—9(3) of the Code, which includes enzymes permitted for a specific technological purpose. The technological purpose of this enzyme would be as a processing aid in baking processes, brewing processes 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 would have to be consistent with GMP. The express permission for the enzyme to be used as a processing aid in Schedule 18 of the Code would also provide the permission for the enzyme's potential presence in the food for sale as a food produced using gene technology.

Mandatory declarations for wheat and gluten would apply when present in a food for sale.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a standard communication strategy to this application. All calls for submissions are notified via the Food Standards Notification Circular, media release, FSANZ's social media tools and Food Standards News.

The process by which FSANZ approaches standards development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options.

The draft variation will be considered for approval by the FSANZ Board taking into account all public comments received from this call for submissions.

2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

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

Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

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

2.4.1 Section 29

2.4.1.1 Consideration of costs and benefits

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for 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 exception relates to the introduction of a food to the food supply that has been determined to be safe.

FSANZ, however, has given consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act

requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

The purpose of this consideration is to determine if the community, government and industry as a whole is likely to benefit, on balance, from a move from the status quo (i.e. rejecting the application). This analysis considers permitting the use of a protein engineered variant of the enzyme glucoamylase (EC 3.2.1.3), sourced from this GM strain of *A. niger* as a processing aid for baking processes, brewing processes and starch processing for the production of starch hydrolysates, including glucose syrups. That enzyme would be listed in the table of subsection S18—9(3) of the Code, which includes enzymes permitted to be used as processing aids for specific technological purposes.

FSANZ's conclusions regarding costs and benefits of the proposed measure are set out below. However, information received from the call for submissions may result in FSANZ arriving at different conclusions.

The consideration of the costs and benefits in this section is 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 seeks to highlight the likely positives and negatives of moving away from the status quo by permitting the proposed use of the enzyme from the new source GM strain of *A. niger*.

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

Industry

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 in the industry believe a net benefit exists for them. An additional source of this enzyme may help industry save on costs of baking processes, brewing processes 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.

Government

Permitting the proposed use of this glucoamylase enzyme may result in a small cost to government in terms of an addition to the current range of sources 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 proposed use of this enzyme (as a processing aid in the baking processes, brewing processes and starch processing for the production of starch hydrolysates, including glucose syrups) most likely outweigh the associated costs.

2.4.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the Application.

2.4.1.3 Any relevant New Zealand standards

The relevant standards apply in both Australia and New Zealand and there are no relevant New Zealand only Standards.

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2 Subsection 18(1)

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

2.4.2.1 Protection of public health and safety

FSANZ undertook a safety assessment (see SD1) and concluded there were no public health and safety concerns associated with the proposed use of this enzyme.

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

The labelling requirements for this enzyme are discussed in Section 2.2.3 of this report.

2.4.2.3 The prevention of misleading or deceptive conduct

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

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ used the best available scientific evidence to conduct the risk analysis, which is provided in SD1. The 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 promotion of consistency between domestic and international food standards**

There are no Codex Alimentarius Standards for processing aids or enzymes. The enzyme processing aid meets international specifications for enzyme preparations, being 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 the enzyme is permitted for use in Denmark.

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

As mentioned 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 foster continued innovation and improvements in food manufacturing techniques and processes.

The conclusion of the risk assessment is there are no public health and safety concerns associated with the production microorganism or with using this protein engineered variant of glucoamylase enzyme (gene donar: *P. oxalicum)* as a food processing aid. It is therefore appropriate that Australian and New Zealand food industries are given the opportunity to benefit from the proposed use of this alternative enzyme.

Ultimately, the domestic food industry will make their own economic decisions, taking into account the costs and benefits of using this protein engineered variant of glucoamylase enzyme (gene donar: *P. oxalicum)*, 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[7]**

The Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*[8] 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 proposed use of this enzyme as a processing aid is consistent with the specific order policy principles for 'Technological Function'. All other requirements of the policy guidelines are similarly met.

[7] Formerly known as the Forum on Food Regulation
[8] https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Substances-other-than-Vitamins-and-Minerals

3 Draft variation

The draft variation to the Code is at Attachment A and, if approved, is intended to take effect on gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

4 References

FAO/WHO (2006) Combined compendium of food additive specifications, Food and Agriculture Organization of the United Nations, Rome. http://www.fao.org/docrep/009/a0691e/A0691E03.htm

IUBMB EC 3.2.1.3. https://iubmb.qmul.ac.uk/enzyme/EC3/2/1/3.html.

The United States Pharmacopeia (2020) Food Chemicals Codex 12th Edition, United States Pharmacopeial Convention, Rockville, MD. http://publications.usp.org/

Attachments

A. Draft variation to the Australia New Zealand Food Standards Code
B. Draft Explanatory Statement

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

Food Standards (Application 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 – Draft Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

The Authority accepted Application A1252 which seeks 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 for use in baking processes, brewing processes 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 prepared a draft variation.

2. Variation will be a legislative instrument

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

If approved, this instrument would not be subject to the disallowance or sunsetting provisions of the *Legislation Act 2003.* Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunsetting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the Food Ministers Meeting (FMM). The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has prepared a draft variation amending the table to subsection S18—9(3) 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 baking processes, brewing processes and starch processing for the production of starch hydrolysates, including glucose syrups. If approved, this permission would be subject to the condition that the maximum permitted level or amount of the enzyme that may be present in the food must be consistent with Good Manufacturing Practice (GMP).

4. Documents incorporated by reference

The draft variation does not incorporate any documents by reference.

However, existing provisions of the Code incorporate documents by reference that will prescribe identity and purity specifications for the processing aid to be permitted by the draft variation. Section 1.1.1—15 of the Code requires substances used as processing aids to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code. Section S3—2 of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) 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 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) will be open for a six-week period.

The Office of Best Practice Regulation (OBPR) 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

If approved, this instrument would be exempt from the requirements for a statement of compatibility with human rights as it would be a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

Item [1] of the Schedule to the draft variation would insert, in alphabetical order, a new entry into the table to subsection S18—9(3) of the Code. The new entry would consist of the following enzyme:

- 'Glucoamylase, protein engineered variant, (EC 3.2.1.3) sourced from *Aspergillus niger* containing the glucoamylase gene from *Penicillium oxalicum*' (column 1)

The permitted technological purpose for this enzyme would be use as a processing aid in:

(a) the manufacture of bakery products;

(b) brewing; and
(c) starch processing for the production of starch hydrolysates, including glucose syrups (column 2).

The permission would be subject to the condition that the maximum permitted level or amount of this enzyme that may be present in the food must be consistent with GMP (column 3).

If approved, the draft variation would 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.