

7 July 2017
[17–17]

Approval report – Application A1125

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

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Puratos NV to permit the use of the enzyme endo β (1,4) xylanase¹, produced by genetically modified *Bacillus subtilis* that contains a *xylanase* gene sourced from *Pseudoalteromonas haloplanktis*. The applicant intends for this enzyme to be used as a processing aid in the manufacture of bakery and other cereal-based products.

On 23 January 2017, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received four submissions.

FSANZ approved the draft variation on 22 June 2017. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 6 July 2017.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

¹ The name of the enzyme that is used throughout the Application is endo β (1,4) xylanase. However, the name that is currently included in Schedule 18 is 'endo-1,4-beta-xylanase'. Both names refer to the same enzyme with an EC number of 3.2.1.8. The latter is the name used in the draft variation for this enzyme.

Table of contents

EXECUTIVE SUMMARY	2
1 INTRODUCTION	3
1.1 THE APPLICANT	3
1.2 THE APPLICATION	3
1.3 THE CURRENT STANDARD	4
1.4 REASONS FOR ACCEPTING APPLICATION	4
1.5 PROCEDURE FOR ASSESSMENT	4
1.6 DECISION	4
2 SUMMARY OF THE FINDINGS	4
2.1 SUMMARY OF ISSUES RAISED IN SUBMISSIONS	4
2.2 RISK ASSESSMENT	6
2.3 RISK MANAGEMENT	7
2.3.1 <i>International standards</i>	8
2.3.2 <i>Enzyme nomenclature</i>	8
2.3.3 <i>Labelling considerations</i>	8
2.3.4 <i>Risk management conclusion</i>	9
2.4 RISK COMMUNICATION.....	9
2.4.1 <i>Consultation</i>	9
2.5 FSANZ ACT ASSESSMENT REQUIREMENTS	9
2.5.1 <i>Section 29</i>	9
2.5.2 <i>Subsection 18(1)</i>	10
2.5.3 <i>Subsection 18(2) considerations</i>	10
3 REFERENCES	12
ATTACHMENT A – APPROVED DRAFT VARIATION TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i>	13
ATTACHMENT B – EXPLANATORY STATEMENT	15
ATTACHMENT C –DRAFT VARIATION TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i> (CALL FOR SUBMISSIONS)	17

Supporting document

The [following document](#) which informed the assessment of this Application is available on the FSANZ website:

SD1 Risk and Technical Assessment Report (at Approval)

Executive summary

Puratos NV submitted an Application seeking permission to use the enzyme endo $\beta(1,4)$ xylanase (EC 3.2.1.8), produced by genetically modified (GM) *Bacillus subtilis* that contains a xylanase gene sourced from *Pseudoalteromonas haloplanktis*. The food enzyme endo $\beta(1,4)$ xylanase is intended for use as a processing aid in the manufacture of bakery and other cereal-based 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 $\beta(1,4)$ 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 to produce and manufacture food are considered processing aids and are regulated by Schedule 18 in the *Australia New Zealand Food Standards Code* (the Code). Permitted enzymes of microbial origin may be listed in the table to subsection S18—4(5) or the table to subsection S18—9(3), depending on whether the permission is for use for any technological purpose and/or any food, or for specific technological purposes and specific foods, respectively.

FSANZ's risk assessment concluded that there were no public health and safety concerns associated with using the enzyme preparation containing endo $\beta(1,4)$ xylanase, produced by GM *B. subtilis* that contains a xylanase gene sourced from *P. haloplanktis*, as a food processing aid. The information presented to support the proposed uses of the enzyme preparation provided adequate assurance that the enzyme preparation, in its commercial form and proposed levels of usage, is technologically justified and effective in achieving its stated purpose. Therefore, the assessment considered that the enzyme should be permitted for use as a processing aid. The FSANZ Board has approved a draft variation to the table to subsection S18—9(3). This will permit the use of the enzyme as a processing aid in the manufacture of bakery and other cereal-based products.

1 Introduction

1.1 The Applicant

The Applicant was Puratos NV (Puratos), Belgium, a company that produces and supplies raw materials for the bakery, confectionery, chocolate and catering industry.

1.2 The Application

The Application was received on 7 January 2016.

The purpose of the Application was to seek permission to use the enzyme endo $\beta(1,4)$ xylanase (also noted in the Application as endo $\beta(1-4)$ xylanase and henceforth referred to as xylanase), produced by genetically modified (GM) *Bacillus subtilis* that contains a xylanase gene sourced from *Pseudoalteromonas haloplanktis*. The food enzyme is intended for use as a processing aid in the manufacture of bakery and other cereal-based 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 and uniformity; and reduced batter viscosity (see section 2.1.3 in Supporting Document (SD) 1).

Xylanase can also be used in processing other cereal-based products, in addition to baked products, such as pasta, noodles and snacks. In addition to the functional properties outlined above, the enzyme can improve dough handling and accelerate the drying step of these foods, thereby shortening the processing time. 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.

The enzyme is produced by a GM strain of *B. subtilis*, Giza 7101. The xylanase gene is obtained from *P. haloplanktis* (an Antarctic bacterium). Whilst xylanase is naturally present in many cereals, the addition of further xylanase (in this instance from a xylanase gene from *P. haloplanktis*) provides improved effectiveness in the manufacture of cereal-based products under typical production conditions.

P. haloplanktis-derived xylanase produced by *B. subtilis* has been evaluated for safety for the intended purpose and authorised in France (strain Giza 3508), Brazil and Canada (strain Giza 3508), and is deemed to be generally recognised as safe (**GRAS**) in the USA (identity of the production strain for Brazil and USA not provided. Similar to the production strain in this Application (Giza 7101), Giza 3508 is produced by *B. subtilis* strain DB105.

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). Information relating to the main production steps was provided in the Application (summarised in section 2.2.1 of SD1).

1.3 The current Standard

Enzymes used to process and manufacture food are considered processing aids. Processing aids perform their technological purpose during processing and manufacture of food and do not perform a technological purpose in the final food. Only processing aids listed in Schedule 18 in the *Australia New Zealand Food Standards Code* (the Code) are permitted to be used to produce food sold in Australia and New Zealand. Permitted enzymes of microbial origin (including enzymes produced by GM microorganisms) may be listed in the table to subsection S18—4(5) or the table to subsection S18—9(3), depending on whether the permission is for use for any technological purpose and/or any food, or for specific technological purposes and specific foods, respectively.

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 merited 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 with amendment after the consideration of submissions. The approved draft variation is at Attachment A. The approved variation takes effect on gazettal.

The related explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

The draft variation on which submissions were sought is at Attachment C.

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for public comment on a draft variation to the Code between 23 January 2017 and 6 March 2017 after assessing the Application. Four submissions were received, two submissions from government (one Australian, one New Zealand), one from the food industry, and one from a consumer organisation.

The government and food industry submissions supported the Application. Submitters noted that the genetically modified strain of *B. subtilis* for the production of xylanase had been evaluated and authorised in France, Brazil and Canada. They were satisfied that the enzyme preparation is technologically justified and presents no risk to public health and safety.

The fourth submission from a consumer organisation did not oppose the use of the enzyme *per se*, but did object to it being classified as a processing aid. A summary of the submitter's main concerns and FSANZ's response to these is provided in Table 1 below.

Table 1: Summary of issues

Issue	FSANZ response
<p>Permitted food additives being deleted or reclassified as processing aids, thereby denying consumers label information and choice, because, in general, processing aids are exempt from declaration in the statement of ingredients.</p>	<p>Processing aids are defined in section 1.1.2—13 as substances used for a technological purpose in the course of processing, and which do not have a technological purpose in a food for sale. In general, enzymes used in the manufacture of food are captured by this definition and are regulated as processing aids in Schedule 18².</p> <p>FSANZ’s assessment of the Application concluded that it was appropriate to permit the xylanase enzyme for use in the manufacture of food as a processing aid and its use meets the definition of a processing aid as defined in section 1.1.2—13.</p> <p>As a general rule, processing aids are exempt from the requirement to be declared in the statement of ingredients, whereas food additives must be labelled according to the requirements in section 1.2.4—7.</p> <p>The issue of labelling processing aids in the statement of ingredients was considered in 1997 as part of Proposal P143 – Assessment of provisions for the statement of ingredients³, and took into due account comments received in public submissions. The exemption for processing aids was developed as a pragmatic approach taking into account the costs to the food industry of additional labelling and possible benefits to consumers. In addition, the exemption is consistent with labelling requirements internationally.</p>
<p>There is some evidence of harm from enzymes that has been presented to Codex (CX/FA 17/49/12)⁴. If enzymes are used in food then it is requested that their presence continues to be shown in the statement of ingredients and they are not hidden as processing aids, so that consumers can make a choice.</p>	<p>The report of the 49th Session of the Codex Committee on Food Additives (CCFA) (REP17/FA) that considered the document, CX/FA 17/49/12, makes no reference to information regarding amylases (INS 1100 i, ii, iii, iv, v, vi), proteases (INS 1101 i, ii, iii, iv, v, vi), and lipases (INS 1104), other than to note that the proposed deletion of these substances from <i>Class Names and the International Numbering System (INS) for Food Additives (CAC/GL 36-1989)</i> is outside the mandate of the working group established to consider such matters.</p> <p>As mentioned above, as a general rule, substances used as processing aids (including enzymes) are exempt from the requirement to be declared in the statement of ingredients.</p>

² Under section 1.1.2—13(3)(b), an additive permitted as a GMP food additive can also be used as a processing aid.

³ Copy available upon request to standards.management@foodstandards.gov.au.

⁴ Paper prepared by an electronic working group led by Iran for the Joint FAO/WHO Food Standards Programme Codex Committee on Food Additives (CCFA) 49th Session (March 2017) *Proposed draft revision to the International Numbering System (INS) for food additives (CAC/GL 36-1989)*.

Issue	FSANZ response
<p>There is recent scientific evidence of harm from genetically modified enzymes (Budnik et al. (2016))⁵.</p>	<p>FSANZ notes that the Budnik et al. paper investigates the sensitising effects of occupational exposure to enzymes used in flavour, detergent and pharmaceutical production.</p> <p>Occupational exposure is very different to exposure via the diet, both in terms of the route of exposure (which would generally be via inhalation and dermal exposure), and the level to which individuals may be exposed. Exposure to enzymes could be potentially high in the case of occupational handling, where the physical form of the enzyme that the individuals may be exposed to may be a purified and concentrated dust or powder, at very high levels, and on a regular basis. This is very different to what consumers would be exposed to, which is likely to be very low concentrations of the enzyme through ingestion of a blended food ingredient. In addition, residual enzyme in the final food is likely to be inactive and susceptible to digestion, like other dietary proteins. Therefore, any findings of this study are not directly relevant to consumers who are exposed to trace levels through food.</p> <p>The hazard assessment considered the potential allergenicity of the xylanase (in terms of ingestion) and concluded that there were no concerns (see section 2.2). The enzyme is digested (i.e. broken down to constituent amino acids) in the gastrointestinal tract and it has no homology to known allergens.</p>
<p>The submitter would resist any attempt to remove the following enzymes from the Code and hide them as processing aids:</p> <p>1100 a-Amylase 1101 Proteases (papain, bromelain, ficin) 1102 Glucose oxidase 1104 Lipases 1105 Lysozyme.</p>	<p>With the exception of lysozyme (which, in terms of its technological purpose, is classified as a preservative (food additive)), the enzymes mentioned are permitted for use as processing aids under Schedule 18.</p> <p>Food additive permissions are provided in Schedules 15 and 16. Lysozyme is the only enzyme listed which is permitted as a GMP food additive in section S16—2 which, because of subsection 1.1.2—13(3), is also a processing aid. How the substance (enzyme) performs its technological purpose determines whether it is considered a food additive or processing aid. If it performs its purpose during the manufacture or processing but not in the final food, then it is considered a processing aid. If it performs its technological purpose in the final food (as does lysozyme, in its role as a preservative) then it is considered a food additive (and so needs to be labelled as per the requirements in section 1.2.4—7).</p>

2.2 Risk assessment

FSANZ's risk assessment concluded that there are no public health and safety concerns associated with using the enzyme preparation, produced by GM *B. subtilis* that contains a *xylanase* gene sourced from *P. haloplanktis* as a food processing aid based on the following considerations:

⁵ Budnik LT, Scheer E, Burge PS, Baur X (2017) Sensitising effects of genetically modified enzymes used in flavour, fragrance, detergence and pharmaceutical production; cross-sectional study. *Occupational and Environmental Medicine* 74(1):39-45.

- 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 enzyme processing aids already permitted in the Code and overseas.
- The food use of *P. haloplanktis* xylanase expressed in *B. subtilis* has been approved in other countries.
- If residual xylanase were to be present in the final food it would, because of exposure to high temperatures during baking, be denatured and hence inactivated. In addition, it would be as susceptible to digestion as any other dietary protein.
- Bioinformatic analysis indicated that *P. haloplanktis*-derived xylanase has no biologically relevant homology to known food protein allergens.
- There were no treatment-related signs of toxicity in a 90-day repeat dose study in rats with endo $\beta(1,4)$ xylanase concentrate at a dose of 13.94 mg total organic solids (TOS)/kg bw/day. This is orders of magnitude higher than the likely exposure to the enzyme preparation according to the proposed uses.
- The enzyme was not genotoxic or mutagenic *in vitro*.

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

In addition, the evidence presented to support the proposed uses of the enzyme preparation provided adequate assurance that the enzyme, in its commercial form and proposed levels of usage, is technologically justified to be effective in achieving its stated purpose. That is, it performs its technological purpose during processing and manufacture of food and does not perform a technological purpose in the final food. It is therefore appropriately categorised as a processing aid and not a food additive. The enzyme preparation meets international purity specifications for enzymes used in the production of food.

Minor editorial amendments were made to SD1 following the call for submissions.

2.3 Risk management

The risk assessment concluded that there were no safety concerns associated with the use of xylanase, produced by GM *B. subtilis* that contains a *xylanase* gene sourced from *P. haloplanktis* as a processing aid. As processing aids require permissions in the Code, the only risk management options available to FSANZ were to approve or reject the draft variation to the Code.

Additionally, as discussed below, the risk management evaluation considered international standards, the appropriate enzyme nomenclature, the applicability of the labelling provisions in the Code, and an analysis of benefits and costs.

The draft variation was changed so that the permission for the enzyme was listed in the table to subsection S18—9(3) instead of the table to subsection S18—4(5). The effect of this change was to permit the enzyme's use as a processing aid only in the manufacture of bakery and other cereal-based products (as sought by the Applicant) as opposed to its use as a processing aid in any food for any technological purpose. This outcome is consistent with the enzyme's intended use (as stated in the Application) and FSANZ's risk assessment (SD1) which was based on that stated intended use.

2.3.1 International standards

The Codex Alimentarius does not have Standards for processing aids or enzymes. Individual countries regulate the use of enzymes differently to how they are regulated in the Code. However, there are internationally recognised specifications for enzymes. These enzyme specifications are provided through 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 2016). These are primary sources of specifications and are listed in Schedule S3—2 of the Code. Enzyme preparations need to meet these specifications, as well as specifications for heavy metals that are also listed in Schedule 3 (section S3—4), if they are not specified within specifications in sections S3—2 or S3—3.

The enzyme preparation has been evaluated for safety for the intended purpose and authorised for use in France, Brazil and Canada. It is deemed to be generally recognised as safe (**GRAS**) in the USA.

2.3.2 Enzyme nomenclature

FSANZ noted 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 (IUBMB 2017). The name used throughout the Application was 'endo β (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 draft variation to the Code for this enzyme.

2.3.3 Labelling considerations

As a general rule, processing aids (which include a number of permitted enzymes as listed in Schedule 18), 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.

The risk assessment concluded that using the enzyme preparation poses no risk to public health and safety. Therefore, the generic labelling exemption will apply to the use of this enzyme preparation in foods.

2.3.3.1 Labelling requirements for food produced using gene technology

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.

The enzyme is produced from a microbial source, namely GM *B. subtilis* containing a *xylanase* gene sourced from the Antarctic bacterium *P. haloplanktis*. However, data submitted with the Application indicated that the *B. subtilis* production strain is not detectable in the final enzyme preparation.

2.3.3.2 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 in Standard 1.2.3 – Information requirements – warning statements, advisory statements and declarations.

Furthermore, the enzyme preparation is intended to be used in the manufacture of bakery and other cereal-based products which use wheat flour or other cereals containing gluten as the main ingredient. Such foods are required to comply with the mandatory declaration requirement for the presence of cereals containing gluten.

2.3.4 Risk management conclusion

The proposed use of xylanase as a processing aid in the manufacture of cereal products, in its commercial form and proposed levels of usage, is technologically justified. The risk assessment conclusions indicated that there were no public health and safety concerns associated with its use. The enzyme preparation has already been assessed as safe and permitted for use in other major jurisdictions. Based on this information, the preferred risk management option was to approve a draft variation to Schedule 18.

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 on an application or proposal 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 FSANZ 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 and organisations that made submissions on this Application will be notified at each stage of the assessment.

2.5 FSANZ Act assessment requirements

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

The Office of Best Practice Regulation (OBPR), 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 the regulatory change is machinery in nature and their use is voluntary.

Notwithstanding this, FSANZ has considered the costs and benefits that would arise from permitting this Application.

Permitting the use of the enzyme preparation as a food processing aid has benefits to the food industry. In particular, this enzyme preparation has enhanced functional properties in the manufacture of certain cereal products.

Consumers might also benefit from the approval of this processing aid, through a possible increase in the range and quality of cereal products currently available, including increased access to products manufactured overseas using xylanase.

No costs to consumers, Governments, or other stakeholders were identified.

Therefore, FSANZ concluded that the direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the Application outweigh the costs to the community, Government and industry that would arise from the development or variation of such a food regulatory measure.

2.5.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed as a result of the Application, namely a draft variation to the table to subsection S18—9(3).

2.5.1.3 Any relevant New Zealand standards

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

2.5.2.1 Protection of public health and safety

FSANZ undertook a safety assessment (SD1) and concluded there were no public health and safety concerns relating to the use of the enzyme preparation as a processing aid in the manufacture of bakery and other cereal-based products.

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 is 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 were no issues identified with this Application relevant to this objective.

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ used the best available scientific evidence to conduct the risk analysis which is provided in SD1, the Risk and Technical Assessment Report.

The Applicant submitted a dossier of scientific studies as part of their Application. Other technical information 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; these being the JECFA Compendium of Food Additive Specifications and the Food Chemicals Codex specifications for enzymes. These are primary sources of specifications and are listed in Schedule S3—2 of the Code. Enzyme preparations need to meet these specifications, among others listed in Schedule 3, as appropriate (see Section 2.3.1).

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

A number of other countries already permit the use of the enzyme preparation, with some, but not all, specifying use in the manufacture of bakery items. Therefore, the approval of this enzyme preparation would bring Australia and New Zealand into line with other countries which already approve its use.

The Applicant advised that the Australia/New Zealand arm of the 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](#) 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', noting that the enzyme preparation, in its commercial form and proposed levels of usage, as specified in the Application, is technologically justified and effective in achieving its stated purpose.

3 References

[Food Chemicals Codex 10th Edition \(2016\)](#), The United States Pharmacopeia. United States Pharmacopeial Convention, Rockville, MD.

FSANZ (2016) [Australia New Zealand Food Standards Code](#).

IUBMB (2017) [EC 3.2.1.8](#).

JECFA (2016) [General specifications and considerations for enzyme preparations used in food processing](#).

Attachments

- A. Approved draft variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement
- C. Draft variation to the *Australia New Zealand Food Standards Code* (call for submissions)

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



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

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

Dated [To be completed by 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 β (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 inserting in the table to subsection S18—9(3), in alphabetical order

Endo-1,4-beta-xylanase (EC 3.2.1.8) from *Bacillus subtilis*, containing the gene for Endo-1,4-beta-xylanase isolated from *Pseudoalteromonas haloplanktis*.

For use in the manufacture of bakery and other cereal-based products. GMP

Attachment B – Explanatory Statement

1. Authority

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

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

The Authority accepted Application A1125 which seeks to permit the use of the enzyme endo $\beta(1,4)$ xylanase produced by genetically modified (GM) *Bacillus subtilis* that contains a xylanase gene sourced from *Pseudoalteromonas haloplanktis* as a processing aid. The Authority noted that it is to be used in the manufacture of bakery and other cereal-based products. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft 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 the use of the enzyme endo $\beta(1,4)$ xylanase, produced by genetically modified *B. subtilis* that contains a xylanase gene sourced from *P. haloplanktis* as a processing aid for use in the manufacture of bakery and other cereal-based products.

This requires an addition to the table to subsection S18—9(3) in Schedule 18.

3. Documents incorporated by reference

The variation to food regulatory measures does not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1125 included one round of public consultation following an assessment and the preparation of a draft Standard and associated report. Submissions were called for on 23 January 2017 for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variations to Standard 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 permits the use of the enzyme endo β (1,4) xylanase (EC number 3.2.1.8), produced by GM *B. subtilis* that contains a *xylanase* gene sourced from *Pseudoalteromonas haloplanktis* as a processing aid in food. Its technological purpose is use in the manufacture of bakery and other cereal-based products.

Attachment C –Draft variation to the *Australia New Zealand Food Standards Code* (call for submissions)



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

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

Dated [To be completed by 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 β (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 *Thermomyces 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