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

25 October 2019
[100-19]

Approval report – Application A1169

Alpha-Glucosidase from *Trichoderma reesei* as a processing aid (Enzyme)

Food Standards Australia New Zealand (FSANZ) has assessed an application made by DuPont Australia Pty Ltd to permit the use of alpha-glucosidase (α-glucosidase) enzyme from a genetically modified strain of *Trichoderma reesei* as a processing aid.

On 20 June 2019, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received two submissions.

FSANZ approved the draft variation on 21 October 2019. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 25 October 2019.

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

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Supporting document

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

SD1 at Approval Risk and technical assessment

Executive summary

DuPont Australia Pty Ltd submitted an application to Food Standards Australia New Zealand (FSANZ) for a new microbial source of the already permitted enzyme processing aid, Alpha-glucosidase (α-glucosidase) (EC 3.2.1.20).The enzyme is derived from a genetically modified (GM) strain of *Trichoderma reesei* which expresses the α-glucosidase gene from *Aspergillus niger.*

The proposed use of the α-glucosidase is for the production of biochemicals such as monosodium glutamate (MSG) and other amino acids, organic acids (e.g. lactic acid, citric acid and succinic acid), potable alcohol, isomalto-oligosaccharides (IMO) and other sweeteners and lysine. These are not foods for sale themselves, but are used as ingredients in foods for sale.

Enzymes used to produce and manufacture food are considered processing aids and are regulated by Schedule 18 of the Australia New Zealand Food Standards Code (the Code). If approved for use, this enzyme would be listed in the table to subsection S18—9(3), which includes enzymes permitted for use for a specific technological purpose.

After undertaking a risk assessment, FSANZ concludes that there are no public health and safety concerns associated with using this new source of the α-glucosidase enzyme. *T. reesei* is not toxigenic or pathogenic. No extraneous coding genetic material is carried across from the donor organism or through the steps leading to the final genetic modification. In the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) of 'not specified' is appropriate. A dietary exposure assessment was therefore not required.

The enzyme preparation may contain traces of soy and wheat protein from the culture medium used to grow the production organism, however, labelling requirements exist to protect soy or wheat-allergic individuals.

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

FSANZ proposes a draft variation to the Code to permit the enzyme α-glucosidase derived from a GM strain of *T. reesei* containing the α-glucosidase gene from *A. niger* as a processing aid for use in the production of a variety of food ingredients. This is subject to the condition that the amount of enzyme used must be consistent with good manufacturing practice (GMP).

1 Introduction

1.1 The applicant

The applicant is DuPont Australia Pty Ltd – a subsidiary of E. I. du Pont de Nemours and Company, a manufacturer and marketer of specialty food ingredients, food additives and food processing aids.

1.2 The application

FSANZ received an application from DuPont Australia Pty Ltd seeking permission for the use of α-glucosidase (EC 3.2.1.20) as a processing aid. The enzyme is produced from fermentation of a GM strain of *Trichoderma reesei,* which is modified to express the α-glucosidase gene from *Aspergillus niger.*

If approved, this particular α-glucosidase will be used for the production of potable alcohol, organic acids (e.g. lactic acid, citric acid and succinic acid), biochemicals, such as MSG and other amino acids, IMO and other sweeteners, and lysine. These are not foods for sale themselves but are used as ingredients in foods for sale.

α-Glucosidase will be used as a processing aid at low levels and is either not present in the final food or present in insignificant quantities, having no technical function in the final food.

1.3 The current Standard

Australian and New Zealand food laws require food for sale to comply with the following requirements of the Code.

Permitted use

Enzymes used to process and manufacture food are considered processing aids as 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) of the Code provides that food for sale cannot contain, as an ingredient or component, a substance 'used as a processing aid' unless that substance's use is expressly permitted by the Code. Section 1.1.2—13 provides that a substance is 'used as a processing aid' if it is added to a food to perform a technological purpose during the course of processing of food; does not perform a technological purpose in the food for sale; and is a substance listed in Schedule 18 or a substance 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. Enzymes of microbial origin listed in the table to subsection S18—4(5) are permitted for use as processing aid for all food. The table to subsection S18—9(3) lists those substances, including enzymes, that are permitted to be used as processing aids for specific technological purposes.

There are currently permissions for α-glucosidase (EC 3.2.1.20) from non-GM *A. oryzae* and *A. niger* within the table to subsection S18—4(5), to be used in the manufacture of all foods. However, α-glucosidase from this particular microbial source, the subject of this application, is not currently permitted.

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. Section 1.5.2—3 of Standard 1.5.2 provides that permission in the Code for use as a processing aid also constitutes the permission required by paragraph 1.1.1—10(6)(g).

Identity and purity requirements

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.

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 2016) and the United States Pharmacopeial Convention (2016) Food Chemicals Codex (10th edition). 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 imposed by the Code for that food.

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

Paragraphs 1.2.4—3(2)(d) and (e) exempt processing aids from the requirement to be declared in the statement of ingredients, unless other requirements prevail.

Section 1.5.2—4 requires processing aids that are foods produced using gene technology to be labelled ‘genetically modified’, where novel DNA and/or novel protein from the processing aid remains present in the final food. The requirement applies to foods for sale that consist of or have as an ingredient, food that is a genetically modified food. The requirements imposed by section 1.5.2—4 generally apply only to foods for retail sale and to foods sold to a caterer under subsection 1.2.1—8(1) and section 1.2.1—15 respectively.

1.4 Reasons for accepting application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the FSANZ Act
- it related to a matter that (b) warranted the variation of a food regulatory measure.

1.5 Procedure for assessment

The application was assessed under the General Procedure.

1.6 Decision

The draft variation as proposed following assessment was approved with amendments after the consideration of submissions to correct minor errors and ensuring there is consistency of drafting terminology being used in processing aid applications. The variation takes effect on 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.

The draft variation on which submissions were sought is at Attachment C

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions on a proposed draft variation on 20 June 2019. Two submissions were received from The Victorian Departments of Health and Human Services and Jobs, Precincts and Regions and New Zealand Ministry for Primary Industries. Both submissions were supportive of the proposed draft variation, with no issues being raised.

Table 1: Summary of submissions

Submitter	Comments
Victorian Department of Health and Human Services and the Victorian Department of Jobs, Precincts and Regions	Supportive
New Zealand Food Safety (Ministry for Primary Industries)	Supportive

2.2 Risk assessment

T. reesei has a long history of safe use as the source of enzyme processing aids, including several that are already permitted in the Code. This fungus is neither toxigenic nor pathogenic. No extraneous coding genetic material is carried across from the donor organism or through the steps leading to the final genetic modification. The modification involving the insertion of the α-glucosidase gene has been shown to be stably inherited.

The enzyme α-glucosidase from genetically modified *T. reesei* shows no significant homology with any known allergens, venoms or toxins.

No evidence of genotoxicity was found in a bacterial reverse mutation assay or in a chromosomal aberration assay in human lymphocytes. In an 18-week study in rats, the No Observed Effect Level (NOEL) was 63.64 mg/kg bw/day α-glucosidase (expressed as total protein), the highest dose tested. This dose corresponds to 77.2 mg TOS/kg bw/day. The Theoretical Maximal Daily Intake (TMDI) in consumers under the proposed conditions of use is 0.443 mg/kg bw/day TOS. Consequently, the Margin of Safety (MoS) between the TMDI and the NOEL in rats is 174.

In the absence of any identifiable hazard an Acceptable Daily Intake (ADI) ‘not specified’ is appropriate, and therefore a dietary exposure assessment is not required.

Nutrient raw materials used in the bacterial fermentation process to produce α-glucosidase include soy protein and glucose derived from wheat. Therefore the enzyme preparation may contain traces of wheat or soy. DuPont has estimated that the highest amount of soy protein or wheat protein in the final food would be 2-3 ppb and 5 ppb, respectively.

The draft variation as proposed following assessment was approved with one minor amendment. The text of the proposed permission was changed from the wording ‘α-

Glucosidase (EC 3.2.1.20) sourced from *Trichoderma reesei* which overexpresses the α-glucosidase gene from *Aspergillus niger'* to 'α-Glucosidase (EC 3.2.1.20) sourced from *Trichoderma reesei* containing the α-glucosidase gene from *Aspergillus niger'.* This change was made to ensure consistency with other enzyme permissions in the Code and in draft variations currently under consideration. The approved draft variation, as varied after consideration of submissions, is at Attachment A.

2.3 Risk management

The risk assessment concluded that there are no safety concerns relating to the use of α-glucosidase as a processing aid. The enzyme is produced from fermentation of a GM strain of *T. reesei,* which is modified to express the α-glucosidase gene from *A. niger.* As processing aids require permissions in the Code, the main risk management options available to FSANZ were to approve or reject the application to amend the Code and, if approved, to impose any conditions that may be appropriate. Other risk management issues for this application related to enzyme nomenclature and labelling, are discussed below. The regulatory options analysed in section 2.3.1 below take account of the safety of the enzyme.

α-Glucosidase will provide the food industry with an alternative source of this enzyme for use in the production of potable alcohol, organic acids (e.g. lactic acid, citric acid and succinic acid), biochemicals, such as MSG and other amino acids, IMO and other sweeteners, and lysine.

2.3.1 Regulatory approval for enzymes

Following a safety assessment FSANZ has concluded that this α-glucosidase meets its stated purpose. The risk assessment has further concluded that, in the absence of any identifiable hazard, an ADI of 'not specified' is appropriate for the enzyme and ingestion of any residual α-glucosidase in food products is unlikely to pose an allergenicity concern.

Therefore, FSANZ approved the draft variation to permit the use of the enzyme as a processing aid for its stated purpose.

The express permission for the enzyme to be used as a processing aid in Schedule 18 will also provide permission for the enzyme's potential presence in 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'.

2.3.2 Enzyme and source microorganism nomenclature

FSANZ noted that the International Union of Biochemistry and Molecular Biology (IUBMB), the internationally recognised authority for enzyme nomenclature, uses the accepted name "α-glucosidase" for the enzyme with an EC number of EC 3.2.1.20 (IUBMB 2018). α-Glucosidase is already listed in the table to subsection S18—4(5) and will remain as such if approved and subsequently listed in the table to subsection S18—9(3).

The nomenclature of the host and gene donor microorganisms was checked and confirmed as being appropriate as listed in the application (see section 3.2 of SD1). The host organism, *T. reesei* and the gene donor, *A. niger* are both commonly listed microorganisms within Schedule 18.

2.3.3 Labelling requirements

The risk assessment concluded that the use of the enzyme poses no public health and safety

concerns and that it performs its technological purpose as a processing aid. Therefore, the generic exemption from declaration of processing aids in the statement of ingredients will apply to foods containing this processing aid, noting that wheat and soy protein may be carried over into the enzyme preparation (see section 2.2.3.2).

2.3.3.1 Labelling requirements for food produced using gene technology

The requirements for labelling as 'genetically modified' differ depending on whether the GM food is an ingredient of the food for sale or not, as follows. If a food for retail sale or sold to a caterer contains the enzyme α-glucosidase as an ingredient, that food would be required to be labelled 'genetically modified' in conjunction with the name of the processing aid, if novel DNA or novel protein from the GM strain of *T. reesei* (that is the source microorganism, not the enzyme) remains in that food for sale.

FSANZ however notes α-glucosidase is used to manufacture IMO, potable alcohol, MSG and organic acids which are not themselves foods for sale, but are used as ingredients in foods for retail sale or in food sold to a caterer. As such, these ingredients are not GM foods and are not subject to labelling requirements set out in section 1.5.2—4(1)).

2.2.3.2 Declaration of certain substances

Section 2.2 above states the enzyme preparation may contain traces of wheat or soy. In accordance with section 1.2.3—4 of Standard 1.2.3 (Information requirements – warning statements, advisory statements and declarations), if wheat or soy is present, including when present as a processing aid or an ingredient or component of a processing aid, it must be declared. If the food is not required to bear a label, the allergen information must be displayed in connection with the display of the food or provided to the purchaser on request (section 1.2.1—9 of Standard 1.2.1).

Certain products are exempt from the requirement to declare wheat. Subparagraph 1.2.3—4(1)(b)(i)(A) of the Code, for example, provides an exemption for alcohol distilled from wheat or whey from the requirement to declare wheat or milk. As noted above, the enzyme is intended to be used in the manufacture of potable alcohol, which in turn will be used as an ingredient for spirits and liqueurs.

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

2.2.4 Risk management conclusion

The risk management conclusion is to permit α-glucosidase sourced from *T. reesei* containing the α glucosidase gene from *A. niger*. for use as a food processing aid. The permission will be listed in the table to subsection S18—9(3), which includes enzymes permitted for a specific technological purpose. The technological purpose is for use in the production of food ingredients such as potable alcohol, lysine, lactic acid, biochemicals, such as MSG and other amino acids, production of IMO syrup and other sweeteners. The level of usage is an amount consistent with GMP. Labelling requirements exist to provide information to wheat-allergic or soy-allergic individuals about the potential presence of soy and wheat proteins in the final enzyme preparation. These involve the declaration of these substances, where appropriate.

The express permission for the enzymes' use as a processing aid in Schedule 18 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

2.4.1 Consultation

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

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

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

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application. Every submission on the application was considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

2.4.2 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 not any relevant international standards and amending the Code to permit a new microbial source of a currently permitted enzyme is unlikely to have a significant effect on international trade as Codex Alimentarius does not have regulations for enzymes used as processing aids. 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.

2.5 FSANZ Act assessment requirements

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for permitting new processing aids (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting processing aids is machinery in nature as they are part of implementing a regulatory framework where the use of the new aids is voluntary once the application has been successfully approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

FSANZ, however, has given consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29 (2)(a)).

The purpose of this consideration is to determine if the community, government and industry as a whole is likely to benefit, on balance, from a move from the status quo (i.e. rejecting the application). This analysis considers permitting the use of α-glucosidase derived from a GM strain of *T. reesei,* as a processing aid into the table to subsection S18—9(3), which includes enzymes permitted for a specific technological purpose. FSANZ is of the view that no other realistic food regulatory measures exist, however information received may result in FSANZ arriving at a different outcome.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo by permitting the use of the enzyme.

Costs and benefits of permitting the use of enzyme α-glucosidase derived from a GM strain of T. reesei as a processing aid

Industry
α-Glucosidase facilitates the production of potable alcohol, lysine, organic acids, MSG and other biochemicals, production of IMO and other sweeteners. This α-glucosidase is claimed by the applicant to be able to increase fermentation rates, recovery yields, reduce viscosity and foaming during fermentation and convert residual DP2 sugars into fermentable sugars. Due to the voluntary nature of the permission, industry will only use the α-glucosidase enzyme where they believe a net benefit exists. There are other enzymes available to industry that perform similar functions and it is of benefit to industry to have additional choice available to them, especially where the enzyme is more effective or cheaper.

The US FDA did not respond with questions to a self-determination of this α-Glucosidase as GRAS in the United States. The international permissions of this enzyme may be a business opportunity for Australia New Zealand industries, although there may also be competing imports from these countries into the domestic market.

Consumers
Industry may pass some of the possible cost savings from using the enzyme onto consumers.

Government
Permitting the enzyme may result in a small cost to government in terms of adding the enzyme to the current range of processing aids that are monitored for compliance.

Conclusions from cost benefit considerations

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting the use of enzyme α-glucosidase derived from a GM strain of *T. reesei* as a processing aid most likely outweigh the associated costs.

2.5.1.2 Other measures

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

2.5.1.3 Any relevant New Zealand standards

Standards 1.1.1, 1.1.2 and 1.3.3 and Schedule 18 apply in both Australia and New Zealand

and there are no other relevant New Zealand only standards.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2. Subsection 18(1)

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

2.5.2.1 Protection of public health and safety

FSANZ has undertaken a safety assessment (SD1) and concluded there are no public health and safety concerns with permitting the use of α-glucosidase sourced from *T. reesei,* which expresses the α-glucosidase gene from *A. niger,* as a processing aid in food for the proposed purpose.

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

The labelling considerations for the processing aid are discussed in Section 2.3.3 above.

2.5.2.3 The prevention of misleading or deceptive conduct

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

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ has used the best available scientific evidence to conduct the risk analysis, which is provided in SD1. The applicant submitted a dossier of scientific studies as part of the application. Other technical information, including scientific literature, was also used to assess the application.

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

There are no Codex Alimentarius Standards for enzymes. However, the US FDA did not respond with questions to a self-determination of this enzyme as GRAS in the US. It is also in the process of being approved in Canada. It also meets international specifications for enzyme preparations, being the JECFA Compendium of Food Additive Specifications and the Food Chemicals Codex.

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

Permission for the α-glucosidase enzyme preparation provides food manufacturers with an alternative enzyme, which should add to competition in supplying enzymes to the food manufacturing industries.

- **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 Forum on Food Regulation**

The Ministerial Policy Guideline Addition to Food of Substances other than Vitamins and Minerals[1] 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 α-glucosidase sourced from *T. reesei* which expresses the α-glucosidase gene from *A. niger,* as a processing aid is consistent with the specific order principles for 'Technological Function'.

6 References

Food Chemicals Codex 10th Edition (2016), The United States Pharmacopeia, United States Pharmacopeial Convention, Rockville, MD. Accessed 07 August 2019

IUBMB (International Union of Biochemistry and Molecular Biology) Enzyme Nomeclature for EC 3.2.1.20. Accessed 07 August 2019

FAO/WHO 2016 General specifications and considerations for enzyme preparations used in food processing. Accessed 07 August 2019

Attachments

A. Approved draft variation to the *Australia New Zealand Food Standards Code*
B. Explanatory Statement
C. Draft variation/s to the *Australia New Zealand Food Standards Code* (call for submissions)

[1] Food regulation website

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

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

Food Standards (Application A1169 – Alpha-glucosidase from *Trichoderma reesei* as a Processing Aid (Enzyme)) Variation

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

Dated [To be completed by Delegate]

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

Note:

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

1 Name

This instrument is the *Food Standards (Application A1169 – Alpha-glucosidase from* Trichoderma reesei *as a Processing Aid (Enzyme)) Variation.*

2 Variation to a standard in the *Australia New Zealand Food Standards Code*

The Schedule varies a Standard in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

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

α-Glucosidase (EC 3.2.1.20) sourced from *Trichoderma reesei* containing the α-glucosidase gene from *Aspergillus niger*	For use in the manufacture and/or processing of the following types of food: (a) potable alcohol; (b) lysine; (c) organic acids; (d) monosodium glutamate and other biochemicals; and (e) isomalto-oligosaccharides and other sweeteners.	GMP

Attachment B – Explanatory Statement

1. Authority

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

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

The Authority accepted application A1169 which seeks to permit the use of an Alpha-glucosidase enzyme preparation from *Trichoderma reesei* which expresses the α-glucosidase gene from *Aspergillus niger* as a processing aid for use in the production of various foods. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft Standard.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunsetting under the *Legislation Act 2003*.

2. Purpose

The Authority has approved a draft variation to permit the enzyme α-glucosidase sourced from a GM *T. reesei,* which expresses the α-glucosidase gene from *A. niger* for use as a food processing aid. The permission will be listed in the table to subsection S18—9(3), which includes enzymes permitted for a specific technological purpose. The technological purpose is for use in the production of food ingredients such as potable alcohol, lysine, lactic acid, biochemicals, such as MSG and other amino acids, production of IMO syrup and other sweeteners. The level of usage is an amount consistent with GMP. This permission requires an addition to the table to subsection S18—9(3) in Schedule 18.

3. Documents incorporated by reference

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

Existing provisions of the Code incorporate a document by reference that will prescribe identity and purity specifications for the processing aid to be permitted by the draft variation. Section 1.1.1—15 of the Code requires substances used as processing aids to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code. Section S3—2 of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Compendium of Food Additive Specifications (FAO/WHO 2016) and the United States Pharmacopeial Convention (2016) Food Chemicals Codex (10th edition). These include specifications for enzyme preparations used in food processing.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of application A1169 included one round of public consultation following assessment and the preparation of a draft variation and associated assessment summary. Submissions were called for on 20 June 2019 for an six-week consultation period.

A Regulation Impact Statement was not required because the proposed variations to Schedule 18 are likely to have a minor impact on business and individuals.

5. Statement of compatibility with human rights

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

6. Variation

The draft variation inserts a new entry into the table to subsection S18—9(3) in Schedule 18.

The new entry will permit the use of the enzyme, α-glucosidase (EC 3.2.1.20) sourced from a GM *T. reesei,* containing the α-glucosidase gene from *A. niger,* for use as a food processing aid in food for a specific technological purpose, with the condition that the maximum permitted level or amount that may be used must be consistent with good manufacturing practice. The technological purpose is for use in the production of food ingredients such as potable alcohol, lysine, lactic acid, biochemicals, such as MSG and other amino acids, production of IMO syrup and other sweeteners.

Attachment C – Draft variation/s to the *Australia New Zealand Food Standards Code* (call for submissions)

1 Name

This instrument is the *Food Standards (Application A1169 – Alpha-glucosidase from* Trichoderma reesei *as a Processing Aid (Enzyme)) Variation.*

2 Variation to a standard in the *Australia New Zealand Food Standards Code*

The Schedule varies a Standard in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

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

α-Glucosidase (EC 3.2.1.20) sourced from *Trichoderma reesei* which overexpresses the α-glucosidase gene from *Aspergillus niger*	For use in the manufacture and/or processing of the following types of food: (f) potable alcohol; (g) lysine; (h) organic acids; (i) monosodium glutamate and other biochemicals; and (j) isomalto-oligosaccharides and other sweeteners.	GMP