6 December 2018
[67–18]

Call for submissions – Application A1168

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

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 permitted enzyme glucoamylase and 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) 31 January 2019

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:

Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604
AUSTRALIA
Tel +61 2 6271 2222

Food Standards Australia New Zealand
PO Box 10559
- The Terrace WELLINGTON 6143
NEW ZEALAND
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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

[1] 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) seeking 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 is to convert starch into glucose to manufacture syrups, beverages, cereal based products, fruit products and vegetable products. It would 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 is derived from a GM strain of *A. niger* containing the *glucoamylase gene* from the fungus, *Talaromyces emersonii*. The *A. niger* production strain is not toxigenic or pathogenic and is 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 Code.

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

The 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 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 meets 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 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 a specific technological purpose. FSANZ proposes a 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 would be 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 seeks 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 would require adding permission for the enzyme and source organism into Schedule 18 – Processing aids of the Australia New Zealand Food Standards Code (the Code). The glucoamylase enzyme is sourced from a genetically modified microorganism, *Aspergillus niger* containing the gene for glucoamylase isolated from *Talaromyces emersonii.*

Its purpose is to hydrolyse (break down) starch to glucose to manufacture syrups, beverages, cereal-based products, fruit products and vegetable products. It would 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 would 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. But glucoamylase from the microbial source of this application in 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 2016) and the United States Pharmacopeial Convention (2016) Food Chemicals Codex (10th 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 2006) and the Food Chemicals Codex (Food Chemicals Codex 2016).

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

The risk assessment concluded that there are no public health and safety concerns associated with the use of glucoamylase from *A. niger* as a processing aid because:

- The *A. niger* production strain is not toxigenic or pathogenic and is absent in the final enzyme preparation proposed to be used as a food processing aid.

- Glucoamylase from *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 searches did not identify any significant homology of the amino acid sequence of the enzyme with those of known toxins or allergens.

- 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 technological 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).

2.2 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 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 glucoamylase which is claimed to provide improved efficiencies and yields.

2.2.1 Regulatory approval for enzymes

FSANZ has 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 has further concluded that, in the absence of any identifiable hazard, an ADI of 'not specified' is appropriate for the enzyme and ingestion of any residual glucoamylase in food products is unlikely to pose an allergenicity concern.

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

The express permission for the enzymes' use as a processing aid will also provide 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).

2.2.2 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 '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 proposed drafting variation to the Code.

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

2.2.3 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 poses 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 will apply to foods containing this processing aid.

2.2.3.1 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 remains 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 notes 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 contains 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) remains in the final food.

FSANZ however, also notes 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)).

2.2.4 Risk management conclusion

The risk management conclusion is 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 is to hydrolyse starch to glucose to manufacture syrups, beverages, cereal-based products, fruit products and vegetable products. The maximum permitted level is an amount consistent with GMP.

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 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.

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 Alimentarius 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 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 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)).

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 a new microbial source organism for the currently permitted enzyme glucoamylase (Enzyme Commission (EC) number 3.2.1.3) as a processing aid. FSANZ is of the view that no other realistic food regulatory measures exist, however information received 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 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 productions 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 is that the direct and indirect benefits that would 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 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 applies in both Australia and New Zealand. There are no 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 glucoamylase sourced from *A. niger* containing the gene for glucoamylase from *T. emersonii* as a processing aid in food for the proposed purpose.

2.4.2.2 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 2.2.3 above. This approach is consistent with the existing provisions in the Code for the labelling of permitted processing aids.

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 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 Minerals[2] 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 the enzyme glucoamylase sourced from *A. niger* containing the gene for glucoamylase from *T. emersonii* as a processing aid is consistent with the specific order principles for 'Technological Function'.

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

Food Chemicals Codex 10th Edition (2016), The United States Pharmacopeia, United States Pharmacopeial Convention, Rockville, MD.
http://www.usp.org/food-ingredients/food-chemicals-codex

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

JECFA (2006) General specifications and considerations for enzyme preparations used in food processing. http://www.fao.org/docrep/009/a0691e/A0691E03.htm

Attachments

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

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

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

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

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 *Aspergillus niger* containing the gene for glucoamylase isolated from *Talaromyces emersonii*	To hydrolyse starch in the manufacture of syrups, beverages, cereal-based products, fruit products and vegetable products	GMP

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 A1168 which seeks 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 prepared a draft Standard.

2. Purpose

The Authority has prepared 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 2016) and the United States Pharmacopeial Convention (2016) Food Chemicals Codex (10th 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 will include one round of public consultation following an assessment and the preparation of a draft Standard and associated assessment summary.

A Regulation Impact Statement was not required because the proposed variations to Schedule 18 are 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 inserts a new entry into the table to subsection S18—9(3) in Schedule 18.

The new entry would permit 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.