22 June 2020
[127-20]

Approval report – Application A1184

Glucoamylase from GM *Aspergillus niger* (donor *Trametes cingulata*) as a processing aid (enzyme)

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Novozymes Australia Pty Ltd to permit the use of glucoamylase from a genetically modified strain of *Aspergillus niger* containing the glucoamylase gene from *Trametes cingulata* as a processing aid in starch processing and the production of potable alcohol.

On 11 February 2020, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received three submissions.

FSANZ approved the draft variation on 17 June 2020. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 22 June 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 document

The following document[1] which informed the assessment of this application is available on the FSANZ website:

SD1 Risk and Technical Assessment Report (revised at approval to clarify composition of fermentation media)

[1] https://www.foodstandards.gov.au/code/applications/Pages/A1184.aspx

Executive summary

Novozymes Australia Pty Ltd submitted an application to Food Standards Australia New Zealand (FSANZ) to use the enzyme glucoamylase (EC 3.2.1.3), derived from a genetically modified (GM) strain of *Aspergillus niger* (*A. niger*) containing the glucoamylase gene from *Trametes cingulata (T. cingulata)*, as a processing aid in starch processing and the production of potable alcohol.

Glucoamylase breaks down starch polysaccharides to release glucose and other fermentable sugars. The benefits of using this enzyme during starch processing and alcohol production, as claimed by the applicant, is that it leads to an increased glucose yield and is able to perform its technological function at high operating temperatures and a low operating pH.

Enzymes used to produce and manufacture food are considered processing aids and are regulated by Standards 1.1.1, 1.1.2, 1.3.3 and 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 specific technological purposes.

The glucoamylase in this application is derived from a GM strain of *A. niger* expressing a glucoamylase gene from *Trametes cingulata* (*T. cingulata*). *A. niger* is neither toxigenic or pathogenic and has a long history of safe use as a source of enzyme processing aids, including several already permitted in the Code. Analysis of the production strain confirmed the presence and stability of the inserted DNA. Glucoamylase from GM *A. niger* was not genotoxic in vitro, and did not cause adverse effects in a short-term toxicity study in rats.

Bioinformatic analyses 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. Soy may be used as an ingredient in the fermentation medium as may a glucose syrup prepared using wheat, however due to washing and filtration processes they are not expected to be present in the final enzyme preparation.

After undertaking a risk assessment, FSANZ concludes that there are no public health and safety concerns associated with the proposed use of glucoamylase. 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 stated technological purposes of this enzyme are clearly articulated in the application. The evidence presented to support the proposed use of the enzyme provides adequate assurance that the enzyme, in the recommended form and amounts is technologically justified and has been demonstrated to be effective in achieving its stated purpose. The enzyme meets international purity specifications and has been assessed and given authorisation for use in France and Denmark.

A total of three submissions were received on FSANZ’s assessment report, all of which were supportive of the application.

The FSANZ Board has approved a draft variation to the Code, which permits the enzyme glucoamylase sourced from a GM strain of *A. niger,* containing the glucoamylase gene from *T. cingulata*, as a processing aid for use in starch processing and the production of potable alcohol, subject to the condition that the amount of enzyme used must be consistent with good manufacturing practice (GMP).

1 Introduction

1.1 The applicant

Novozymes Australia Pty Ltd is a biotechnology company that manufactures industrial and food enzymes.

1.2 The application

The application was received on 18 July 2019.

The application sought to change the Australia New Zealand Food Standards Code (the Code) to permit use of glucoamylase (EC 3.2.1.3), from a genetically modified (GM) strain of *Aspergillus niger (A. niger)* containing the glucoamylase gene from *Trametes cingulata (T. cingulata)* (the enzyme) as a processing aid in starch processing and the production of potable alcohol.

Glucoamylase hydrolyses 1,4-alpha-D-glucosidic linkages in starch polysaccharides successively from the non-reducing ends to release beta-D-glucose and other fermentable sugars. Most forms of the enzymes can hydrolyse 1,6-alpha-D-glucosidic linkages when the next bond in the polysaccharide sequence is 1,4.

In starch processing, glucoamylase degrades polysaccharides into glucose, to produce syrups. In the production of alcohol, glucoamylase is used to degrade gelatinised starch and dextrins into glucose and other fermentable sugars. The use of this enzyme leads to a higher glucose yield.

The enzyme preparation will be used as a processing aid where the enzyme is not present or or else present in negligible amounts, with no technological function in the final food.

The enzyme will provide food processors with an alternative preparation in starch processing and alcohol production, which has the benefit of being able to be used at high operating temperatures and low operating pH.

The enzyme is produced by submerged fed-batch pure culture fermentation, which involves the growth of the microorganism and production of the enzyme. Subsequent steps involve the separation of the enzyme from the microbial biomass, purification, concentration and formulation of the enzyme preparation.

The enzyme has been assessed for safety and given authorisation for use in France and Denmark. Evidence of these authorisations was provided with the application.

1.3 The current standard

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

Permitted use

Enzymes used to process and manufacture food are considered processing aids. Paragraph 1.1.1—10(6)(c) provides that a food for sale must not have, as an ingredient or a component, a substance that is used as a processing aid unless expressly permitted.

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), depending on whether a technological purpose has been specified. An enzyme of microbial origin listed in the table to subsection S18—4(5) is permitted for use as a processing aid to perform *any* technological purpose if the enzyme is derived from the corresponding source specified in the table. 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.

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).

Identity and purity requirements

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

Subsection S3—2(1) 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

Subsection 1.1.1—10(8) 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. 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 only to foods for retail sale and to foods sold to a caterer under subsection 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). Codex does not establish standards for processing aids or for enzymes. Individual countries regulate the use of enzymes differently to the Code. However, there are internationally recognised specifications for enzymes, as set out above. These enzyme specifications are established by JECFA (FAO/WHO 2017) and the Food Chemicals Codex (Food Chemicals Codex 2018).

1.3.2 EU 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 at EU level.

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 an EU list. Currently, there is no EU list of authorised food enzymes. Until the establishment of such a list (anticipated for release in 2020- 2021), EU countries' legislation applies.

Within the EU, France and Denmark have required safety evaluations for enzymes used as processing aids before they could 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[2] 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 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 and
- it related to a matter that might be developed as a food regulatory measure.

[2] Report of the Scientific Committee on Food, 27th series, EUR 14181 – Guidelines for the presentation of data on food enzymes (1992)

1.5 Procedure for assessment

The application was assessed under the General Procedure.

1.6 Decision

The food technology component of the Risk and Technical Assessment Report concluded that the enzyme meets its stated purpose, which is to aid in starch processing and the production of potable alcohol. The risk assessment concluded that, in the absence of any identifiable hazard, an ADI of 'not specified' is appropriate for the enzyme. Bioinformatic analyses 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. 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 11 February 2020. Three submissions were received, two from government agencies and one from industry. All supported the application (Table 1).

Table 1: Summary of issues raised by submissions

Raised by	Issue	FSANZ response
Victorian Department of Health and Human Services and the Victorian Department of Jobs, Precincts and Regions	Supportive.	Noted. No response required.
New Zealand Food Safety, Ministry for Primary Industries	Supportive.	Noted. No response required.

Raised by	Issue	FSANZ response
New Zealand Food and Grocery Council (NZFGC)	Supportive. NZFGC notes the draft variation to permit the use of this enzyme will be inserted into Schedule 18, specifically, the table to S18—9(3). NZFGC also expected an amendment to S18—4: Permitted Enzymes, along the lines of *Aspergillus niger* containing the gene for glucoamylase isolated from *Trametes cingulata.*	An enzyme of microbial origin permitted to be used as a processing aid can be listed in either the table to subsection S18—4(5) or the table to subsection S18—9(3) of the Code, depending on whether the enzyme performs *any* technological purpose or *specific* technological purposes. Permitted enzymes of microbial origin are listed in the table to subsection S18—4(5). Enzymes listed in this table may perform *any* technological purpose (see section 1.3.3—6). Permitted enzymes (irrespective of origin) listed in the table to subsection S18—9(3) only perform *specific* technological purposes (see section 1.3.3—11). For A1184 – the enzyme performs specific technological purposes i.e. 'For use in starch processing and the production of potable alcohol'. This was the only technological purpose that was sought by the applicant. The safety assessment was also conducted on that basis. Therefore, the permission for the glucoamylase must be listed in the table to subsection S18—9(3), not in the table to subsection S18—4(5).

2.2 Risk assessment

FSANZ's risk assessment concluded that there are no public health and safety concerns associated with the proposed use of the enzyme as a food processing aid.

The host organism *A. niger,* has a long history of safe use as a source of enzyme processing aids, including several already permitted in the Code and is neither toxigenic or pathogenic. Molecular characterisation of the production strain confirmed that the gene insert was as expected and would encode the glucoamylase as specified. The insert was also shown to be genetically stable and heritable.

The enzyme showed no evidence of genotoxicity in a bacterial reverse mutation assay or a micronucleus assay in human lymphocytes. The enzyme did not cause any adverse effects in a sub-chronic toxicity study in rats. The no observed adverse effect level (NOAEL) was the highest dose tested, 10 mL/kg bw/day or 1135 mg/kg bw/day on a total organic solids (TOS) basis. The applicant's estimated theoretical maximal daily intake (TMDI) of glucoamylase is 0.31 mg kg bw/day TOS, resulting in a Margin of Exposure (MoE) of more than 3000 between the NOAEL and TMDI.

Bioinformatic analyses did not identify significant homology with any known toxins or food allergens, and the enzyme is unlikely to pose an allergenicity or toxicity concern. Soy may be used as an ingredient in the fermentation medium as may a glucose syrup prepared using wheat, however due to washing and filtration processes, they are not expected to be present in the final product.

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

For further details on the risk assessment, refer to the Risk and Technical Assessment Report (SD1).

2.3 Risk management

The Risk and Technical Assessment Report concluded that there are no safety concerns from using the enzyme for its stated purpose, in the form and quantities consistent with GMP. 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 considerations for this application are related to enzyme nomenclature and labelling, which are discussed below. The regulatory options analysed in section 2.5.1.1 take account of the safety of the enzyme.

The express permission in section 1.6 for the enzyme's use as a processing aid will also provide the permission for the potential presence of the enzyme 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 section 1.3 for further details regarding permissions for use for foods produced using gene technology.

2.3.1 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 'glucan 1,4-α-glucosidase' for the enzyme with an EC number of EC 3.2.1.3 (IUBMB 2018). 'Other' names for this enzyme include 'glucoamylase', which is the name used throughout the application, this document, and Supporting Document 1. 'Glucoamylase' (with the number EC 3.2.1.3) is the name that is used in the draft variation to the Code for this enzyme.

The nomenclature of the gene donor and production microorganisms was checked and confirmed as being appropriate as listed in the application (see section 3.1 of SD1). The source organism *A. niger* is already permitted as a production microorganism for numerous enzymes within Schedule 18 of the Code.

2.3.2 Labelling considerations

The risk assessment concluded that the use of the enzyme poses no concern to public health and safety, and that it performs its specific technological purposes as a processing aid. Therefore, the generic exemption from declaration of processing aids in the statement of ingredients will apply to foods manufactured using the enzyme as a processing aid. No new labelling requirements are proposed.

2.3.2.1 Labelling requirements for food produced using gene technology

The requirements for labelling as 'genetically modified' differ depending on whether the GM food remains present as 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 as an ingredient, that food will be required to be labelled with 'genetically modified' in conjunction with the name of the processing aid, if novel DNA or novel protein from the GM strain of *A. niger* (that is the source microorganism, not the enzyme) remains in that food for sale.

FSANZ however, notes that the enzyme may be used to produce foods that are not for retail sale themselves (or for sale to a caterer) but are used as ingredients in food for retail sale/sale to a caterer. For example, the enzyme may be used in starch processing to produce syrups. If the syrup is not a food for sale itself but is used as an ingredient in a food for retail sale or in food sold to a caterer, the enzyme will not be an ingredient in the food for sale containing the syrup. The requirement to label with 'genetically modified' will not apply for that food for sale because the labelling requirements only apply to food that consists of, or has as an ingredient, a GM food (section 1.5.2—4(1) of the Code).

2.3.2.2 Declaration of certain substances

The risk and technical assessment (SD1) has identified that soy may be used as an ingredient in the fermentation medium for the production of the enzyme. A glucose syrup prepared using wheat may also be used in the fermentation medium. Neither soy nor wheat are expected to be present in the final product. If however, soy or wheat is present in a food for sale, including when present as a processing aid or an ingredient or component of a processing aid, these must be declared in accordance with section 1.2.3—4 of the Code.

Certain products are exempt from the requirement to declare wheat (subparagraph 1.2.3—4(1)(b)(i) of the Code). This includes glucose syrups made from wheat starch, if they have been subject to a refining process that has removed gluten protein content to the lowest level that is reasonably achievable, and they have a gluten protein content that does not exceed 20 mg/kg. Beer, spirits, and alcohol distilled from wheat are also exempt from the requirement to declare wheat (and any other cereals containing gluten).

Certain foods are exempt from the requirement to declare soy (see subparagraph 1.2.3—4(b)(iv) of the Code), but these exemptions do not apply to soy bean meal, which is the specific soy ingredient that may be used during the production of this enzyme.

2.3.3 Risk management conclusion

The risk management conclusion is to permit the enzyme, glucoamylase (EC 3.2.1.3), sourced from *A. niger* containing the glucoamylase gene from *T. cingulata,* for use as a food processing aid. The permission will be listed in the table to S18—9(3) of the Code, which lists enzymes permitted for specific technological purposes. The technological purposes for the enzyme are use in starch processing and the production of potable alcohol. The maximum level at which the enzyme may be present in the food is an amount consistent with GMP. Labelling requirements exist to inform allergic individuals of the presence of soy or 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 its 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 standards development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options.

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 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 processing aids (OBPR correspondence dated 24 November 2010, reference number 12065). This standing exemption was provided as permitting processing aids is machinery in nature and the use of the 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 outlined in this section is not intended to be an exhaustive, quantitative economic analysis of the measure and, 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 starch processing and the production of potable alcohol.

Costs and benefits of permitting the use of the enzyme as a processing aid

A. niger is the production organism for numerous enzyme processing aids, with more than 30 different enzymes already permitted in the Code. The enzyme in this application is glucoamylase sourced from a GM strain of *A. niger* (*A. niger* containing a glucoamylase gene from *T. cingulata*). This particular enzyme will provide manufacturers with an alternative enzyme preparation that, according to the applicant, performs its technological function at high operating temperatures and a low operating pH, and provides an increased glucose yield, thus giving manufacturers a wider choice of products to suit their specific food processing application.

Due to the voluntary nature of the permission, industry will only use the enzyme where they believe a net benefit exists. There are other glucoamylase preparations available to industry and it is of benefit to industry to have additional choices available to them, especially where the enzyme is more effective or cheaper.

The enzyme is already authorised for use in two countries (being Denmark and France). This may be a business opportunity for Australian and New Zealand industries, although there may also be competing imports from these countries into the domestic market.

Glucoamylase breaks down starch polysaccharides for the production of several products including syrups and distilled beverages. Using the enzyme may assist in expanding the range of these products available to consumers.

Where using the enzyme is more effective or cheaper for manufacturers, there may be benefits to the consumer where cost savings are passed on.

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 the enzyme as a processing aid is likely to 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 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 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 safety assessment (SD1) and concluded there were no public health and safety concerns associated with the use of the 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 2.3.2.

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 – the Risk and Technical Assessment Report. The applicant submitted a dossier of scientific studies as part of their application. Other technical information sourced by FSANZ, including scientific literature, was also used 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 JECFA Compendium of Food Additive Specifications and the Food Chemicals Codex specifications for enzymes.

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

The enzyme is already being used in countries overseas including France and Denmark. Therefore, the approval for use of the enzyme would bring Australia and New Zealand into line with jurisdictions overseas. 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 that there are no public health and safety concerns associated with the production microorganism or with using 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 using the enzyme as a processing aid for starch processing and the production of potable alcohol.

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 businesss.

- **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[3] 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'.

3 References

FAO/WHO (2017) General specifications and considerations for enzyme preparations used in food processing. http://www.fao.org/docrep/009/a0691e/A0691E03.htm
IUBMB (2017) EC 3.2.1.3. https://www.qmul.ac.uk/sbcs/iubmb/enzyme/EC3/2/1/3.html

The United States Pharmacopeia (2018) Food Chemicals Codex 11th Edition, United States Pharmacopeial Convention, Rockville, MD. http://publications.usp.org/

Attachments

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

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

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

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

Food Standards (Application A1184 – Glucoamylase from GM *Aspergillus niger* (donor *Trametes cingulata*)) 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 A1184 – Glucoamylase from GM* Aspergillus niger *(donor* Trametes cingulata*)) 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

Glucoamylase (EC 3.2.1.3) sourced from *Aspergillus niger* containing the glucoamylase gene from *Trametes cingulata*	For use in starch processing and the production of potable alcohol	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 A1184 which seeks permission to use the enzyme glucoamylase (EC 3.2.1.3) from a genetically modified (GM) strain of *Aspergillus niger* (*A. niger*) as a processing aid in starch processing and the production of potable alcohol. 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 *A. niger* containing the glucoamylase gene from *Trametes cingulata* (*T. cingulata*) as a processing aid in starch processing and the production of potable alcohol.

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 A1184 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 11 February 2020 for a six-week consultation period.

The Office of Best Practice Regulation (OBPR) granted the Authority a standing exemption from needing to develop a Regulatory Impact Statement for proposed variations of the Code to permit additional processing aids (OBPR correspondence dated 24 November 2010 - reference 12065). This standing exemption was provided as permitting additional processing aids is likely to have only a minor impact on business and individuals. It is a minor, deregulatory change that allows for the introduction of a food product to the food supply that has been determined to be safe. The use of the approved processing aid is also voluntary.

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 variation inserts 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 *Aspergillus niger* containing the glucoamylase gene from *Trametes cingulata',* for use as a processing aid in food for specific technological purposes.

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

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', although the International Union of Biochemistry and Molecular Biology (IUBMB) uses the accepted name of 'glucan 1,4-α-glucosidase', with 'glucoamylase' being listed as an alternative name for the enzyme with EC number 3.2.1.3 (IUBMB 2017).