24 September 2019
[94-19]

Call for submissions – Application A1174

Xylanase[1] from *Trichoderma reesei* as a processing aid (enzyme)

FSANZ has assessed an application made by DuPont Australia Pty Ltd to permit the use of endo-1,4-beta-xylanase from a genetically modified strain of *Trichoderma reesei* as a processing aid in the manufacture of bakery 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 to receive submissions electronically through the FSANZ website via the link on documents for public comment. Submissions can be emailed 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) 5 November 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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[1]The application seeks permission for xylanase, but the accepted IUBMB name and the name used throughout this document (which also reflects the listing in the Code), is endo-1,4-beta-xylanase.

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Supporting document

The following document[2] which informed the assessment of this application is available on the FSANZ website:

SD1 Risk and technical assessment report

[2] http://www.foodstandards.gov.au/code/applications/Pages/A1174–Xylanase-from-Trichoderma-reesei-as-a-PA-(Enzyme).aspx

Executive summary

DuPont Australia Pty Ltd submitted an application to Food Standards Australia New Zealand (FSANZ) seeking permission to use the enzyme endo-1,4-beta-xylanase (Enzyme Commission (EC) number 3.2.1.8) from a new source (being a genetically modified (GM) strain of *Trichoderma reesei*) as a processing aid. The enzyme's purpose is in the manufacture of bakery and other cereal-based products.

The enzyme is derived from a GM strain of *T. reesei* containing the gene for endo-1,4-beta-xylanase from *Aspergillus niger*. The *T. reesei* production strain is not toxigenic or pathogenic and is absent in the final enzyme preparation. Further, both *T. reesei* and *A. niger* have a long history of safe use as the production or donor microorganisms for a number of enzyme processing aids that are already permitted in the Code. Bioinformatic data indicated a lack of homology of the enzyme protein with known toxins or allergens.

After undertaking a risk assessment, FSANZ concludes that there are no public health and safety concerns associated with using this endo-1,4-beta-xylanase. 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 contains wheat starch and wheat flour, and wheat bran may be present, however, labelling requirements exist to inform wheat-allergic individuals.

The enzyme preparation has been approved for use in food production in Denmark, Norway and Peru and is considered Generally Recognized as Safe (GRAS) in the USA.

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 a specific technological purpose. FSANZ proposes a draft variation to the Code to permit endo-1,4-beta-xylanase derived from a GM strain of *T. reesei* as a processing aid for the manufacture of bakery and other cereal-based 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

DuPont Australia Pty Ltd is a manufacturer and marketer of food ingredients, food additives and processing aids, including enzymes.

1.2 The application

The application seeks permission for a new microbial source for the currently permitted enzyme, endo-1,4-beta-xylanase[3] (Enzyme Commission (EC) number 3.2.1.8), as a processing aid. The enzyme is derived from a genetically modified (GM) strain of *Trichoderma reesei*, expressing the endo-1,4-beta-xylanase gene from *Aspergillus niger*. The enzyme is proposed to be used as a processing aid in the manufacture of bakery and cereal-based products.

The enzyme performs its technological function in the baking industry to improve dough stability and dough handling properties.

1.3 The current standards

Australian and New Zealand food laws require food for sale to comply with the following Code requirements.

1.3.1 Permitted use

Enzymes used in processing and manufacturing food are considered processing aids.

Paragraph 1.1.1—10(6)(c) provides that food for sale cannot contain, as an ingredient or component, a substance 'used as a processing aid' unless that substance's use as a processing aid is expressly permitted.

Section 1.1.2—13 defines the expression 'used as a processing aid'. That definition imposes certain conditions on substances permitted by Standard 1.3.3 and Schedule 18 to be used as a processing aid, such that it does not perform a technological function in the final food for sale.

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) of Schedule 18, depending on whether a technological purpose has been specified.

Endo-1,4-beta-xylanase from different microorganisms is permitted in the table to subsection S18—4(5) and the table to subsection S18—9(3).

Endo-1,4-beta-xylanase derived from *T. reesei*, containing the gene for endo-1,4-beta-xylanase isolated from *A. niger* is not currently permitted to be used as a processing aid.

1.3.2 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.

[3] Referred to as 'xylanase' in the application

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

1.3.3 Labelling requirements

Subsection 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.

Subsection 1.2.3—4(1) requires certain foods and substances to be declared when present in a food for sale. Subsection 1.2.3—4(2) states the food or substance may be present as a substance or food used as a processing aid, or an ingredient or component of such a substance or food.

Standard 1.2.4 of the Code generally requires food products to be labelled with a statement of ingredients. Paragraph 1.2.4—3(2)(d) of that Standard exempts substances used as processing aids from the requirement to be declared in the statement of ingredients.

Section 1.5.2—4 requires processing aids that are foods produced using gene technology to be labelled 'genetically modified', where novel DNA and/or novel protein from the processing aid remains present in the final food. The requirement applies to foods for sale that consist of or have as an ingredient, food that is a GM food. The requirements imposed by section 1.5.2—4 generally apply only to foods for retail sale and to foods sold to a caterer under subsection 1.2.1—8(1) and section 1.2.1—15 respectively.

1.3.4 International standards

The applicant's endo-1,4-beta-xylanase has been determined as Generally Recognized as Safe (GRAS) in the United States, and is permitted in Denmark.

The Codex Alimentarius does not establish standards for processing aids or 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 JECFA and the Food Chemicals Codex as noted above.

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

No public health and safety concerns were identified in the assessment of endo-1,4-beta-xylanase produced from a GM strain of *T. reesei*.

This endo-1,4-beta-xylanase has a history of safe use in other countries. Endo-1,4-beta-xylanase produced directly from *A. niger* is also already permitted in the Code. *T. reesei* also has a history of safe use as the production organism for a number of enzyme processing aids that are permitted in the Code. The *T. reesei* production strain is neither toxigenic nor pathogenic and is absent in the final enzyme preparation. Molecular characterisation of the production strain confirmed the inserted DNA is present and is stably inherited.

The enzyme showed no evidence of genotoxicity in a bacterial reverse mutation assay or a chromosomal aberration assay. In a 90-day oral gavage study in rats, the No Observed Adverse Effect Level (NOAEL) was the highest dose tested, 1000 mg/kg bw/day total protein, which is equivalent to 1214.4 mg/kg bw/day total organic solids (TOS). The Theoretical Maximum Daily Intake (TMDI) is calculated to be 0.488 mg/kg bw/day TOS. From these values, the Margin of Exposure (MoE) is approximately 2489.

Bioinformatic data indicated a lack of homology of the enzyme protein with known toxins or allergens. The enzyme preparation contains wheat starch and wheat flour, and wheat bran may be present.

Based on the reviewed 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 was therefore not required.

2.2 Risk management

The risk assessment concluded that there are no safety concerns from the use of endo-1,4-beta-xylanase produced from a GM strain of *T. reesei* as a food processing aid in the manufacture of bakery and other cereal-based 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, the enzyme preparation will provide the food industry with an alternative source of endo-1,4-beta-xylanase.

2.2.1 Regulatory approval for enzymes

FSANZ has concluded that the enzyme meets its stated purpose as a processing aid in the manufacture of bakery and other cereal-based products. The risk assessment has concluded that, in the absence of any identifiable hazard, an ADI of 'not specified' is appropriate for the enzyme. Ingestion of any residual endo-1,4-beta-xylanase 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 enzyme's 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 fungus). 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 'endo-1,4-beta-xylanase' for the enzyme with an EC number of EC 3.2.1.8 (IUBMB 2019). This is the name already listed in the table to subsection S18—4(5) and subsection S18(9)(3). 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 *T. reesei*, while *A. niger* is the gene donor microorganism. These are both already listed as either production, source or donor microorganisms within Schedule 18.

2.2.3 Labelling requirements

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 and no new labelling requirements are proposed.

2.2.3.1 Labelling requirements for food produced using gene technology

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 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 GM strain of *T. reesei* (that is the source microorganism, not the enzyme) remains in that 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, 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 GM food (section 1.5.2—4(1)).

2.2.3.2 Declaration of certain substances

As noted in section 2.1, the powdered form of the enzyme preparation comprises various levels of wheat-based ingredients being wheat starch and wheat flour as carriers.

In accordance with section 1.2.3—4 of Standard 1.2.3 (Information requirements – warning statements, advisory statements and declarations), if wheat is present in a food for retail sale or food sold to a caterer, including when present as a processing aid or an ingredient or component of a processing aid, it must be declared. If the food is not required to bear a label, the allergen information must be displayed in connection with the display of the food or provided to the purchaser on request (section 1.2.1—9 of Standard 1.2.1).

2.2.4 Risk management conclusion

The risk management conclusion is to add the permission for the enzyme endo-1,4-beta-xylanase derived from a GM strain of *T. reesei* as a food processing aid into the table to subsection S18—9(3). This table includes enzymes permitted for a specific technological purpose. In this case, the technological purpose is the manufacture of bakery and other cereal-based products. The maximum permitted level is an amount consistent with GMP.

Labelling requirements exist to provide information to wheat-allergic individuals about the possible presence of wheat proteins in the final enzyme preparation.

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; Codex Alimentarius does not have regulations for enzymes used as processing aids. Amending the Code to permit a new microbial source of a currently permitted enzyme is unlikely to have a significant effect on international trade. 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 the use of processing aids (OBPR correspondence dated 24 November 2010, reference number 12065). This standing exemption was provided as permitting processing aids is machinery in nature and the use of the processing aid is voluntary once the application has been successfully approved. This standing exemption relates to the introduction of a processing aid to the food supply that has been determined to be safe.

FSANZ, however, 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 (section 29 (2)(a)).

This analysis considers permitting the use of endo-1,4-beta-xylanase derived from a GM strain of *T. reesei*, as a processing aid into the table to Schedule 18. That table includes enzymes permitted for a specific technological purpose. 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. 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 of permitting the use of the enzyme endo-1,4-beta-xylanase derived from a GM strain of T. reesei as a processing aid

The enzyme, in certain circumstances, would help improve the dough stability and dough handling properties in bakery products. Food processors would benefit from having another option to improve effectiveness and efficiency of bakery production. Using that option may reduce costs and improve the quality of certain ingredients. Due to the voluntary nature of the permission, industry will only use the enzyme where they believe a net benefit exists.

The enzyme has GRAS status in the USA and is permitted in Denmark. Domestic permissions for this enzyme may provide opportunities for Australian and New Zealand industries to export final products to other countries where the enzyme is or will be permitted as a processing aid.

Consumers may pay lower prices for certain bakery products, if businesses pass-on some of the cost savings from using the enzyme. The quality of certain products for consumers may also improve. The enzyme would have no technical function in the food consumed.

Permitting the enzyme may result in a small cost to government from adding the enzyme to the current range of processing aids that are monitored for compliance.

Conclusions from cost benefit considerations

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting the use of enzyme endo-1,4-beta-xylanase (derived from a GM strain of *T. reesei)* as a processing aid 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 undertook a safety assessment (SD1) and concluded there were no public health and safety concerns associated with the use of endo-1,4-beta-xylanase sourced from a GM strain of *T. reesei* as a food processing aid for use in the baking industries.

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

The labelling considerations for endo-1,4-beta-xylanase are discussed in section 2.2.3 – Labelling requirements.

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 when undertaking the risk analysis, which is provided in SD1. The applicant submitted a dossier of scientific studies and other technical information. This 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 processing aids or enzymes. However, the enzyme has been permitted for use in the US and Denmark. In addition, it meets international specifications for enzyme preparations; being the JECFA Compendium of Food Additive Specifications and the Food Chemicals Codex specifications for enzymes.

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

As mentioned above, the use of this enzyme is already permitted in the United States and Denmark. Therefore, the approval for use of this enzyme would bring Australia and New Zealand into line with other jurisdictions where it is already authorised for use. In this way, Australia and New Zealand will remain competitive with other international markets. This will also help foster continued innovation and improvements in food manufacturing techniques and processes.

The outcome of the risk assessment indicated that there are no public health and safety issues associated with the production microorganism *T. reesei* or with using endo-1,4-beta-xylanase as a food processing aid in the baking industries. It is therefore appropriate that Australian and New Zealand food industries are given the opportunity to benefit from the use of this enzyme as an alternative to those currently permitted. Which enzyme preparation a food manufacturing company uses will depend on a number of economic and other factors.

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

FSANZ identified no issues 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*[4] 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 endo-1,4-beta-xylanase, sourced from *T. reesei*, as a processing aid in the baking industries is consistent with these 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

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

IUBMB (2019) EC 3.2.1.8 https://www.qmul.ac.uk/sbcs/iubmb/enzyme/EC3/2/1/8.html

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

Attachments

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

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

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 A1174 – Xylanase from *Trichoderma reesei* 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 A1174 – Xylanase from* Trichoderma reesei *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

Endo-1,4-beta-xylanase (EC 3.2.1.8) sourced from *Trichoderma reesei* containing the endo-1,4-beta-xylanase gene from *Aspergillus niger*.	For use in the manufacture of bakery and other cereal-based 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.

FSANZ accepted application A1174 which seeks to permit the use of endo-1,4-beta-xylanase from a genetically modified strain of *Trichoderma reesei* as a processing aid 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 prepared a draft Standard.

2. Purpose

The purpose of the draft variation is to amend the table to subsection S18—9(3) in Schedule 18 of the Code to permit the use of endo-1,4-beta-xylanase from a GM strain of *T. reesei* as a food processing aid in the manufacture of bakery and other cereal-based products.

3. Documents incorporated by reference

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

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

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of application A1174 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.

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from needing to develop a Regulatory Impact Statement for proposed variations of the Code to permit additional processing aids (OBPR correspondence dated 24 November 2010 - reference 12065). This standing exemption was provided as permitting additional processing aids is likely to have only a minor impact on business and individuals. It is a minor, deregulatory change that allows for the introduction of a food product to the food supply that has been determined to be safe. The use of the approved processing aid is also voluntary.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

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

The new entry would permit the use of endo-1,4-beta-xylanase (EC 3.2.1.8) from *Trichoderma reesei* containing the endo-1,4-beta-xylanase gene from *Aspergillus niger* as a processing aid. The specific technological purpose for the permission is in the manufacture of bakery and other cereal-based products. A condition of the permission is that the maximum permitted level or amount that may be used must be consistent with good manufacturing practice.