9 March 2023
234-23

Call for submissions – Application A1245

Alpha-glucosidase from GM *Trichoderma reesei* as a processing aid in brewing

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FSANZ has assessed an application made by Danisco New Zealand Limited to permit an additional use of alpha-glucosidase from *Trichoderma reesei* containing the alpha-glucosidase gene from *Aspergillus niger* as a processing aid in brewing of beer, and has 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 by emailing 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) 25 April 2023

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
AUSTRALIA
Tel +61 2 6271 2222

Food Standards Australia New Zealand
PO Box 10559
WELLINGTON 6140
NEW ZEALAND
Tel +64 4 978 5630

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Supporting document

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

SD Risk and Technical Assessment

Executive summary

Danisco New Zealand Limited (Danisco) 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 the enzyme alpha-glucosidase as a processing aid in the brewing of brewed beverages, specifically low alcohol and lower carbohydrate beer. The enzyme is produced from a genetically modified (GM) strain of *Trichoderma reesei* containing the alpha-glucosidase gene from *Aspergillus niger*.

FSANZ previously assessed this enzyme under Application A1169 (Alpha-Glucosidase from *Trichoderma reesei* as a processing aid (Enzyme)) for use as a processing aid in the manufacture or processing of various foods not including the brewing of beer. It was subsequently approved for use as a processing aid in the manufacture and/or processing of those foods. FSANZ has undertaken a further assessment to determine whether the enzyme achieves the proposed technological purposes in brewing and to evaluate any public health and safety concerns that may arise from extending the use of the enzyme as proposed.

FSANZ concludes that the proposed use of this enzyme as a processing aid in brewing low alcohol and lower carbohydrate beer is consistent with its functions of catalysing the transfer of glycosyl units and hydrolysis releasing glucose, respectively. The enzyme can be added during the brewing process at the mashing step to produce a higher proportion of non-fermentable sugars which reduces fermentation therefore producing low alcohol beer. It can also be added during the fermentation stage to reduce the non-fermentable carbohydrates thereby increasing the fermentable carbohydrates. This means more of the carbohydrates (as sugars) are fermented, leaving less in the final fermented beer.

Alpha-glucosidase performs the above technological functions during the brewing of beer and is not performing the technological purpose in the food for sale, therefore functioning as a processing aid for the purposes of the Code.

No public health and safety concerns were identified in the assessment of the alpha-glucosidase under the additional proposed use. A toxicological assessment combined with a revised dietary exposure assessment concluded the enzyme is safe under the additional proposed use.

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

FSANZ has therefore prepared a draft variation to subsection S18—9(3) of the Code. The draft variation, if approved, would permit the use of the enzyme alpha-glucosidase (3.2.1.20) sourced from *T. reesei* containing the alpha-glucosidase gene from *A. niger* as a processing aid in the manufacture and/or processing of beer (in addition to the enzyme’s existing permitted technological purposes). The 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 an amount consistent with good manufacturing practice (GMP).

FSANZ seeks submissions on the draft variation.

1 Introduction

1.1 The applicant

The applicant is Danisco New Zealand Limited (Danisco). Danisco is a subsidiary of International Flavors and Fragrances Inc (IFF).

1.2 The application

The purpose of the application is to amend the Australia New Zealand Food Standards Code (the Code) to permit an additional use of the enzyme alpha-glucosidase as a processing aid in the brewing of beer, specifically low alcohol and lower carbohydrate beer. The enzyme is produced from a genetically modified (GM) strain of *Trichoderma reesei* containing the alpha-glucosidase gene from *Aspergillus niger*.

The Code was amended in January 2020 to permit the use of this alpha-glucosidase following assessment of an application from DuPont Australia Pty Ltd – Application A1169 – Alpha-Glucosidase from *Trichoderma reesei* as a processing aid (Enzyme). The enzyme was permitted for use in the manufacture and/or processing of a range of foods not including beer. That permission is subject to the condition that the maximum permitted level or amount of this enzyme that may be present in the food must be consistent with good manufacturing practice (GMP).

1.3 The current standard

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

1.3.1 Permitted use

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

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

- it is used to perform a technological purpose during the course of processing
- it does not perform a technological purpose in the food for sale, and
- it is a substance listed in Schedule 18 or identified in section S16—2 as an additive permitted at GMP.

Standard 1.3.3 and Schedule 18 of the Code list the permitted processing aids. Enzymes of microbial origin permitted to be used as processing aids are listed in the table to subsection S18—4(5) or in the table to subsection S18—9(3) of Schedule 18, depending on whether a technological purpose has been specified. Enzymes of microbial origin listed in the table to subsection S18—4(5) are permitted for use as a processing aid to perform any technological purpose if the enzyme is derived from the corresponding source specified in the table. The table to subsection S18—9(3) lists those substances, including enzymes derived from

particular sources, that are permitted to be used as processing aids for specific technological purposes in relation to:

- if a food is specified—that food; or
- if no food is specified—any food.

Additionally, paragraph 1.3.3—11(c) specifies that the substance may only be used as a processing aid if it is not present in the food at greater than the maximum permitted level for that substance indicated in the table to section S18—9.

Paragraph 1.1.1—10(6)(g) requires that the presence as an ingredient or component in a food for sale of a food produced using gene technology must be expressly permitted by the Code. Paragraph 1.5.2—3(b) provides that permission in the Code for use as a processing aid also constitutes the permission required by paragraph 1.1.1—10(6)(g).

As outlined in Section 1.2 above, the Code already permits alpha-glucosidase from *T. reesei* containing the alpha-glucosidase gene from *A. niger* to be used as a processing aid in certain foods, however not in beer (see the table to subsection S18—9(3)).

1.3.2 Identity and purity requirements

Paragraph 1.1.1—15(1)(b) of the Code requires substances used as processing aids in food to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code.

Subsection S3—2(1) of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications (FAO JECFA Monographs 23 (2019)), and the United States Pharmacopeial Convention (2020) Food chemicals codex (12th edition). These include general specifications for enzyme preparations used in food processing for identity and purity parameters.

1.3.3 Labelling requirements

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[1] 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 retail sale. If a food for retail sale is not required to bear a label, the required name must be displayed in connection with the display of the food or provided to the purchaser on request. If food sold to a caterer is not required to bear a label, the required name must be provided to the caterer with the food.

Section 1.5.2—4 of the Code requires a food for sale that consists of a *genetically modified*

[1] ***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)).

food[2] (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, 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 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 is being assessed under the General Procedure in the FSANZ Act.

2 Summary of the assessment

2.1 Risk assessment

FSANZ previously assessed this *A. niger* alpha-glucosidase enzyme produced by GM *T. reesei* under A1169, for use as a processing aid in the manufacture or processing of various foods but not including use in brewing beer. FSANZ has undertaken a further assessment to consider the enzyme for use in brewing beer (see SD1).

No public health and safety concerns were identified in the assessment of the alpha-glucosidase under the additional proposed use. A microbiological assessment confirmed that the GM host strain is neither pathogenic nor toxigenic, and a biotechnology assessment confirmed the genetic modification is as previously described and that the inserted gene has been stably introduced.

[2] 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*).

A toxicological assessment combined with a revised dietary exposure assessment concluded the enzyme is safe under the proposed additional use. Bioinformatics analysis confirmed that the produced enzyme itself has no significant similarity with known toxins or food allergens.

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

Nutrient raw materials used in the production of the applicant's alpha-glucosidase include glucose derived from wheat. Therefore the enzyme preparation may contain traces of wheat.

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 use of alpha-glucosidase produced using a GM strain of *T. reesei* containing the alpha-glucosidase gene from *A. niger* as a processing aid in manufacture and/or processing of beer. If approved, this permission would be subject to the condition that the maximum permitted level or amount of enzyme used in the food must be consistent with GMP.

The conclusions from the risk and technical assessment were that the proposed use of the enzyme is technologically justified and there were no safety concerns associated with its proposed use.

Other risk management considerations for this application are related to the enzyme and source microorganism nomenclature, specifications and labelling. These are discussed below.

2.2.1 Regulatory approval for enzymes

As stated above, FSANZ has prepared a draft variation to permit the use of the enzyme as a processing aid in the manufacture and/or processing of beer. ***Beer*** is currently defined in Standard 1.1.2 to mean:

> (a) the product, characterised by the presence of hops or preparations of hops, prepared by the yeast fermentation of an aqueous extract of malted or unmalted cereals, or both; or
> (b) such a product with any of the following added during production:
> (i) cereal products or other sources of carbohydrate;
> (ii) sugar;
> (iii) salt;
> (iv) herbs and spices.

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. 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) [3].

2.2.2 Nomenclature and specifications

The International Union of Biochemistry and Molecular Biology (IUBMB) uses the accepted name ‘α-glucosidase’. This is the name used in the proposed draft variation and the name used in existing permissions for alpha-glucosidase in Schedule 18. The word ‘alpha’ has however, been used in this report and was used by the applicant in the application, instead of its symbol.

Nomenclature for the host and gene donor organisms (*Trichoderma reesei* and *Aspergillus niger* respectively) is in accordance with accepted international norms for fungal taxonomy.

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).

2.2.3 Labelling requirements

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

2.2.3.1 Declaration of certain substances

Section 4 of the SD states that wheat may be present in the final enzyme preparation. When wheat and gluten (which may be present in wheat) are present in a food for sale they must be declared. However, alpha-glucosidase is intended to be used in the brewing of beer. Beer is exempt from the requirement to declare wheat and gluten (table to subsection S9—3).

2.2.3.2 Voluntary representations

FSANZ notes this enzyme is intended to be used in brewing to produce low alcohol and lower carbohydrate beer. Representations made about beer produced using this enzyme would be subject to conditions in the Code.

Specific labelling requirements for alcoholic beverages are set out in Standard 2.7.1. An alcoholic beverage must not be represented as a low alcohol beverage if it contains more than 1.15% alcohol by volume (ABV).

Nutrition content claims about carbohydrate made about a beer produced using this enzyme would need to comply with requirements in Standard 1.2.7 and Schedule 4. Schedule 4 sets out general and specific claim conditions for nutrition content claims which must be met. For nutrition content claims about carbohydrate there are no general conditions and only specific conditions for making increased and reduced (or synonyms, e.g. lower) carbohydrate claims. FSANZ is currently considering the regulation of claims about the carbohydrate content of alcoholic beverages containing more than 1.15% ABV under Proposal P1049 – Carbohydrate and sugar claims on alcoholic beverages.

[3] 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’.

2.2.4 Risk management conclusion

The risk management conclusion is to permit the enzyme alpha-glucosidase (EC 3.2.1.20) sourced from *T. reesei* containing the alpha-glucosidase gene from *A. niger* for use as a processing aid in the manufacture and/or processing of beer. If 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 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 also provides the permission for the enzyme's potential presence in the food for sale as a food produced using gene technology.

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 channels 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 the draft variation.

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 Impact Analysis (OIA)[4] granted FSANZ a standing exemption from the requirement to develop an Regulatory Impact Statement for applications relating to permitting

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

processing aids and GM foods (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting processing aids and GM foods is deregulatory as their use will be voluntary if the application concerned is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

FSANZ, however, 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 (where status quo is rejecting the application). This analysis considers extending the current permissions in the Code for the use of alpha-glucosidase, for use in brewing beer.

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 potential positives and negatives of moving away from the status quo by extending the use of the processing aid to brewing.

FSANZ's conclusions regarding the 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 a different outcome.

2.4.1.1.1 Costs and benefits of extending the use of the processing aid

Industry may benefit from being able to use this processing aid to assist in brewing low alcohol and lower carbohydrate beer. Due to the voluntary nature of the permission, industry will only use the processing aid where they believe a net benefit exists for them in terms of cost saving or being able to deliver a new product that appeals to consumers.

The processing aid has been approved in other countries which may be a business opportunity to Australia and New Zealand industries, although there may also be competing imports from these countries into the domestic market.

Consumers may benefit from an increase in variety and choice of beer products available to them. If the use of the processing aid results in any cost savings industry may pass some of the savings onto consumers.

Permitting this extension of use may result in a small, inconsequential cost to government in terms of an addition to the technological purposes of a processing aid that is already monitored for compliance.

2.4.1.1.2 Conclusions from cost benefit considerations

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting alpha-glucosidase for use in brewing beer, 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. There are no other 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 the SD) and concluded there were no public health and safety concerns associated with the proposed additional 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 relevant to this application are discussed in Section 2.2.3 of this report.

2.5.2.3 The prevention of misleading or deceptive conduct

There were 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. The applicant submitted a dossier of information and scientific literature as part of its application. This dossier, together with information provided with the previous application for the same enzyme, A1169, and other technical and scientific information and was considered by FSANZ in assessing the application. The risk assessment is provided in the SD.

- **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 of this report.

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

The applicant provided confidential commercial information (CCI) about the approval of their enzyme in other countries since the assessment of A1169. Approval for use of the

applicant's alpha-glucosidase in brewing beer would bring Australia and New Zealand into line with other jurisdictions where it is already permitted for use. In this way, Australia and New Zealand would remain competitive with other international markets. This would also help support 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 the enzyme as a food processing aid. It is therefore appropriate that Australian and New Zealand food industries are given the opportunity to benefit from the extended use of this enzyme for use at levels as proposed by the applicant.

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

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

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

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

The Ministerial Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*[5] 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 determined that permitting the proposed use of this enzyme is consistent with these specific order policy principles for 'Technological Function'. All other relevant requirements of the policy guideline are similarly met.

3 Draft variation

The draft variation to the Code is at Attachment A and 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.

Attachments

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

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

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

Food Standards (Application A1245 – Alpha-glucosidase from GM *Trichoderma reesei* as a processing aid in brewing) 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 A1245 – Alpha-glucosidase from GM* Trichoderma reesei *as a processing aid in brewing) 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 item dealing with "α-Glucosidase (EC 3.2.1.20) sourced from *Trichoderma reesei* containing the α-glucosidase gene from *Aspergillus niger*", column headed "*Technological purpose and food*", paragraph (e))

Repeal the paragraph, substitute:

(e)	isomalto-oligosaccharides and other sweeteners; and
(f)	beer.

Attachment B – Draft Explanatory Statement

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1245 – Alpha-glucosidase from GM* Trichoderma reesei *as a processing aid in brewing) 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 A1245 which seeks to amend the Code to permit an additional use of the enzyme, alpha-glucosidase (α-glucosidase) from a genetically modified (GM) strain of *Trichoderma reesei* containing the α-glucosidase gene from *Aspergillus niger*, as a processing aid in brewing of beer. The Code currently permits this enzyme to be used as a processing aid in the manufacture and/or processing of certain foods but not including beer, subject to the condition that the maximum permitted level or amount of this enzyme that may be present in the food must be consistent with good manufacture practice (GMP). The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation – the *Food Standards (Application A1245 – Alpha-glucosidase from GM* Trichoderma reesei *as a processing aid in brewing) 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 α-glucosidase (EC 3.2.1.20) sourced from a GM strain of *Trichoderma reesei* containing the alpha-glucosidase gene from *Aspergillus niger* as a processing aid in the manufacture and/or processing of beer. If approved, this permission would be subject to the existing condition that the maximum permitted level or amount of this enzyme that may be present in the food must be consistent with 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 the identity and purity 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 A1245 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 Impact Analysis[6] granted the Authority a standing exemption from the requirement to develop a Regulatory Impact Statement for applications relating to permitting processing aids and GM foods (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting 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 amend the table item dealing with 'α-Glucosidase (EC 3.2.1.20) sourced from *Trichoderma reesei* containing the α-glucosidase gene from *Aspergillus niger*' (the enzyme) in the table to subsection S18—9(3) of the Code by:

- repealing existing paragraph (e) in the column headed 'Technological purpose and food' in relation to that table item; and
- substituting existing paragraph (e) with a new paragraph (e) that has a semicolon at the end of it followed by new paragraph (f) listing 'beer' as a food.

Paragraph (e) is currently the final listing of food in which the enzyme may be used as a processing aid and, as such, the paragraph has a full stop at the end of it. Therefore,

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

paragraph (e) needs to be repealed and substituted with the new paragraph (e) for the purposes of adding ‘beer’ to that list.

The permission to use the enzyme as a processing aid in the manufacture and/or processing of beer would be subject to the existing condition that the maximum permitted level or amount of this enzyme that may be present in the food must be consistent with GMP.

If approved, the draft variation would permit the proposed use of the enzyme, α-glucosidase (EC 3.2.1.20) sourced from *Trichoderma reesei* containing the α-glucosidase gene from *Aspergillus niger*, as a processing aid in the manufacture and/or processing of beer in accordance with the Code.