25 September 2020
[135-20]

Approval report – Application A1194

Glucoamylase from GM *Trichoderma reesei* as a PA (enzyme)

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Danisco New Zealand Ltd to permit a glucoamylase enzyme preparation from a genetically modified (GM) *Trichoderma reesei* for use as a processing aid in brewing, the manufacture of bakery products, the production of potable alcohol and starch processing.

On 12 June, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received three submissions.

FSANZ approved the draft variation on 16 September 2020. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 24 September 2020.

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 documents

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

Supporting Document 1 Risk and technical assessment report

Executive summary

Danisco New Zealand Ltd submitted an application to Food Standards Australia New Zealand (FSANZ) to permit a new microbial source of the already permitted enzyme processing aid, glucoamylase (EC 3.2.1.3) for use as a processing aid in brewing, the manufacture of bakery products, the production of potable alcohol and starch processing. The enzyme is derived from a genetically modified (GM) strain of *Trichoderma reesei* (*T. reesei*) (i.e. the production organism). This production organism contains additional functional copies of the glucoamylase gene, also from *T. reesei.*

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

After undertaking a risk assessment, FSANZ concluded that there are no public health and safety concerns associated with the proposed use of this new source of glucoamylase. The *T. reesei* production strain is neither pathogenic nor toxigenic, and has a history of safe use for the production of processing aid enzymes. In the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) of 'not specified' is appropriate for this enzyme. A dietary exposure assessment was therefore not required.

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 identity and purity specifications set out in Schedule 3 of the Code.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation on 12 June 2020. Three submissions were received, all of which FSANZ has had regard to.

FSANZ has decided to approve the draft variation proposed following assessment without change. The draft variation amends the Code to permit glucoamylase derived from a GM strain of *T. reesei* containing the glucoamylase gene from *T. reesei* as a processing aid for use in brewing, the manufacture of bakery products, the production of potable alcohol and starch processing. 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 Danisco New Zealand 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 seeking permission for an already permitted enzyme, glucoamylase (EC 3.2.1.3) from a new source, as a processing aid. The enzyme is produced from a genetically modified (GM) strain of *T. reesei,* modified to contain additional functional copies of the glucoamylase gene from *T. reesei* itself. Increasing the functional gene copy number increases the amount of enzyme produced by the production organism. This improves production efficiency for enzyme manufacturers that operate on a commercial scale.

If approved, this particular glucoamylase will be used as a processing aid in brewing, the manufacture of bakery products, the production of potable alcohol and starch processing. Glucoamylase from this particular source 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 standards

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. 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 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). An enzyme of microbial origin listed in the table to subsection S18—4(5) is permitted for use as a processing aid to perform any technological purpose if the enzyme is derived from the corresponding source specified in the table. 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 in relation to:
  - if a food is specified—that food; or
  - if no food is specified—any food; and
- present in the food at a level not greater than the maximum permitted level specified in the table.

There are currently permissions for glucoamylase (EC 3.2.1.3) from other source organisms within the table to subsection S18—4(5), to be used in the manufacture of all foods. Glucoamylase is also permitted in S18—9(3) to hydrolyse starch in the manufacture of syrups, beverages, cereal-based products, fruit products and vegetable products. However, glucoamylase from this particular microbial source that is the subject of this application, is not currently permitted.

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

Identity and purity requirements

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

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 20 (2017)), and the United States Pharmacopeial Convention (2018) Food chemicals codex (11th edition). These include specifications for enzyme preparations used in food processing.

Labelling requirements

Paragraph 1.1.1—10(8) provides that a 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. Paragraph 1.2.3—4(2)(c) 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, or have as ingredients, 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 to foods for retail sale and to foods sold to a caterer under subsections 1.2.1—8(1) and 1.2.1—9(3), and section 1.2.1—15 respectively.

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). Standards set by Codex provide a benchmark against which national food measures and regulations can be assessed. In certain situations however, FSANZ might receive an application to amend the Code for permission to use a new processing aid or food additive before an international standard exists.

There are also situations where domestic food standards will necessarily vary from international standards.

This could include circumstances where:

- new data for the domestic situation that was not available at the time the international standard was set becomes available for assessment
- the domestic environment (climate and growing conditions) results in different levels of risk from contaminants, natural toxicants or nutrient levels in foods
- domestic consumption patterns result in different dietary exposures
- particular manufacturing and production processes have been adapted to meet specific domestic requirements.

1.3.2 European Union regulations

Regulation (EC) No 1332/2008 (which became fully effective from January 2010) (the Regulation) harmonises for the first time the rules for food enzymes in the European Union (EU). Previous to the Regulation, food enzymes used as processing aids were not regulated in the EU.

According to the Regulation, all food enzymes currently on the EU market, as well as new food enzymes, are subject to a safety evaluation by the European Food Safety Authority (EFSA) and subsequently approved by the European Commission by means of a Union list. Currently, there is no Union list of authorised food enzymes. Until the establishment of such a list (anticipated for release in 2020- 2021), EU countries' legislation applies.

This glucoamylase enzyme preparation, which is the subject of the current application, is permitted for use in France, Denmark, as well as the USA where the enzyme has been determined as Generally Recognized as Safe (GRAS).

Within the EU, only France and Denmark require safety evaluations for enzymes used as processing aids before they can be used in food production. Prior authorisation for use in these two countries is taken into consideration as part of the evaluation for inclusion on the Union list, and may streamline the evaluation process.

In France, applications to permit the use of food enzymes must be prepared as per EFSA guidance and submitted to the French Agency for Food, Environmental and Occupational

Health and Safety (ANSES) for a safety evaluation. If authorised for use, the enzyme is included in the French positive list for processing aids, including food enzymes.

In Denmark, applications submitted as per the same European guidance are assessed by the Danish Veterinary and Food Administration. Approved food enzymes are not published on a positive list, rather, the approval for each individual food enzyme is granted directly to the applicant.

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 warranted the variation of a food regulatory measure.

1.5 Procedure for assessment

The application is being assessed under the General Procedure.

1.6 Decision

As reported in the Risk and Technical Assessment Report (SD1), FSANZ conducted a food technology assessment and concluded that glucoamylase from this particular source meets its stated purpose, which is to aid in brewing, the manufacture of bakery products, the production of potable alcohol and starch processing. Also, from its risk assessment, FSANZ concluded that there are no safety concerns relating to this particular glucoamylase. Bioinformatic analysis indicated that the enzyme has no significant homology with any known toxins or food allergens, and is unlikely to pose an allergenicity or toxicity concern. Based on the reviewed toxicological data FSANZ concluded that, in the absence of any identifiable hazard, an acceptable daily intake (ADI) of ‘not specified’ is appropriate for this enzyme. A dietary exposure assessment was therefore not required.

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

The draft variation as proposed following assessment was approved without change after the consideration of submissions. The approved draft variation is at Attachment A. The approved variation takes effect on gazettal.

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.

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions on a proposed draft variation on 12 June 2020. Three submissions were received, two from government agencies and one from an industry body. All supported the application (Table 1).

Table 1: Summary of submissions

Submitter	Comments	FSANZ response
Victorian Department of Health and Human Services and the Victorian Department of Jobs, Precincts and Regions	Supportive	Noted
New Zealand Food Safety	Supportive	Noted
New Zealand Food & Grocery Council	Supportive, but noted that in the future, the assessment and approval process for enzymes and other processing aids might be streamlined so as to reduce the need for repetitive assessment of very similar products.	Review and reform of the approval process for enzymes and other processing aids is outside the scope of A1194. FSANZ's approval processes for enzyme processing aids are regulated by requirements set out in the FSANZ Act. The Australian Government is undertaking a review of the FSANZ Act. Further information regarding the review and updates thereof are accessible at: https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/Modernisation-of-the-food-regulation-system

2.2 Risk assessment

After conducting a risk assessment, FSANZ concluded that the use of glucoamylase from this particular GM *T. reesei* under the proposed conditions raises no public health and safety concerns.

The gene for glucoamylase was obtained by polymerase chain reaction amplification of the endogenous glucoamylase gene from *T. reesei,* an anamorphic fungus commonly found in soil. Molecular characterisation of the production strain confirmed the presence of the inserted DNA and showed that the introduced DNA is stably inherited. The *T. reesei* production organism is neither toxigenic nor pathogenic and is absent in the final enzyme preparation. Further, *T. reesei* has a long history of safe use as the production organism for a number of enzyme processing aids that are already permitted in the Code.

Glucoamylase from this particular GM *T. reesei* has 100% homology to that assessed

previously by JECFA in 2013. JECFA identified a NOAEL (No Observed Adverse Effect level) of 166.4 mg/kg bw/day (body weight per day) total organic solids (TOS), the highest dose tested. The glucoamylase preparation was not genotoxic in a bacterial reverse mutation assay or a chromosomal aberration test. A closely related trehalase enzyme from host strain M1-1.1 was not genotoxic *in vitro* and caused no adverse effects in a 13-week repeat dose toxicity study in rats. The NOAEL was 1000 mg/kg bw/day TOS, the highest dose tested. The applicant's estimated theoretical maximal daily intake (TMDI) based on the proposed use pattern is 3.18 mg/kg bw/day TOS. A comparison of this value with the NOAEL of the closely-related trehalase (1000 mg/kg/day TOS) enzyme indicates that the Margin of Exposure between the NOAEL and TMDI is more than 300.

Bioinformatic analysis indicated that the enzyme has no significant homology with any known toxins or food allergens, and is unlikely to pose an allergenicity or toxicity concern. Based on the reviewed toxicological data it is concluded that, in the absence of any identifiable hazard, an ADI of 'not specified' is appropriate for this enzyme. A dietary exposure assessment was therefore not required.

The applicant has indicated that glucose from wheat may be used on occasion in the fermentation process, however it is highly unlikely that any wheat protein would be present in the final product.

The food technology assessment concluded that glucoamylase, when used at GMP levels, is technologically justified and effective in achieving its stated purpose. It performs its technological purpose during manufacture of the specified foods, and is therefore appropriately categorised as a processing aid. Glucoamylase meets international identity and purity specifications set out in Schedule 3 of the Code.

2.3 Risk management

From its risk assessment, FSANZ concluded that there are no safety concerns relating to glucoamylase from this particular source as a food processing aid in brewing, the manufacture of bakery products, the production of potable alcohol and starch processing. As processing aids require permissions in the Code, the main risk management option available to FSANZ is to approve or reject the request to amend the Code and, if approved, to impose any conditions that may be appropriate. Other risk management issues for this application are related to enzyme nomenclature and labelling, which are discussed below. The regulatory options analysed in section 2.5.1.1 of this report take account of the safety of the enzyme.

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

2.3.1 Regulatory approval for enzymes

From its food technology assessment, FSANZ has concluded that the glucoamylase from this particular source meets its stated purpose as a processing aid in brewing, the manufacture of bakery products, the production of potable alcohol and starch processing.

From its risk assessment, FSANZ has further concluded that in the absence of any identifiable hazard, an ADI of 'not specified' is appropriate for the enzyme. FSANZ also concluded that the enzyme itself, is unlikely to pose an allergenicity or toxicity concern. Wheat glucose syrup may be used on occasion in the fermentation process, however it is highly unlikely that any wheat protein would be present in the final product.

Therefore, FSANZ prepared a 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 will also provide the permission for its potential presence in the food for sale as a food produced using gene technology. The enzyme is a food produced using gene technology for Code purposes as it is derived from 'an organism that has been modified using gene technology' (see subsection 1.1.2—2(3) of the Code).

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 "glucoamylase" for the enzyme with an EC number of EC 3.2.1.3 (IUBMB 2018).

Glucoamylase is already listed in the tables to subsections S18—4(5) and S18—9(3) of the Code and, if approved, will be listed in the table to subsection in S18—9(3).

The nomenclature of the host and gene donor microorganism, *T. reesei,* was confirmed as being appropriate as listed in the application. The host organism, *T. reesei* is a commonly listed microorganism within Schedule 18 of the Code.

2.3.3 Labelling requirements

In preparing a draft variation to permit the use of the enzyme as a processing aid, the generic exemption from listing processing aids in the statement of ingredients will apply to foods containing this processing aid. However, Standard 1.2.3 declaration requirements will nevertheless apply to wheat as a component of the enzyme, which may be carried over into the enzyme preparation (see section 2.2.3.2 of this report).

2.3.3.1 Labelling requirements for food produced using gene technology

The requirements to label food as 'genetically modified' differ depending on whether the GM food is an ingredient of the food for sale or not, as follows.

For example: if a food is for retail sale or sold to a caterer, and contains the enzyme glucoamylase sourced from the GM strain of *T. reesei* (for example, the enzyme is used in the manufacture of bread), that food will be required to be labelled 'genetically modified' in conjunction with the name of the GM food ingredient, if novel DNA or novel protein from the GM strain of *T. reesei* remains present in that food for sale (see paragraph 1.5.2—4(1)(b)).

However, FSANZ notes if the bread made using the enzyme is not a food for sale itself (for example, an ingredient in a mixed food such as a crumb coating on frozen fish fillets), the enzyme will not be an ingredient in the food for sale. Therefore, the requirement to label glucoamylase as 'genetically modified' will not apply because the labelling requirements only apply to food that consists of, or has as an ingredient, a GM food (subsection 1.5.2—4(1)).

FSANZ notes it is highly unlikely that novel DNA or novel protein will be present in brewed products, such as beer or brewed soft drinks, because very low levels of glucoamylase are likely to be present in the final product. Also in the case of potable alcohol manufactured using a distillation process, the 'genetically modified' statement will not apply because it will not contain novel DNA or novel protein.

2.3.3.2 Declaration of certain substances

Section 2.2.2 of SD1 has identified the enzyme preparation may contain wheat protein.

When wheat 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 declaration must be displayed in connection with the display of the food or provided to the purchaser on request (see paragraph 1.2.1—9(7)(b)).

FSANZ notes glucoamylase from this particular source will be used in the manufacture of bakery products. Bakery and other cereal-based products that contain wheat as an ingredient will already require a mandatory wheat declaration. However, a wheat declaration will be required if wheat protein is present from the glucoamylase enzyme when it is used in the manufacture of wheat-free bakery and other cereal-based products.

Another intended use of glucoamlyase from this particular source is in starch processing to produce glucose syrups. These glucose syrups may be processed further to produce ingredients such as dextrose, or organic acids. It is highly unlikely that wheat protein from the enzyme will remain in these ingredients after processing, however its presence in a food for sale containing these ingredients will trigger the requirement for a wheat declaration. In the case of glucose syrups made from wheat starch, the Code exempts the requirement to declare wheat if certain conditions are met (see sub-subparagraph 1.2.3—4(1)(b)(i)(B)). This exemption is based on a previous assessment (FSANZ 2016) in which residual protein levels were considered to be within limits safe for consumption by the majority of wheat allergic individuals.

Glucoamylase will also be used in brewing and the production of potable alcohol. The Code exempts alcohol distilled from wheat from the requirement to declare wheat (see sub-subparagraph 1.2.3—4(1)(b)(i)(C)). However, the requirement to declare wheat will apply if wheat protein is present in other brewed products such as brewed soft drinks. For potable alcohol that has undergone a distillation process, wheat protein will not be present.

2.3.4 Risk management conclusion

The risk management conclusion is to permit the enzyme, glucoamylase (EC 3.2.1.3) sourced from *T. reesei* containing the glucoamylase gene from *T. reesei*, for use as a food processing aid. If approved, the permission will be listed in the table to subsection S18—9(3) of the Code, which includes enzymes permitted for a specific technological purpose. The technological purpose of this enzyme is use as a processing aid in brewing, the manufacture of bakery products, the production of potable alcohol and starch processing. The maximum level at which the enzyme may be present in the food is an amount consistent with GMP. Labelling requirements exist to inform wheat-allergic individuals about the presence of wheat in food for sale. The express permission for the enzyme to be used as a processing aid in Schedule 18 of the Code will also provide the permission for the enzyme's potential presence in the food for sale as a food produced using gene technology.

2.4 Risk communication

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 were called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options.

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

2.5 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:

2.5.1 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 the use of new processing aids (OBPR correspondence dated 24 November 2010, reference number 12065). This standing exemption was provided as permitting new processing aids is machinery in nature and the use of the new processing aid is voluntary once the application has been successfully approved. This standing exemption relates to the introduction of a processing aid to the food supply that has been determined to be safe.

FSANZ, however, gave consideration to the costs and benefits that would arise from this 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 (see paragraph 29(2)(a) of the FSANZ Act).

The purpose of this consideration was to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo (i.e. rejecting the application). This analysis considered either approving or rejecting the application. A consideration of costs and benefits was included in the call for submissions (CFS) report based on the information and data held at that time. No further information was received during the consultation process that changed the findings from the analysis of costs and benefits in the CFS.

The consideration of the costs and benefits was not intended to be an exhaustive, quantitative economic analysis of the measure. In fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment sought to highlight the likely positives and negatives of moving away from the status quo by permitting the use of the enzyme as a processing aid in brewing, the manufacture of bakery products, the production of potable alcohol and starch processing.

FSANZ's assessment was that the direct and indirect benefits from permitting the use of this enzyme as a processing aid for the proposed technological purposes, would most likely outweigh the associated costs. Industry would use the enzyme where they believe a net benefit exists for them. Industry may pass some of the possible cost savings from using the enzyme onto consumers. Consumers may also benefit from better and/or more consistent quality of certain in brewed and baked products, and in potable alcohol and starch processing. There may be a small, but likely inconsequential cost to government from adding the enzyme to the current range of processing aids that are monitored for compliance.

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 this application.

2.5.1.3 Any relevant New Zealand standards

Standards in the Code that apply or may apply to processing aids, e.g. 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 undertook a risk assessment (SD1) and concluded there were no public health and safety concerns associated with the use of this enzyme.

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

The labelling considerations for using the enzyme as a processing aid are discussed in section 2.3.3 of this report. FSANZ considers that those labelling requirements ensure that this objective is satisfied.

2.5.2.3 The prevention of misleading or deceptive conduct

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

2.5.3 Subsection 18(2) considerations

FSANZ 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. FSANZ had regard to a dossier of scientific studies submitted by the applicant as part of their application. FSANZ also had regard to technical information from other sources, including scientific literature, 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. However, it meets general specifications for enzymes set out in the FAO JECFA Monographs 20 and the Food Chemicals Codex specifications for enzymes.

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

The enzyme is currently used in France, Denmark and the USA, therefore, the approval for use of the enzyme would bring Australia and New Zealand into line with those countries. In this way, Australia and New Zealand will remain competitive with the international market. This will also help foster continued innovation and improvements in food manufacturing techniques and processes.

The conclusion of the risk assessment was there are no public health and safety issues associated with the production microorganism, *T.* reesei containing additional functional copies of the glucoamylase gene, also from *T. reesei*; or with using glucoamylase from this particular source as a food processing aid in brewing, the manufacture of bakery products, the production of potable alcohol and starch processing. It is therefore appropriate that Australian and New Zealand food industries are given the opportunity to benefit from the use of this enzyme for these purposes as an alternative to those currently permitted

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 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 determined that permitting this enzyme is consistent with these specific order policy principles for 'Technological Function'.

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

6 References

FAO/WHO (2017) General specifications and considerations for enzyme preparations used in food processing. Accessed 6 August 2020

IUBMB (2018) EC 3.2.1.3. Accessed 6 August 2020

USP (2018) Food Chemicals Codex 11th Edition, United States Pharmacopeial Convention, Rockville, MD. Accessed 6 August 2020

Attachments

A. Approved draft variation to the *Australia New Zealand Food Standards Code*
B. Explanatory Statement

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

Food Standards (Application A1194 – Glucoamylase from GM Trichoderma reesei as a Processing Aid (Enzyme)) Variation

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

Dated [To be completed by the Delegate]

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

Note:

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

1 Name

This instrument is the *Food Standards (Application A1194 – Glucoamylase from GM 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 into the table to subsection S18—9(3), in alphabetical order

Glucoamylase (EC 3.2.1.3) sourced from *Trichoderma reesei* containing the glucoamylase gene from *Trichoderma reesei*	For use in: (a) brewing; (b) the manufacture of bakery products; (c) the production of potable alcohol; and (d) starch processing.	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 A1194 which seeks permission to use a new microbial source of the already permitted enzyme processing aid, glucoamylase (EC 3.2.1.3) for use in brewing, the manufacture of bakery products, the production of potable alcohol and starch processing. The enzyme is derived from a genetically modified (GM) strain of *Trichoderma reesei* (*T. reesei)* modified to contain additional functional copies of the glucoamylase gene from *T. reesei* itself. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation.

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 amending the table to subsection S18—9(3) of the Code to permit the use of the enzyme, glucoamylase (EC 3.2.1.3) sourced from *T. reesei* modified to contain additional functional copies of the glucoamylase gene from *T. reesei* itself, as a processing aid in brewing, the manufacture of bakery products, the production of potable alcohol and starch processing.

3. Documents incorporated by reference

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

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of application A1194 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. Submissions were called for on 12 June 2020 for a six-week consultation period.

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for permitting the use of new processing aids (OBPR correspondence dated 24 November 2010, reference number 12065). This standing exemption was provided as permitting new processing aids is machinery in nature and the use of the new processing aid is voluntary once the application has been successfully approved. This standing exemption relates to the introduction of a

processing aid to the food supply that has been determined to be safe.

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

Item [1] of the variation amends Schedule 18 of the Code by inserting a new entry, in alphabetical order, into the table to subsection S18—9(3) of the Code.

The new entry consists of the enzyme 'glucoamylase (EC 3.2.1.3) sourced from *Trichoderma reesei* containing the glucoamylase gene from *Trichoderma reesei*' for use as a processing aid in food for specific technological purposes.

The technological purposes for this enzyme are 'For use in brewing, the manufacture of bakery products, the production of potable alcohol and starch processing'.

The 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.

The variation refers to 'glucoamylase' which is the accepted name used by the International Union of Biochemistry and Molecular Biology (IUBMB) for the enzyme with EC number 3.2.1.3 (IUBMB 2017).