

16 May 2019
[80-19]

Approval report – Application A1168

Glucoamylase 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 a new genetically modified strain of *Aspergillus niger* as a source for the already-permitted enzyme, glucoamylase.

On 6 December 2018 FSANZ sought submissions on a draft variation and published an associated report. FSANZ received two submissions.

FSANZ approved the draft variation on 1 May 2019. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 15 May 2019.

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 (at Approval)

¹ [http://www.foodstandards.gov.au/code/applications/Pages/A1168%20-%20Glucoamylase-from-GM-Aspergillus-niger-as-a-Processing-Aid-\(Enzyme\)-.aspx](http://www.foodstandards.gov.au/code/applications/Pages/A1168%20-%20Glucoamylase-from-GM-Aspergillus-niger-as-a-Processing-Aid-(Enzyme)-.aspx)

Executive summary

Novozymes Australia Pty Ltd submitted an application to Food Standards Australia New Zealand (FSANZ) which sought to permit the use of the enzyme glucoamylase (EC 3.2.1.3) from a new source (a genetically modified (GM) strain of *Aspergillus niger*) as a processing aid. The enzyme's purpose was to convert starch into glucose to manufacture syrups, beverages, cereal-based products, fruit products and vegetable products. It will be used in the baking, brewing and distilling industries, as well as in the manufacture of fruit and vegetable juices, and sugar syrup.

The enzyme was derived from a GM strain of *A. niger* containing the *glucoamylase gene* from the fungus, *Talaromyces emersonii*. The *A. niger* production strain was not toxigenic or pathogenic and was absent in the final enzyme preparation. Further, *A. niger* has a long history of safe use as the production organism for a number of enzyme processing aids that are already permitted in the Australia New Zealand Food Standards Code (the Code).

After undertaking a risk assessment, FSANZ concluded that there are no public health and safety concerns associated with using this glucoamylase, including allergenicity. In the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) of 'not specified' was appropriate. A dietary exposure assessment was therefore not required.

The evidence presented to support the proposed use of the enzyme provided adequate assurance that the enzyme, in the form and prescribed amounts, was technologically justified and had been demonstrated to be effective in achieving its stated purpose. The enzyme performed its technological purpose during production and manufacture of foods and was therefore appropriately categorised as a processing aid and not a food additive. The enzyme met international purity specifications.

The enzyme preparation has been approved for use in food production in Denmark, Canada, France, Brazil, China and Mexico.

Enzymes used to produce and manufacture food are considered processing aids and are regulated by Schedule 18 of the Code. The enzyme has been listed in the table to subsection S18—9(3), which includes enzymes permitted for use for a specific technological purpose. FSANZ approved the draft variation to the Code to permit the enzyme glucoamylase derived from a GM strain of *A. niger*, as a processing aid to convert starch into glucose in the manufacture of syrups, beverages, cereal-based products, fruit products and vegetable products. The permission 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

Novozymes Australia Pty Ltd manufactures and supplies enzymes, as well as other biotechnology products, to the food industry among many other industries.

1.2 The application

The application sought permission for a new microbial source organism for the currently permitted enzyme, glucoamylase (Enzyme Commission (EC) number 3.2.1.3) as a processing aid. This required adding permission for the enzyme and source organism into Schedule 18 – Processing aids of the Australia New Zealand Food Standards Code (the Code). Glucoamylase is sourced from a genetically modified microorganism, *Aspergillus niger* containing the gene for glucoamylase isolated from *Talaromyces emersonii*.

The purpose of glucoamylase is to hydrolyse (break down) starch to glucose to manufacture syrups, beverages, cereal-based products, fruit products and vegetable products. It will be used in the baking, brewing and distilling industries, as well as in the manufacture of fruit and vegetable juices, and sugar syrup. Therefore, the enzyme will be used in the processing of a large range of products such as syrup, distilled alcohol, beer, bread and juices.

1.3 The current standards

Australian and New Zealand food laws require food for sale to comply with the Code. In relation to this application, the relevant requirements are:

Permitted use

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

Paragraphs 1.1.1—10(6)(c) and (g) of the Code provides that food for sale cannot contain, as an ingredient or component, a substance ‘used as a processing aid’, or a ‘food produced using gene technology’ respectively, unless expressly permitted.

Section 1.1.2—13 provides that a substance is ‘used as a processing aid’ if it is added to a food to perform a technological purpose during the course of processing of food; does not perform a technological purpose in the food for sale; and is a substance listed in Schedule 18 or a substance identified in section S16—2 as an additive permitted at GMP (Good Manufacturing Practice).

Standard 1.3.3 and Schedule 18 of the Code list the permitted processing aids. Enzymes of microbial origin permitted to be used as processing aids are listed in the table to subsection S18—4(5) or in the table to subsection S18—9(3). 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.

There are currently permissions for glucoamylase from different microbial sources within the table to subsection S18—4(5) to be used in the manufacture of all foods although glucoamylase from the applicant’s microbial source is not permitted to be used as a processing aid.

Identity and purity requirements

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

Section S3—2 of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Compendium of Food Additive Specifications (FAO/WHO 2017) and the United States Pharmacopeial Convention (2018) Food Chemicals Codex (11th edition). These include specifications for enzyme preparations used in food processing.

1.3.1 International standards

The enzyme preparation in this application has been approved for use in food production in Denmark, Canada, France, Brazil, China and Mexico.

The Codex Alimentarius 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. These enzyme specifications are established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA 2017) and the Food Chemicals Codex (Food Chemicals Codex 2018).

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 was assessed under the General Procedure.

1.6 Decision

The draft variation as proposed following assessment was approved without change. The variation takes effect on gazettal. The approved draft variation is at [Attachment A](#).

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 sought public comments on the draft variation included in the call for submissions report between 6 December 2018 and 31 January 2019.

Two submissions were received from government agencies. One was supportive and no issues were raised whereas one raised a specific concern which FSANZ has addressed in Table 1 below.

Table 1: Summary of issues

Issue	Submitter	FSANZ response
<p>The submitter noted differences in wording between the safety assessment discussion in SD1 (Section 3.4.5) and the Executive Summary of SD1 and the Summary of the assessment in the Call for Submissions (Section 2.1) in the discussion of potential allergenicity of the enzyme protein.</p> <p>For example, in Section 3.4.5, there is a discussion about the significant homology between the applicant’s glucoamylase to the same protein from <i>Schizophyllum commune</i> (fungus), which has been identified as a respiratory allergen. Whereas in the Executive Summary of SD1 and Call for Submissions documents, the wording used is that “bioinformatic analyses did not identify significant homology between the amino acid sequence of the glucoamylase and known allergens.”</p> <p>The submitter also noted that FSANZ did not discuss any evidence for the food allergy potential of <i>S. commune</i> in countries with comparable rates of food allergies as Australia.</p>	<p>Victorian Departments of Health and Human Services; and Jobs, Precincts and Regions</p>	<p>The Risk and Technical Assessment Report has been amended to clarify the bioinformatics analyses. Although homology exists between glucoamylase produced by GM <i>A. niger</i> and <i>S. commune</i>, the homology does not translate to a food safety hazard. Glucoamylase from <i>S. commune</i> is a respiratory allergen and therefore would not be subjected to the same digestive processes that would degrade glucoamylase if present in the diet.</p> <p>Other glucoamylases from a large number of microbial sources have been widely used in the food industry since the 1960s.</p> <p>A search of the scientific literature did not identify any reports of allergy to glucoamylase when present in the diet.</p> <p>FSANZ has further identified that glucoamylase from <i>T. emersonii</i> (the gene donor organism) has greater similarity to the same protein in <i>Penicillium camemberti</i>, to that of <i>S. commune</i>. <i>P. camemberti</i> is used in the production of camembert and brie cheeses, which are common foods in Australia and New Zealand.</p> <p>Based on the weight of scientific evidence, the conclusion reached by FSANZ at call for submissions remains unchanged, in that the homology between the two glucoamylases is not considered to represent a food safety hazard.</p>

2.2 Risk assessment

The risk assessment concluded that there are no public health and safety concerns

associated with the use of glucoamylase from GM *A. niger* as a processing aid because:

- The production strain is not toxigenic or pathogenic and is absent in the final enzyme preparation proposed to be used as a food processing aid.
- The same glucoamylase from GM *A. niger* has a history of safe use in several other countries, with the earliest specified date of approval being 2008. Other glucoamylases from a large number of microbial sources have been widely used in the food industry since the 1960s.
- Glucoamylase was not genotoxic in a bacterial reverse mutation assay (Ames test) or a micronucleus assay in cultured human peripheral blood lymphocytes. No adverse effects were observed in rats administered glucoamylase produced by a strain of *A. niger* of the same strain lineage as the production strain for 13 weeks.
- Bioinformatic analyses identified homology between the recombinant glucoamylase from GM *A. niger* and a respiratory allergen from *S. commune*. Further analysis indicated this did not represent a food safety hazard.
- In the absence of any identifiable hazard an Acceptable Daily Intake (ADI) 'not specified' is appropriate. A dietary exposure assessment was therefore not required.

The food technology assessment concluded 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 performs its technological purpose during production and manufacture of foods and is therefore appropriately categorised as a processing aid and not a food additive. The enzyme preparation meets international purity specifications.

For further details on the risk assessment, refer to the Risk and technical assessment report (SD1).

Some minor changes in the SD1 released with the call for submissions have been made, clarifying that glucoamylase from GM *A. niger* is not considered to represent a food safety hazard, including assessing it for its allergenic potential.

2.3 Risk management

The risk assessment concluded that there are no safety concerns from the use of glucoamylase from a GM strain of *A. niger* as a food processing aid to hydrolyse starch to glucose to manufacture syrups, beverages, cereal-based products, fruit products and vegetable products. As processing aids require permissions in the Code, the main risk management option available to FSANZ was to approve or reject the request to amend the Code and, if approved, to impose any conditions that may be appropriate. Other risk management issues for this application are related to enzyme nomenclature and labelling, which are discussed below. The regulatory options analysed in section 2.5.1.1 take account of the safety of the enzyme.

This enzyme preparation will provide the food industry with an alternative source of glucoamylase.

2.3.1 Regulatory approval for enzymes

FSANZ concluded that the enzyme meets its stated purpose, for use as a processing aid to hydrolyse starch to glucose to manufacture syrups, beverages, cereal-based products, fruit

products and vegetable products. The risk assessment further concluded that, in the absence of any identifiable hazard, an ADI of 'not specified' was appropriate for the enzyme and ingestion of any residual glucoamylase in food products was unlikely to pose an allergenicity concern.

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

The express permission for the enzyme's use as a processing aid also provides the permission for the enzyme's 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' (i.e., genetically modified yeast). 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. Section 1.5.2—3 of Standard 1.5.2 provides that permission for use as a processing aid also constitutes the permission required by paragraph 1.1.1—10(6)(g).

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 'glucan 1,4-alpha-glucosidase' for the enzyme with an EC number of EC 3.2.1.3 (IUBMB 2018). The first other name listed is glucoamylase, which is the enzyme name already listed in the table to subsection S18—4(5). It is also the name that is used in this report and in the drafting variation to the Code.

The nomenclature of the production and gene donor microorganisms was verified and confirmed as appropriate as listed in the application (see section 3.2 of SD1). The production organism is *A. niger*, which is listed as either a production or source microorganism many times within Schedule 18, and *T. emersonii* is the gene donor microorganism.

2.3.3 Labelling requirements

Paragraph 1.1.1—10(8) of the Code provides that food for sale must comply with all relevant labelling requirements imposed by the Code for that food. Standard 1.2.4 of the Code generally requires food products to be labelled with a statement of ingredients. Sections 1.2.4—3(2)(d) and (e) of that Standard exempt processing aids from the requirement to be declared in the statement of ingredients.

The risk assessment concluded that the use of the enzyme posed no concern to public health and safety and that it performs its technological purpose as a processing aid. Therefore, the generic exemption from declaration of processing aids in the statement of ingredients applies to foods containing this processing aid.

2.3.3.1 Labelling requirements for food produced using gene technology

Standard 1.5.2 outlines provisions for labelling of foods produced using gene technology. The enzyme is a food produced using gene technology for Code purposes. Section 1.5.2—4 indicates that labelling requirements apply for processing aids that are foods produced using gene technology, where novel DNA or novel protein from the processing aid remain present in the final food.

Section 1.5.2—4 requires certain foods for sale that consist of or have as an ingredient, food that is a GM food to be labelled as 'genetically modified'. FSANZ also noted that the Code's labelling requirements – including those 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 section 1.2.1—15 respectively. The requirements for labelling as ‘genetically modified’ differ depending on whether the GM food is an ingredient of the food for sale or not, as follows.

If a food for retail sale or sold to a caterer contained the enzyme glucoamylase as an ingredient, that food would be required to be labelled ‘genetically modified’ in conjunction with the name of the processing aid, if novel DNA or novel protein from the genetically modified strain of *A. niger* (that is the source microorganism, not the enzyme) remained in the final food.

FSANZ however, also noted that if the food made with the enzyme is not a food for sale itself but is used as an ingredient in a food for retail sale or food sold to a caterer (for example, a syrup used as an ingredient to manufacture another food), the enzyme would not be an ingredient in the food for sale. The requirement to label as ‘genetically modified’ would not apply to that food for sale because the labelling requirements only apply to food that consists of, or has as an ingredient, a genetically modified food (section 1.5.2—4(1)).

2.3.4 Risk management conclusion

The risk management conclusion was to add the permission for the new enzyme glucoamylase derived from a genetically modified strain of *A. niger* containing the gene for glucoamylase isolated from *T. emersonii*, as a processing aid into the table to subsection S18—9(3), which includes enzymes permitted for a specific technological purpose. The technological purpose was to hydrolyse starch to glucose to manufacture syrups, beverages, cereal-based products, fruit products and vegetable products. The maximum permitted level was an amount consistent with GMP.

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ’s standards development process. 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.

FSANZ developed and applied a basic communication strategy to this application. The call for submissions was 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.

The applicant, individuals and organisations that made submissions on this application will be notified at each stage of the 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 new processing aids (OBPR correspondence dated 24 November 2010, reference 12065).

This standing exemption was provided as permitting processing aids is machinery in nature as they are part of implementing a regulatory framework where the use of the new processing aids 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 required FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

The purpose of this consideration was to determine if the community, government and industry as a whole was likely to benefit, on balance, from a move from the status quo (i.e. rejecting the application). This analysis considered permitting the use of a new microbial source organism for the currently permitted enzyme glucoamylase (Enzyme Commission (EC) number 3.2.1.3) as a processing aid. FSANZ was of the view that no other realistic food regulatory measures exist.

The consideration of the costs and benefits in this section was not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered could not 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.

Costs and benefits permitting the use of a new microbial source organism for the currently permitted enzyme glucoamylase (Enzyme Commission (EC) number 3.2.1.3) as a processing aid

This enzyme is an alternative to already permitted forms of the enzyme which provides options to food manufacturers. The production organism contains a number of copies of the glucoamylase gene which may make it more efficient and cost effective. Which enzyme preparation a food manufacturer purchases for specific uses will depend on a range of factors, including economic and performance for the proposed use.

There are unlikely to be any direct benefits or costs to consumers of this option. However, reduced production costs, depending on how competitive the relevant markets are, could result in reduced costs for consumers. Likewise, there are unlikely to be any direct costs or benefits to governments associated with this option.

Conclusions from cost benefit considerations

FSANZ's assessment was that the direct and indirect benefits that arise from permitting the use of a new microbial source organism for the currently permitted enzyme glucoamylase (Enzyme Commission (EC) number 3.2.1.3) as a processing aid would 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 or varied as a result of the application.

2.5.1.3 Any relevant New Zealand standards

Schedule 18 applies in both Australia and New Zealand. There are no 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 had 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 had undertaken a safety assessment (SD1) and concluded there are no public health and safety concerns with permitting the use of glucoamylase sourced from *A. niger* containing the gene for glucoamylase from *T. emersonii* as a processing aid in food for the proposed purpose.

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

The labelling approach for the processing aid is discussed in Section 2.3.3 above. This approach was consistent with the existing provisions in the Code for the labelling of permitted processing aids.

2.5.2.3 The prevention of misleading or deceptive conduct

There are 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 when undertaking the risk analysis, which is provided in SD1 – the risk and technical assessment report. The applicant submitted a dossier of scientific studies and other technical information including scientific literature. This information 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, this enzyme is permitted for use in Denmark, France, Brazil, Canada, China and Mexico. It also meets international specifications for enzyme preparations, being the JECFA Compendium of Food Additive

Specifications and the Food Chemicals Codex.

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

Permission for this enzyme preparation provides food manufacturers with an alternative enzyme, which should add to competition in supplying enzymes to the food manufacturing industries.

- **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 had determined that permitting the use of the enzyme glucoamylase sourced from *A. niger* containing the gene for glucoamylase from *T. emersonii* as a processing aid was consistent with the specific order principles for 'Technological Function'.

3 References

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

International Union of Biochemistry and Molecular Biology (IUBMB) Enzyme Nomenclature for EC 3.2.1.3 located at <http://www.sbcs.qmul.ac.uk/iubmb/enzyme/EC3/2/1/3.html> Accessed 3 October 2018.

JECFA (2017) General specifications and considerations for enzyme preparations used in food processing. <http://www.fao.org/docrep/009/a0691e/A0691E03.htm>

Attachments

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

² <http://foodregulation.gov.au/internet/fr/publishing.nsf/Content/food-policies>

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



Food Standards (Application A1168 – Glucoamylase from GM *Aspergillus niger* as a PA (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 A1168 – Glucoamylase from GM Aspergillus niger as a PA (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

Glucoamylase (EC 3.2.1.3) sourced from <i>Aspergillus niger</i> containing the gene for glucoamylase isolated from <i>Talaromyces emersonii</i>	To hydrolyse starch in the manufacture of syrups, beverages, cereal-based products, fruit products and vegetable products	GMP
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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 A1168 which sought a variation to permit a new genetically modified strain of *Aspergillus niger* as a source for the permitted enzyme glucoamylase. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation of a standard.

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 sunseting under the *Legislation Act 2003*.

2. Purpose

The Authority has approved a draft variation to permit the enzyme glucoamylase sourced from *Aspergillus niger* containing the gene for glucoamylase from *Talaromyces emersonii* to be used as a processing aid for the purpose of hydrolysing starch in the manufacture of syrups, beverages, cereal-based products, fruit products and vegetable products, at GMP. This permission requires an addition to the table to subsection S18—9(3) in Schedule 18.

3. Documents incorporated by reference

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

Existing provisions of the Code incorporate a document by reference that will prescribe identity and purity specifications for the processing aid to be permitted by the draft variation. Section 1.1.1—15 of the Code requires substances used as processing aids to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code. Section S3—2 of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Compendium of Food Additive Specifications (FAO/WHO 2017) and the United States Pharmacopeial Convention (2018) Food Chemicals Codex (11th edition). These include specifications for enzyme preparations used in food processing.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of application A1168 included one round of public consultation following an assessment and the preparation of a draft Standard and associated reports. Submissions were called for on 6 December 2018 for an eight-week consultation period.

A Regulation Impact Statement was not required because the proposed variation to Schedule 18 was likely to have a minor impact on business and individuals.

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 inserted a new entry into the table to subsection S18—9(3) in Schedule 18.

The new entry permits the use of the enzyme, glucoamylase (EC 3.2.1.3) sourced from *Aspergillus niger* containing the gene for glucoamylase from *Talaromyces emersonii*, as a processing aid in food for a specific technological purpose, with the condition that the maximum permitted level or amount that may be used must be consistent with good manufacturing practice. The technological purpose is to hydrolyse starch in the manufacture of syrups, beverages, cereal-based products, fruit products and vegetable products.