22 June 2020
[127-20]

Approval report – Application A1185

Alpha-amylase from GM *Aspergillus niger* 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 alpha-amylase from a genetically modified strain of *Aspergillus niger* containing the alpha-amylase gene from *Rhizomucor pusillus* 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 and allergen considerations)

[1] https://www.foodstandards.gov.au/code/applications/Pages/A1185.aspx

Executive summary

Novozymes Australia Pty Ltd submitted an application to Food Standards Australia New Zealand (FSANZ) to use the enzyme alpha-amylase (EC 3.2.1.1), derived from a genetically modified (GM) strain of *Aspergillus niger* (*A. niger*) containing the alpha-amylase gene from *Rhizomucor pusillus* (*R. pusillus*), as a processing aid in starch processing and the production of potable alcohol.

Alpha-amylase breaks down the 1,4-alpha-D-glucosidic linkages in starch polysaccharides to form maltose, glucose and dextrins. The stated benefits of using this enzyme during starch processing is the efficient breakdown of the starch to produce dextrins, which are then further processed to manufacture syrups. For alcohol production, the benefits in relation to the production of dextrins are similar, and the use of this enzyme also results in higher ethanol yields, fast fermentation and efficient production of fermentable sugars.

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 safety assessment of the GM production strain concluded there were no public health and safety concerns. The host *A. niger* strain is neither pathogenic or toxigenic 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.

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 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, Denmark and Mexico.

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 alpha-amylase sourced from a GM strain of *A. niger,* containing the alpha-amylase gene from *R. pusillus*, 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 alpha-amylase (EC 3.2.1.1), from a genetically modified (GM) strain of *Aspergillus niger* (*A. niger*) containing the alpha-amylase gene from *Rhizomucor pusillus* (*R. pusillus*) (the enzyme), as a processing aid in starch processing and the production of potable alcohol.

Alpha-amylase hydrolyses the 1,4-alpha-D-glucosidic linkages in starch polysaccharides randomly, to release maltose, glucose and dextrins for further processing to a wide range of products such as syrups and distilled alcohol.

The benefits of using this enzyme during starch processing, as stated by the applicant, is the efficient breakdown of the starch to produce dextrins, which are then further processed to manufacture syrups. For alcohol production, the benefits in relation to the production of dextrins are similar, and the use of this enzyme also results in higher ethanol yields, fast fermentation and efficient production of fermentable sugars.

The enzyme preparation will be used as a processing aid where the enzyme is not present or else present in negligible amounts, with no technological function in the final food. It will provide food processors with an alternative enzyme preparation in starch processing and alcohol production.

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, Denmark and Mexico.

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 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). The Codex Alimentarius Commission 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.

1.3.3 Mexican regulations

In Mexico, applications comprise technical dossiers and, if approved, the food enzymes are included in the positive list *An agreement that establishes the substances allowed as additives and processing aids in foods, beverages and nutritional supplements (Annex VI Enzymes)* maintained and updated by the Federal Commission for Protection against Sanitary Risks (COFEPRIS), which is the operational arm of the Secretariat of Health (SALUD).

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

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.

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 and is unlikely to pose a toxigenic concern. The risk of food allergy from consumption of alpha-amylase is considered to be low. 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.
New Zealand Food and	Supportive.	An enzyme of microbial origin permitted

Raised by	Issue	FSANZ response
Grocery Council (NZFGC)	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 α-Amylase isolated from *Rhizomucor pusillus.*	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 A1185 – 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 alpha-amylase 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 introduced DNA had been inserted into the genome and is stably inherited.

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 1220 mg/kg bw/day on a total organic solids (TOS) basis. The applicant's estimated theoretical maximal daily intake (TMDI) of alpha-amylase is 2.86 mg kg bw/day TOS, resulting in a Margin of Exposure (MoE) of greater than 400 between the NOAEL and TMDI.

Bioinformatic analyses did not identify any homology with any known toxins. However a

degree of homology between the enzyme and two respiratory allergens was found, including an alpha-amylase from *A. oryzae* which has been implicated in three cases of food allergy in occupationally sensitised individuals, 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 *A. niger* 667-91-15 is considered to be low.

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 (SD1) 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 Potential for allergenicity

At the call for submission stage (February 2020), FSANZ's risk assessment (SD1) identified that this enzyme showed significant similarity to the alpha-amylases from *A. oryzae* (up to 60.3%) providing some evidence that the *A. niger* alpha-amylase has the potential to be an allergen. FSANZ concluded, based on a weight-of-evidence approach (which included no knowledge of reports of allergic reactions associated with consumption) that the enzyme was not a cause for concern with respect to food allergy.

Since then, FSANZ became aware of three historical (prior to 2004) cases of food allergy in occupationally sensitised individuals linked to alpha-amylase from *A. oryzae.* FSANZ noted

that these case reports of food allergy are not recent, however they were considered 'new' information to FSANZ and, as such, needed to be taken into account as part of the weight-of-evidence risk assessment process. FSANZ requested and was provided with further information by the applicant addressing this issue and, based on FSANZ's assessment of that information, FSANZ determined that the risk of food allergy from the enzyme's proposed uses is low.

2.3.2 Enzyme and source microorganism nomenclature

FSANZ noted that the International Union of Biochemistry and Molecular Biology (IUBMB), the internationally recognised authority for enzyme nomenclature, uses the 'accepted' name 'α-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 source organism *A. niger* is already permitted as a production microorganism for numerous enzymes within Schedule 18 of the Code.

2.3.3 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.

2.3.3.1 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).

2.3.3.2 Declaration of certain substances

The risk assessment 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.

2.3.4 Risk management conclusion

The risk management conclusion is to permit the enzyme, alpha-amylase (EC 3.2.1.1), sourced from *A. niger* containing the alpha-amylase gene from *R. pusillus,* 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 standard development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options.

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 alpha-amylase sourced from a GM strain of *A. niger* (*A. niger* containing an alpha-amylase gene from *R. pusillus*). This particular enzyme may be an option for the food and beverage industry to reduce costs or increase efficiency of producing syrups and potable alcohol, through improved starch liquefaction and production of fermentable sugars.

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

The enzyme is already authorised for use in several countries (Denmark, France and Mexico since 2015). 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.

Alpha-amylase 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 used in several countries including France, Denmark and Mexico. 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 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[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 3.2.1.1. https://www.qmul.ac.uk/sbcs/iubmb/enzyme/EC3/2/1/1.html

The United States Pharmacopeia (2018) Food Chemicals Codex 11th Edition, United States

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

Pharmacopeial Convention, Rockville, MD. http://publications.usp.org/

Attachments

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

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

Food Standards (Application A1185 – Alpha-amylase from GM *Aspergillus niger* as a processing aid (enzyme)) Variation

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

Dated [To be completed by Delegate]

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

Note:

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

1 Name

This instrument is the *Food Standards (Application A1185 – Alpha-amylase from GM* Aspergillus niger *as a processing aid (enzyme)) Variation*.

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

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

3 Commencement

The variation commences on the date of gazettal.

Schedule

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

α-Amylase (EC 3.2.1.1) sourced from *Aspergillus niger* containing the α-Amylase gene from *Rhizomucor pusillus*	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 A1185 which seeks permission to use the enzyme alpha-amylase (EC 3.2.1.1) 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 alpha-amylase (EC 3.2.1.1), sourced from *A. niger* containing the alpha-amylase gene from *Rhizomucor pusillus* (*R. pusillus*), 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 A1185 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 ‘α-Amylase (EC 3.2.1.1), sourced from *Aspergillus niger* containing the α-Amylase gene from *Rhizomucor pusillus*’, 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 ‘α-Amylase’ which is the accepted name used by the International Union of Biochemistry and Molecular Biology (IUBMB) for the enzyme with EC number 3.2.1.1 (IUBMB 2017).