

9 June 2020
[125–20]

Call for submissions – Application A1195

Alpha-amylase from GM *Trichoderma reesei* as a PA (enzyme)

FSANZ has assessed an application made by Danisco New Zealand Ltd to permit an alpha-amylase enzyme preparation from a genetically modified (GM) *Trichoderma reesei* for use as a processing aid in brewing and the production of potable alcohol. FSANZ 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 [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

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](#).

Submissions should be made in writing; be marked clearly with the word ‘Submission’ and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

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) 21 July 2020

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 submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

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Supporting document

The [following documents](#)¹ which informed the assessment of this Application are available on the FSANZ website:

SD1 Risk and technical assessment report

¹<https://www.foodstandards.gov.au/code/applications/Pages/A1195.aspx>

Executive summary

Danisco New Zealand Ltd submitted an application to Food Standards Australia New Zealand (FSANZ) for a new microbial source of the already permitted enzyme processing aid, alpha-amylase (EC 3.2.1.1) for use in brewing and the production of potable alcohol. The enzyme is derived from a genetically modified (GM) strain of *Trichoderma reesei* expressing the alpha-amylase gene from *Aspergillus kawachii*.

Enzymes used to produce and manufacture food are considered processing aids and are regulated by Standard 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 lists enzymes permitted for use for a specific technological purpose.

After undertaking a risk assessment, FSANZ concludes that the use of this new source of alpha-amylase under the proposed conditions is safe. 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. 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 purity specifications.

FSANZ proposes a draft variation to the Code to permit alpha-amylase derived from a GM strain of *T. reesei* containing the alpha-amylase gene from *A. kawachii* as a processing aid for use in brewing and the production of potable alcohol. 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, alpha-amylase (EC 3.2.1.1) from a new source, as a processing aid. The enzyme is produced from a genetically modified (GM) strain of *Trichoderma reesei* expressing the alpha-amylase gene from *Aspergillus kawachii*.

If approved, this particular alpha-amylase will be used as a processing aid in brewing and the production of potable alcohol. Alpha-amylase 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 alpha-amylase (EC 3.2.1.1) from both GM and a non-GM source organisms within the table to subsection S18—4(5), to be used in the manufacture of

all foods. However, alpha-amylase from this particular microbial source, 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 adopted to meet specific domestic requirements.

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.

The EFSA Panel on Food Contact Materials, Enzymes and Processing Aids completed a safety evaluation of Danisco's alpha-amylase in December 2018 (EFSA 2019). The Panel did not identify any safety issues with this α -amylase. This alpha-amylase preparation 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 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 EU 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 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.

2 Summary of the assessment

2.1 Risk assessment

FSANZ concluded that the use of alpha-amylase from GM *T. reesei* under the proposed conditions is safe. The gene for alpha-amylase was isolated from *A. kawachii*, a filamentous fungus commonly used for brewing the traditional Japanese distilled spirit shōchū.

The production organism *T. reesei* is neither toxigenic nor pathogenic and is absent in the final enzyme preparation proposed to be used as a food processing aid. 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. Molecular characterisation of the production strain confirmed the presence of the inserted DNA and showed that the introduced DNA is stably inherited.

Alpha-amylase from GM *T. reesei* was not genotoxic *in vitro*, and did not cause adverse effects in short-term toxicity studies in rats. The no observed adverse effect level (NOAEL) in a 90-day repeated dose oral toxicity study in rats was the highest dose tested, 229.6 mg/kg bw/day on a total organic solids (TOS) basis. The TOS will be removed from potable alcohol by the distillation process, but dietary exposure to the enzyme may arise from use in brewing processes. The applicant's estimated theoretical maximal daily intake (TMDI) based on the proposed use in brewing is 0.39 mg/kg bw/day TOS. A comparison of these values indicates that the Margin of Exposure between the NOAEL and TMDI is more than 500.

Bioinformatic analysis indicated that the enzyme shows no significant homology with any known toxins. However a degree of homology between the recombinant alpha-amylase and several respiratory allergens was found, including an alpha-amylase from *A. oryzae* which has been implicated in three case reports of food allergy, but not in other food challenge studies with sensitised individuals. Taking into account that respiratory allergens are usually not food allergens, the very low number of case reports of food allergy to alpha-amylase from *A. oryzae* compared with its widespread use in food, and the low levels expected to be present in final food products, the risk of food allergy from the proposed uses of alpha-amylase from *T. reesei* LOH4AkAaPaA is likely to be low.

Based on the reviewed toxicological data it is concluded that, in the absence of any identifiable hazard, an acceptable daily intake (ADI) 'not specified' is appropriate and a dietary exposure assessment was therefore not required.

The food technology assessment concluded that alpha-amylase, 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. Alpha-amylase needs to meet international purity specifications, or those set out in the Code to be sold in Australia and New Zealand.

2.2 Risk management

The risk assessment concluded that there are no safety concerns relating to Danisco's alpha-amylase when used as a processing aid in brewing and the production of potable alcohol. 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 2.4.1.1 take account of the safety of the enzyme.

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

2.2.1 Regulatory approval for enzymes

FSANZ has concluded that Danisco's alpha-amylase meets its stated purpose as a processing aid in brewing and the production of potable alcohol. The risk assessment concluded that the enzyme itself, is unlikely to pose an allergenicity or toxicity concern and further concluded that in the absence of any identifiable hazard, an ADI of 'not specified' is appropriate for the enzyme.

Wheat glucose syrup may be used on occasion in the fermentation process. If wheat protein is present in the final product, labelling requirements are in place to inform consumers who are sensitive to wheat.

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).

2.2.2 Enzyme and source microorganism nomenclature

FSANZ noted that the International Union of Biochemistry and Molecular Biology (IUBMB), the internationally recognised authority for enzyme nomenclature, uses the 'accepted' name 'α-amylase' for the enzyme with an EC number of EC 3.2.1.1 (IUBMB 2018). This is the name that is used in the draft variation to the Code. A variation of the accepted name i.e. 'alpha-amylase' has been used throughout the application, this document, and SD1.

The nomenclature of the gene donor and production microorganisms were checked and confirmed as being appropriate as listed in the application (see section 3.1 of SD1). The host organism, *T. reesei* is a commonly listed microorganism within Schedule 18 of the Code.

2.2.3 Labelling requirements

The risk assessment concluded the use of the enzyme poses no public health and safety concerns and that it performs its technological purpose as a processing aid. 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 requirements will nevertheless apply to wheat as a component of the enzyme preparation, which may be carried over into the enzyme preparation (see section 2.2.3.2).

2.2.3.1 Labelling requirements for food produced using gene technology

A food for retail sale or sold to a caterer that contains the enzyme alpha-amylase sourced from the GM strain of *T. reesei* would be required to be labelled 'genetically modified' in conjunction with the name of the GM food, if novel DNA or novel protein from the GM strain of *T. reesei* remains present in that food for sale (paragraph 1.5.2—4(1)(b)).

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

2.2.3.2 Declaration of certain substances

The risk assessment (section 2.1) has identified the enzyme preparation may contain wheat. FSANZ notes alpha-amylase will be used in brewing and the production of potable alcohol. The Code exempts beer, spirits, and alcohol distilled from wheat from the requirement to declare wheat (subparagraph 1.2.3—4(1)(b)(i)). However, the requirement to declare wheat would apply if wheat protein was present in other brewed products such as brewed soft drinks. For potable alcohol that has undergone a distillation process, wheat protein would not be present.

2.2.4 Risk management conclusion

The risk management conclusion is to permit the enzyme, alpha-amylase (EC 3.2.1.1) sourced from *T. reesei* containing the alpha-amylase gene from *A. kawachii*, for use as a food processing aid. 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 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 wheat-allergic individuals from 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.

2.3 Risk communication

2.3.1 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.

The draft variation will be considered for approval by the FSANZ Board taking into account 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 not any relevant international standards and amending the Code to permit a new microbial source of a currently permitted enzyme is unlikely to have a significant effect on international trade as Codex does not have regulations for enzymes used as processing aids. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

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

2.4.1 Section 29

2.4.1.1 Consideration of costs and benefits

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

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

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

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

*Costs and benefits of permitting the use of enzyme alpha-amylase derived from a GM strain of *A. kawachii* as a processing aid*

Industry

Alpha-amylase facilitates brewing and the production of potable alcohol. Due to the voluntary nature of the permission, industry will use the alpha-amylase enzyme where they believe a net benefit exists. There are other enzymes available to industry that perform similar functions and it is of benefit to industry to have additional choice available to them, especially where the enzyme is more effective or cheaper.

Danisco's enzyme preparation is permitted for use in France, Denmark and the USA. The international permissions for this enzyme 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.

Consumers

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 product quality.

Government

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

Conclusions from cost benefit considerations

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting the use of the enzyme alpha-amylase derived from a GM strain of *T. reesei* as a processing aid for the proposed technological purposes 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

Schedule 18 of the Code applies 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 has undertaken a safety assessment (SD1) and concluded there are no public health and safety concerns with permitting the use of alpha-amylase sourced from a GM *T. reesei*, as a processing aid in food for the proposed technological purposes.

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

The labelling requirements related to alpha-amylase sourced from a GM *T. reesei* are discussed in Section 2.2.3 above. FSANZ considers that those labelling requirements ensure that this objective is satisfied.

2.4.2.3 The prevention of misleading or deceptive conduct

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

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

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

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

There are no Codex Alimentarius Standards for enzymes. However, the US FDA did not respond with questions to a self-determination of this enzyme as GRAS in the US. The enzyme is also permitted in France and Denmark. It also meets international specifications for enzyme preparations, being 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**

As mentioned above, the use of this enzyme is already permitted in the United States, France and Denmark. Therefore, the approval for use of this enzyme would bring Australia and New Zealand into line with other jurisdictions where it is already authorised for use. In this way, Australia and New Zealand will remain competitive with other international markets. This will also help foster continued innovation and improvements in food manufacturing techniques and processes.

The conclusion of the risk assessment was there are no public health and safety issues associated with the production microorganism *T. reesei* containing the alpha-amylase gene from *A. kawachii* as a food processing aid in brewing and the production of potable alcohol. It is therefore appropriate that Australian and New Zealand food industries are given the opportunity to benefit from the use of this enzyme as an alternative to those currently permitted. Which enzyme preparation a food manufacturing company uses will depend on a number of economic and other factors.

- **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

Minerals² includes specific order policy principles for substances added to achieve a solely technological function, such as processing aids. These specific order policy principles state that permission should be granted where:

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the 'stated purpose')
- the addition of the substance to food is safe for human consumption
- the amounts added are consistent with achieving the technological function
- the substance is added in a quantity and a form which is consistent with delivering the stated purpose
- no nutrition, health or related claims are to be made in regard to the substance.

FSANZ has determined that permitting the use of alpha-amylase sourced from *T. reesei* containing the alpha-amylase gene from *A. kawachii* as a processing aid is consistent with the specific order principles for 'Technological Function'. All other requirements of the policy guidelines 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.

4 References

EFSA (2019) EFSA Panel on Food Contact Materials, Enzymes and Processing Aids. [Scientific Opinion on the safety evaluation of the food enzyme alpha-amylase from a genetically modified *Trichoderma reesei*](#). EFSA Journal 2019;17(1):5553, 16 pp. Accessed 5 May 2020

FAO/WHO (2017) [General specifications and considerations for enzyme preparations used in food processing](#). Accessed 17 September 2019

IUBMB (2018). EC 1.1.3.4 <https://www.qmul.ac.uk/sbcs/iubmb/enzyme/EC1/1/3/4.html>
Accessed 16 September 2019

The United States Pharmacopeia (2018) [Food Chemicals Codex 11th Edition](#), United States Pharmacopeial Convention, Rockville, MD. Accessed 17 September 2019

Attachments

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

² [Food regulation website](#)

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



Food Standards (Application A1195 – Alpha-amylase as a processing aid (enzyme)) Variation

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

Dated [To be completed by 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 A1195 – Alpha-amylase 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

α -Amylase (EC 3.2.1.1) sourced from <i>Trichoderma reesei</i> containing the α -Amylase gene from <i>Aspergillus kawachii</i>	For use in brewing and the production of potable alcohol.	GMP
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Attachment B – Draft Explanatory Statement

1. Authority

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

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

The Authority accepted application A1195 which seeks to permit the use of alpha-amylase (α -Amylase) enzyme preparation from a particular GM strain of *Trichoderma reesei* (*T. reesei*) as a processing aid for use in the manufacture and processing of specified foods. The Authority considered the application in accordance with Division 1 of Part 3 and has prepared a draft variation.

2. Purpose

The Authority has prepared a draft variation amending the table to section S18—9(3) of the Code to permit the use of α -Amylase (EC 3.2.1.1) sourced from *T. reesei* containing the α -Amylase gene from *Aspergillus kawachii* (*A. kawachii*), as a processing aid in brewing and the production of potable alcohol.

3. Documents incorporated by reference

The variation in this instrument does 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 A1195 will include one round of public consultation following an assessment and the preparation of a draft Standard and associated assessment summary. A call for submissions (including the draft variation) will occur for a four-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, α -Amylase (EC 3.2.1.1) sourced from *T. reesei* containing the α -Amylase gene from *A. kawachii*, as a processing aid in food for a specific technological purpose.

The technological purpose is 'For use in brewing 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.