23 January 2016
[03–17]

Call for submissions – Application A1125

Endo ß(1,4) Xylanase as a Processing Aid (Enzyme)

FSANZ has assessed an Application made by Puratos NV to permit the use of the enzyme endo ß(1,4) xylanase, derived from *Pseudoalteromonas haloplanktis,* and produced by a genetically modified source of *Bacillus subtilis,* for use as a processing aid in the manufacture of cereal products, 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 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 and quicker 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) 6 March 2017

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
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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/A1125-Xylanase-BacillusSubtilisPA-Enzyme.aspx

Executive summary

Puratos NV has submitted an Application seeking permission to use the enzyme endo β(1,4) xylanase (EC 3.2.1.8), derived from *Pseudoalteromonas haloplanktis*, and produced by a genetically modified (GM) source of *Bacillus subtilis*, as a processing aid in the manufacture of certain cereal products.

Xylanases catalyse the conversion of arabinoxylan (polysaccharides naturally present in cereals that impart important functional properties) into arabinoxylan oligosaccharides. While xylanases are naturally present in many cereals, the addition of further endo β(1,4) xylanase (in this case from a microbial source) during processing allows the solubilisation of the arabinoxylans, which improves the functional properties of these polysaccharides, leading to better and/or more consistent product quality.

Enzymes used in the production and manufacture of food are considered processing aids and are regulated by Schedule 18 of the *Australia New Zealand Food Standards Code* (the Code). Permitted enzymes of microbial origin are listed in the Table to subsection S18—4(5).

After undertaking a risk assessment, FSANZ concludes that there are no public health and safety issues associated with the use of the enzyme preparation containing endo β(1,4) xylanase derived from *P. haloplanktis* and produced by GM *B. subtilis* as a food processing aid. It is likely that any residual enzyme in the final food would be present as denatured protein and susceptible to digestion like other dietary proteins. FSANZ also concludes that in the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) 'not specified' is appropriate. A dietary exposure assessment is therefore not required.

The evidence presented to support the proposed uses of the enzyme preparation 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 preparation meets international purity specifications.

FSANZ has therefore prepared a draft variation to permit endo β(1,4) xylanase (EC 3.2.1.8) derived from *P. haloplanktis* and produced by a GM source of *B. subtilis* as a processing aid. The nomenclature for the enzyme is consistent with the International Union of Biochemistry and Molecular Biology (IUBMB) naming system, the internationally recognised authority for enzyme nomenclature (IUBMB 2016).

1 Introduction

1.1 The Applicant

The Applicant is Puratos NV (Puratos), Belgium, a company specialising in developing, producing, distributing and marketing high quality raw materials for the bakery, confectionery, chocolate and catering industry.

1.2 The Application

The purpose of the Application is to seek permission to use the enzyme endo ß(1,4) xylanase (also noted in the Application as endo β(1-4) xylanase and henceforth referred to as xylanase), derived from *Pseudoalteromonas haloplanktis*, and produced by a genetically modified (GM) source of *Bacillus subtilis*, for use as a processing aid in the manufacture of cereal products.

Xylanase catalyses the conversion of the arabinoxylan (polysaccharides naturally present in cereals) into constituent arabinoxylan oligosaccharides. Arabinoxylans provide important functional properties in bread-making due to their ability to interact with gluten, bind water, and provide dough viscosity. The limited hydrolysis of arabinoxylans to arabinoxylan oligosaccharides by xylanase results in solubilised arabinoxylans with lower molecular weights. This improves the functional properties of the arabinoxylans in bread-making and in the manufacture of other bakery products such as biscuits and cakes. The improved functional properties include dough handling; dough structure, behaviour and uniformity; and reduced batter viscosity (see section 2.1.2 in SD1).

Xylanase can also be used in processing other cereal-based products such as, but not limited to, pasta, noodles and snacks where, in addition to the functional properties outlined above, the enzyme can improve dough handling and accelerate the drying step, thereby shortening the process time.

The enzyme is sourced from a GM strain of *B. subtilis.* The production strain is designated Gizα7101. The *xylanase* gene is derived from *P. haloplanktis* (an Antarctic bacterium). Whilst xylanase is naturally present in many cereals, the addition of further xylanase (in this instance from *P. haloplanktis*) provides improved effectiveness in the manufacture of bakery and other cereal-based products under typical production conditions.

The xylanase concentrate is sourced from the production strain of *B. subtilis* through fermentation; each fermentation run is started from pure starter cultures. After filtration and purification, the concentrated liquid enzyme is spray dried and sprayed on a carrier, which is food grade wheat flour. The trade name of the product being assessed and referred to in this report is Premix X-608 (but it is also sold commercially as Premix X-618 and Bel'Ase B218).

The Applicant reported that the enzyme preparation has optimal activity at temperatures and pH typically used in dough proofing, resulting in increased efficiency during dough preparation and superior batch to batch consistency. The enzyme preparation is inactivated by changing either the pH or temperature of the food; in this way the enzyme has no function in the final food product after baking due to the high temperature.

1.3 The current Standard

Enzymes used in processing and manufacturing food are considered processing aids. Only those processing aids listed in Schedule 18 in the *Australia New Zealand Food Standards Code* (the Code) are permitted to be used in producing food sold in Australia and New Zealand.

Permitted enzymes of microbial origin (including enzymes derived from GM microorganisms) are listed in the table to subsection S18—4(5) (FSANZ 2016).

There is already approval for xylanase (EC 3.2.1.8) from a range of production organisms including *B. subtilis* in the Code. However, there is currently no permission for this enzyme derived from a GM *B. subtilis.* Therefore, approval is required for the use of a genetically modified source microorganism for the preparation of the enzyme. *B. subtilis* is the host microorganism for ten other permitted enzymes in the Code.

1.3.1 International Standards

P. haloplanktis-derived xylanase produced by *B. subtilis* strain Gizα 3508 that is the subject of this Application has been evaluated and authorised in France, Brazil and Canada.

The enzyme preparation was approved in France in 2006 for use in making biscuits, rusks, Viennese bread products, pastries, everyday (excluding traditional French bread) and special bread (Appendix 2 of the Application). It has since been approved in Brazil and Canada (strain Gizα 3508), and is deemed to be **g**enerally **r**egarded **a**s **s**afe (**GRAS**) in the USA (Appendices 3, 4 & 5 of the Application). The Applicant did not provide the identity of the production strain for Brazil or the USA. Similar to the production strain in this Application (Gizα 7101), Gizα 3508 is derived from *B. subtilis* strain DB105.

The Applicant has submitted an application for the *P. haloplanktis*-derived xylanase produced in *B. subtilis* strain LMG S-24584 to the European Commission for inclusion of a food enzyme in the Union list (deadline for submission was 11 March 2015). The dossier for this application was considered valid and will be included in the future Register once it is established (see Appendix 6 of the Application). Additionally, xylanase derived from *Pseudoalteromonas* sp. and produced in *B. subtilis* is listed on the updated inventory of substances used as processing aids prepared by New Zealand and presented to the Codex Committee on Food Additives (CCFA) 45th session in 2013 (Appendix 1 of the Application).

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 Hazard assessment

There are no public health and safety issues associated with the use of the endo ß(1-4) xylanase enzyme preparation derived from *P. haloplanktis* and produced by GM *B. subtilis* as a food processing aid on the basis of the following considerations:

- The production organism is not toxigenic or pathogenic. Further, GM and non-GM *B. subtilis* have a history of safe use as the production organism for a number of processing aids already permitted in the Code and overseas.

- *P. haloplanktis*-derived xylanase produced in *B. subtilis* has been approved for food use overseas.

- Residual xylanase is expected to be present in the final food but would be inactive and susceptible to digestion like any other dietary protein.

- Bioinformatic analysis indicated that *P. haloplanktis*-derived xylanase has no biologically relevant homology to known food protein allergens.

- The xylanase preparation caused no observable effects at the highest tested doses in a 90-day repeated dose toxicity study in rats. The NOAEL for the xylanase concentrate was determined to be 1450 GDXU/kg bodyweight/day, or 0.1394 mg Total Organic Solids (TOS)/kg bodyweight/day for rats.

- The enzyme was not genotoxic or mutagenic in vitro.

Based on the reviewed toxicological data, it is concluded that, in the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) 'not specified' is appropriate. A dietary exposure assessment is therefore not required.

The evidence presented to support the proposed uses 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 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 hazard assessment conclusions provided evidence that there are no safety risks from the use of xylanase, derived from *P. haloplanktis*, and produced by GM *B. subtilis* as a processing aid. As processing aids require permissions in the Code, the only risk management options available to FSANZ are to approve or reject the request to amend the Code. The regulatory options analysed in section 2.4.1.1 take account of the safety of the enzyme preparation.

Whilst xylanase is naturally present in many cereals, if this Application is permitted, it will allow the addition of additional xylanase type enzyme preparations during processing for the solubilisation of the arabinoxylans, which in turn will help improve the functional properties of these polysaccharides.

2.2.1 Enzyme nomenclature

FSANZ notes that the International Union of Biochemistry and Molecular Biology (IUBMB), the internationally recognised authority for enzyme nomenclature, uses the 'accepted' name 'endo-1,4-β-xylanase' for enzymes with an EC number of 3.2.1.8. The name that is used throughout this Application is endo ß(1,4) xylanase and the name that is currently included in Schedule 18 of the Code is 'endo-1,4-beta-xylanase'. These names all refer to the same enzyme with an EC number of 3.2.1.8. The latter is the name used in the proposed draft variation to the Code for this enzyme.

2.2.2 Labelling considerations

As the risk assessment concludes that the use of the enzyme preparation poses no risk to public health and safety, FSANZ considers that the existing labelling requirements in the Code are appropriate for the use of the enzyme in foods.

As a general rule, processing aids are exempt from the requirement to be declared in the statement of ingredients in accordance with paragraphs 1.2.4—3(2)(d) and (e) in Standard 1.2.4 – Information requirements – statement of ingredients.

Labelling requirements do apply where novel DNA and/or novel protein from the processing aid remains present in the final food (paragraph 1.5.2—4(1)(b) of Standard 1.5.2 – Food produced using gene technology). In such cases, the statement 'genetically modified' must be declared on the label of the food in conjunction with the name of the processing aid. Data submitted with the Application indicates that the *B. subtilis* production strain is not detectable in the final enzyme preparation and, as such, no novel DNA or novel protein remains in the final food treated with the enzyme preparation. Therefore, there are no genetically modified labelling requirements for use of this enzyme when used as a processing aid in the production of food.

2.2.2.1 Declaration of certain substances

Maltodextrin and starch (which may be produced from wheat) may be among the raw materials used as fermentation media in the production of the enzyme. In addition, the carrier of the commercial enzyme preparation is food grade wheat flour. If cereals containing gluten are present in a food for sale, including when present as a processing aid or an ingredient or component of a processing aid, they are required to be declared in accordance with section 1.2.3—4 of Standard 1.2.3 – Information requirements – warning statements, advisory statements and declarations.

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 no relevant international standards (i.e. Codex) and amending the Code to approve the enzyme preparation as a processing aid is unlikely to have a significant effect on international trade as the enzyme preparation meets the international specifications for enzymes (i.e. the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Compendium of Food Additive Specifications (JECFA 2016) and the Food Chemicals Codex specifications for enzymes (Food Chemicals Codex 2014)). 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

FSANZ is required to consider the impact of various regulatory and non-regulatory options on all sectors of the community, especially relevant stakeholders who may be affected by this Application. The benefits and costs associated with the proposed amendments to the Code are analysed using regulatory impact principles. The level of analysis is commensurate with the nature of the Application and significance of the impacts.

Two regulatory options were considered:

(1) prepare a draft variation to Schedule 18 to permit the use of the xylanase enzyme (EC number 3.2.1.8), derived from *P. haloplanktis*, and produced by GM *B. subtilis* as a processing aid

(2) reject the Application.

The Office of Best Practice Regulation, in a letter dated 24 November 2010 (reference 12065), provided a standing exemption from the need to assess if a Regulation Impact Statement is required for Applications relating to processing aids, as they are machinery in nature and their use is voluntary. However, FSANZ undertook a limited impact analysis.

A consideration of the costs and benefits of the regulatory options was not intended to be an exhaustive, quantitative economic analysis of the options and, in fact, most of the effects that were considered cannot be assigned a dollar value.

Rather, the assessment sought to highlight the qualitative effects of criteria that were relevant to each option. These criteria are deliberately limited to those involving broad areas such as trade, consumer information and compliance.

Option 1 – Prepare a draft variation

Sector	Costs or benefits to sector
Consumers	The overall benefits to consumers include: • choice of an additional range of food products that become available due to the use of xylanase by Australian and New Zealand manufacturers • access to products manufactured using xylanase that are currently manufactured overseas.

Sector	Costs or benefits to sector
	There are no additional costs to consumers associated with this option.
Industry	Xylanase has been used in the food industry for over 25 years including in baking (particularly bread-making) and other cereal based processes. Levels of endogenous xylanase are often inadequate or may vary from batch to batch of raw material, and the specificity of the enzyme may not be optimal to provide the desired process advantages. It is in these situations that microbial xylanase can be used to the advantage of the food industry, for example, during baking and other cereal based processes. Approval of the xylanase preparation will benefit the food industry in that it will offer a source of xylanase with different properties including optimum activity under various pH and temperature conditions; resistance to *in vivo* inhibitors present in wheat flour; and enhanced functional properties including easier dough handling and improved dough structure and behaviour. This results in better and/or more consistent product quality and more effective production processing, which, in turn, results in better production economy and environmental benefits due to the use of less raw materials and the production of less waste. Businesses will make their own decisions as to whether or not they will use the enzyme preparation, taking into account their own particular costs and benefits.
Governments	There are no costs or benefits to governments associated with this option. *B. subtilis* (both GM and non-GM) is the production microorganism for 11 other permitted enzymes in the Code.

Option 2 – Reject the Application

Sector	Costs or benefits to sector
Consumers	There are no costs or benefits to consumers of this option.
Industry	There are no benefits to industry from this option. However, it is possible that there will be costs to industry, by not allowing them to use an alternative method for manufacturing certain cereal products using this enzyme preparation. The enzyme preparation has already been permitted for use overseas (see section 1.3.1). Therefore, there is a potential cost to the manufacturer of this enzyme preparation, as well as to overseas food manufacturers and importers, in that they will be unable to expand the international trade of their enzyme preparation and products made using this enzyme preparation, respectively, to Australia/New Zealand.
Governments	There are no benefits or costs to governments for this option.

The direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the Application outweighed the costs to the community, Government or industry that would arise from the development or variation of the food regulatory measure. Therefore, the preferred option was to prepare a draft variation to Schedule 18 of the Code.

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 and there are no other relevant New Zealand only standards.

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2 Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.4.2.1 Protection of public health and safety

FSANZ undertook a safety assessment (SD1) and concluded there were no public health and safety issues associated with the use of the xylanase enzyme preparation derived from *P. haloplanktis* and produced by GM *B. subtilis* as a food processing aid.

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

The labelling requirements for the enzyme processing aid are discussed in Section 2.2.2 – Labelling considerations. These requirements are considered to be appropriate for the permitted use of the enzyme in foods.

2.4.2.3 The prevention of misleading or deceptive conduct

There were 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 to conduct the risk analysis which is provided in SD1. The Applicant submitted a dossier of scientific studies as part of their Application. Other technical information 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, the enzyme preparation has been permitted for use in a number of countries overseas. 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**

As mentioned above, the use of the enzyme preparation is already permitted in a number of countries overseas.

Therefore, the approval of this enzyme preparation would bring Australia and New Zealand into line with other countries where it is already approved for use.

The Applicant advises that the Australia/New Zealand business (Puratos Australia-New Zealand Pty Ltd) intends to market the enzyme once it is approved. However, the domestic food industry will make their own economic decisions, taking into account the costs and benefits of using a new enzyme preparation, to determine if it is of benefit to their business.

- **the promotion of fair trading in food**

The enzyme preparation has been assessed as safe and permitted for use in other countries. It is therefore appropriate that the local Australian and New Zealand food industries also benefit by gaining permission to use this same enzyme preparation.

- **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 determined that permitting the use of the enzyme xylanase produced by GM *B.* subtilis as a processing aid is consistent with the specific order policy 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 9th Edition (2014), The United States Pharmacopeia. United States Pharmacopeial Convention, Rockville, MD.
http://www.usp.org/food-ingredients/food-chemicals-codex.

FSANZ (2016) *Australia New Zealand Food Standards Code*.
http://www.foodstandards.gov.au/code/Pages/default.aspx

IUBMB (2015) EC 3.2.1.8. http://www.chem.qmul.ac.uk/iubmb/enzyme/EC3/0201a.html#008

[2] http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx

JECFA (2016) 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

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

Food Standards (Application A1125 – Endo ß(1,4) Xylanase as a Processing Aid (Enzyme)) Variation

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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 Standards Management Officer]

Standards Management Officer
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.

Name

This instrument is the *Food Standards (Application A1125 – Endo ß(1,4) Xylanase 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 omitting from the table to subsection S18—4(5)

Endo-1,4-beta-xylanase (EC 3.2.1.8)	*Aspergillus niger* *Aspergillus oryzae* *Aspergillus oryzae*, containing the gene for Endo-1,4-beta-xylanase isolated from *Aspergillus aculeatus* *Aspergillus oryzae*, containing the gene for Endo-1,4-beta-xylanase isolated from T*hermomyces lanuginosus* *Bacillus amyloliquefaciens* *Bacillus subtilis* *Humicola insolens* *Trichoderma reesei*

and substituting

Endo-1,4-beta-xylanase (EC 3.2.1.8)	*Aspergillus niger* *Aspergillus oryzae* *Aspergillus oryzae*, containing the gene for Endo-1,4-beta-xylanase isolated from *Aspergillus aculeatus* *Aspergillus oryzae*, containing the gene for Endo-1,4-beta-xylanase isolated from *Thermomyces lanuginosus* *Bacillus amyloliquefaciens* *Bacillus subtilis* *Bacillus subtilis*, containing the gene for Endo-1,4-beta-xylanase isolated from *Pseudoalteromonas haloplanktis* *Humicola insolens* *Trichoderma reesei*

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.

FSANZ accepted Application A1125 which seeks to permit the use of the enzyme endo ß(1,4) xylanase derived from *Pseudoalteromonas haloplanktis* and produced by a genetically modified source of *B. subtilis* as a processing aid in the manufacture of cereal products. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation to the Code.

2. Purpose

The purpose of this amendment is to permit the use of the enzyme endo ß(1,4) xylanase, derived from *P. haloplanktis* and produced by a genetically modified source of *Bacillus. subtilis* as a processing aid. This requires an addition to the table to subsection S18—4(5) in Schedule 18.

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 A1125 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) will occur for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variation to Schedule 18 is 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—4(5) in Schedule 18. The new entry would permit the use of the enzyme endo ß(1,4) xylanase (EC number 3.2.1.8), derived from *P. haloplanktis* and produced by a genetically modified source of *B. subtilis* as a processing aid in food.