

**10 March 2020**  
**[117-20]**

## **Approval report – Application A1174**

### **Xylanase from GM *Trichoderma reesei* as a Processing Aid (Enzyme)**

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by DuPont Australia Pty Ltd to permit the use of the enzyme 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, including cereal-based beverages.

On 24 September 2019, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received three submissions.

FSANZ approved the draft variation on 4 March 2020. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 6 March 2020.

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

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## Supporting document

The [following document](#)<sup>1</sup> which informed the assessment of this application is available on the FSANZ website:

SD1 Risk and Technical Assessment Report (at Approval)

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<sup>1</sup> [http://www.foodstandards.gov.au/code/applications/Pages/A1174-Xylanase-from-Trichoderma-reesei-as-a-PA-\(Enzyme\).aspx](http://www.foodstandards.gov.au/code/applications/Pages/A1174-Xylanase-from-Trichoderma-reesei-as-a-PA-(Enzyme).aspx)

## Executive summary

DuPont Australia Pty Ltd sought permission to use the enzyme endo-1,4-beta-xylanase (Enzyme Commission (EC) number 3.2.1.8) from a new genetically modified (GM) strain of *T. reesei* as a processing aid for use in the manufacture of bakery and other cereal-based products, including cereal-based beverages.

The enzyme is derived from a GM strain of *T. reesei* containing the gene for endo-1,4-beta-xylanase from *Aspergillus niger* ("*A. 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 concluded 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 for baking purposes contains wheat starch and wheat flour as carrier, and wheat bran may be present due to its use as a fermentation nutrient. The enzyme preparation for the manufacture of cereal-based beverages uses glucose sourced from wheat and soy flour as fermentation nutrients. Labelling requirements exist to inform both wheat allergic and soy 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.

A total of three submissions were received on FSANZ's assessment report, two of which were supportive of the application and proposed draft variation to the Code.

A submission from the applicant at the Call for Submission stage requested the purpose of use of the enzyme be expanded to also include the production of cereal-based beverages, which includes brewing. Technological justification and evidence supporting the request was provided in the submission which was separately assessed and accepted. The approved draft variation is therefore slightly different to that provided in the Call for Submission. The difference is explained in section 1.6 of this report and sections 2.1.2 and 2.1.3 of SD1.

The FSANZ Board has approved a draft variation to the Code, which permits this endo-1,4-beta-xylanase as a processing aid in the manufacture of bakery and other cereal-based products, including cereal-based beverages. 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 food processing aids, including enzymes, for industrial applications.

## 1.2 The application

The application was received by FSANZ on 3 December 2018.

The application originally sought to change the Australia New Zealand Food Standards Code (the Code) to permit use of endo-1,4-beta-xylanase (Enzyme Commission (EC) number 3.2.1.8) from a genetically modified (GM) strain of *T. reesei* as a processing aid in the manufacture of bakery products. The microorganism has been genetically modified to express the endo-1,4-beta-xylanase gene from *A. niger*. The applicant uses the term 'xylanase'<sup>2</sup> within its application.

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

The applicant in a submission at the Call for Submission stage (see section 2.1) sought the permission to also apply for the use in brewing and cereal-based beverage production. The technological justification and evidence provided, supported its use to improve process efficiencies and flexibility of ingredient use (e.g. able to use percentage of barley as alternative to malt for brewing).

## 1.3 The current standards

Australian and New Zealand food laws require food for sale must comply with the Code. The requirements relevant to this application are summarised below.

### *Permitted use*

Enzymes used to process and manufacture food are considered processing aids. Paragraph 1.1.1—10(6)(c) of the Code provides that a food for sale must not contain, as an ingredient or a component, a substance that is 'used as a processing aid', unless expressly permitted by the Code.

Section 1.1.2—13 of the Code provides a definition of '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 purpose 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.

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

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<sup>2</sup> 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.

Code. Paragraph 1.5.2—3(b) of Standard 1.5.2 provides that permission in the Code for use as a processing aid also constitutes the permission required by paragraph 1.1.1—10(6)(g).

#### *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.

#### *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.

Paragraphs 1.2.4—3(2)(d) and (e) exempt processing aids from the requirement to be declared in the statement of ingredients, unless other requirements prevail.

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 genetically modified 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.

### **1.3.1 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, as well as for use in baking in Norway and Peru.

The Codex Alimentarius Commission does not establish standards for processing aids or for enzymes. Individual countries regulate the use of enzymes differently to the Code. However, there are internationally recognised specifications for enzymes. These enzyme specifications are established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) (FAO/WHO 2017) and the Food Chemicals Codex (Food Chemicals Codex 2018).

## **1.4 Reasons for accepting application**

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the FSANZ Act; and
- it related to a matter that might be developed as a food regulatory measure.

## **1.5 Procedure for assessment**

The application was assessed under the General Procedure.

## **1.6 Decision**

The food technology aspect of the Risk and Technical Assessment Report concluded that the enzyme meets its stated purpose in the manufacture of bakery products as well as for cereal-based beverages. The risk assessment concluded that, in the absence of any identifiable hazard, an ADI of 'not specified' is appropriate for the enzyme. Labelling requirements exist to protect wheat-allergic and soy-allergic individuals from any traces of wheat and soy that may be present in the enzyme product (see section 2.3.3 below). FSANZ has approved the use of the enzyme as a processing aid for its stated purpose which has been revised to include the assessment of its use in the manufacture of cereal-based beverages. 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 (which was subsequently amended) is at Attachment C.

## **2 Summary of the findings**

### **2.1 Summary of issues raised in submissions**

FSANZ called for submissions on a proposed draft variation on 24 September 2019. Three submissions were received: one from the applicant and two from government agencies. The applicant requested an amendment to the draft variation by requesting the enzyme be permitted also for use in brewing and cereal-based beverage production. The two submissions from government agencies supported the application and the proposed draft variation to the Code (Table 1) and did not raise any issues. Table 1 below sets out a summary of issues raised in the submissions and FSANZ's responses to those issues (where required).

**Table 1: Summary of issues raised by submissions**

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>The submitter (applicant) requested that the draft variation at the Call-for-Submissions stage be amended so that the stated technological purpose also includes use of the enzyme in “brewing and cereal based food beverage production”.</p> <p>The submission provided additional information explaining that the enzyme (in combination with beta-glucanase) can also be used in the cereal-based beverage production process in either the mashing stage especially when barley is used as a partial alternative to malt (malted barley). Alternatively the enzyme can be used in the fermentation stage of the brewing process. Details of efficiency improvements were provided to support the claim of technological justification in the manufacture of cereal-based beverages.</p>	<p><b>DuPont Australia Pty Ltd (the applicant)</b></p>	<p>FSANZ assessed the request of the submission to consider the use of the enzyme for the manufacture of cereal-based beverages, in addition to its proposed use in the manufacture of bakery and other cereal-based products as proposed in the draft variation at the Call for Submission stage.</p> <p>The technical information provided with the submission provided evidence supporting the claim of technological justification and benefits of using the enzyme for the extra proposed purpose. An assessment of this additional information by FSANZ supported the request. Amendments to the food technology section of SD1 have been made summarising the assessment of the technological purpose and justification, in sections 2.1.2 and 2.1.3 respectively.</p> <p>As an outcome of the assessment of this additional request and technical information provided, FSANZ has amended the draft variation (amendments indicated by underline) so that the enzyme is permitted ‘for use in the manufacture of bakery and other cereal-based products, <u>including cereal-based beverages</u>’.</p>
<p>Supportive</p>	<p>Victorian Department of Health and Human Services and the Victorian Department of Jobs, Precincts and Regions</p>	<p>No response required</p>
<p>Supportive</p>	<p>New Zealand Food Safety (Ministry for Primary Industries)</p>	<p>No response required</p>

## 2.2 Risk assessment

No public health and safety concerns associated with the use of this endo-1,4-beta-xylanase were identified as a result of the hazard assessment.

This endo-1,4-beta-xylanase has a history of safe use in other countries. The enzyme, produced directly from different microbial sources is 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 bodyweight (bw)/day total protein, which is equivalent to 1214 mg/kg bw/day total organic solids (TOS). The Theoretical Maximum Daily Intake (TMDI) was calculated by the applicant to be 0.635 mg/kg bw/day TOS. Comparison of the NOAEL and the TMDI gives a Margin of Exposure (MoE) of approximately 1900.

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 and soy may be present due to their use as nutrients in the fermentation process to produce the enzyme.

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.

For further details on the risk assessment, refer to the Risk and Technical Assessment Report (SD1).

## **2.3 Risk management**

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

### **2.3.1 Regulatory approval for enzymes**

The express permission for the enzyme's use as a processing aid will also provide the permission for the potential presence of the enzyme 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'.

### **2.3.2 Enzyme and source microorganism nomenclature**

FSANZ noted that the International Union of Biochemistry and Molecular Biology (IUBMB), the internationally recognised authority for enzyme nomenclature, uses the 'accepted' name '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.

### **2.3.3 Labelling considerations**

The risk assessment concluded that the use of the enzyme preparation 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.

#### **2.3.3.1 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 for sale.

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 in 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 (subsection 1.5.2—4(1)).

#### **2.3.3.2 Declaration of certain substances**

As noted in section 2.2, the powdered form of the enzyme preparation comprises various levels of wheat-based ingredients, being wheat starch and wheat flour as carriers. Also wheat and soy may be present in the enzyme preparation since products from wheat and soy are used as nutrients in the enzyme fermentation.

FSANZ notes the enzyme will be used to manufacture of bakery and other cereal-based products, including cereal-based beverages. Bakery and other cereal-based products, including cereal-based beverages that contain wheat as an ingredient will already require a mandatory wheat declaration. However, a wheat declaration will still be required if the enzyme is used in the manufacture of such products where those products themselves are wheat-free.

Certain products are, however, exempt from the requirement to declare wheat. Subparagraph 1.2.3—4(1)(b)(i)(A) of the Code, for example, provides an exemption for beer from the requirement to declare cereals containing gluten, including wheat. As noted in section 1.2, the enzyme is intended to be used in the manufacture of cereal-based beverages, including those which are brewed.

Certain products are also exempt from the requirement to declare soy, but these exemptions do not apply to soy protein, which is a nutrient raw material used during the production of this enzyme.

### **2.3.4 Risk management conclusion**

The risk management conclusion is to add the permission for endo-1,4-beta-xylanase from a GM strain of *T. reesei* as a processing aid into the table to S18—9(3), which includes enzymes permitted for a specific technological purpose. The technological purpose is for use in the manufacture of bakery and other cereal-based products, including cereal-based

beverages. The maximum permitted level is an amount consistent with GMP. Labelling requirements exist to protect wheat and soy allergic individuals from the potential presence of wheat and soy proteins in the final enzyme preparation. These involve the declaration of these substances, where appropriate.

## **2.4 Risk communication**

### **2.4.1 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.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application. Every submission was considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

## **2.5 FSANZ Act assessment requirements**

When assessing this application and the subsequent development of a food regulatory measure, FSANZ had regard to the following matters in section 29 of the FSANZ Act:

### **2.5.1 Section 29**

#### **2.5.1.1 Consideration of costs and benefits**

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for permitting new processing aids (OBPR correspondence dated 24 November 2010, reference number 12065). This standing exemption was provided as permitting processing aids is machinery in nature as they are part of implementing a regulatory framework where the use of new processing aids is voluntary once an application has been 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, gave consideration to the costs and benefits that would arise from this measure, for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

The purpose of this consideration was to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo (i.e. rejecting the application). This analysis considered either approving or rejecting the application (retain the status quo). A consideration of costs and benefits was included in the Call for Submissions (CFS) report based on the information and data held at that time. No further information has been received during the consultation process to date that influenced the findings from the analysis of costs and benefits in the CFS in relation to the enzyme being used in the manufacture of bakery and other cereal-based products. However, the request from the applicant in response to the CFS to also include use of the enzyme in the

manufacture of cereal-based beverages has not changed the consideration of the costs and benefits.

The consideration of the costs and benefits outlined in this section was not intended to be an exhaustive, quantitative economic analysis of the measure and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment sought to highlight the likely positives and negatives of moving away from the status quo by permitting the use of endo-1,4-beta-xylanase from a GM strain of *T. reesei*, as a processing aid in the manufacture of bakery and other cereal-based products, including cereal-based beverages.

#### *Costs and benefits permitting the use of 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. For use in brewing and cereal-based beverage production, the use of the enzyme may assist in process efficiencies and flexibility to use alternative 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, Norway and Peru. 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 and other cereal-based products, including cereal-based beverages, 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 was that the direct and indirect benefits that would arise from permitting endo-1,4-beta-xylanase (from a GM strain of *T. reesei*) as a processing aid outweigh the associated costs.

#### **2.5.1.2 Other measures**

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed as a result of the application.

#### **2.5.1.3 Any relevant New Zealand standards**

Standards 1.1.1, 1.1.2 and 1.3.3 and Schedule 18 apply in both Australia and New Zealand and there are no other 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 Risk and technical assessment (SD1) and concluded there are no public health and safety issues associated with the use of this endo-1,4-beta-xylanase.

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

The labelling considerations for the enzyme processing aid are discussed in section 2.3.3.

### **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 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 – Risk and technical assessment report. The applicant submitted a dossier of scientific studies as part of their application and subsequent request to extend the scope of their application. Other technical information sourced by FSANZ, including scientific literature, was also used in assessing the application and subsequent request.

- **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 several countries overseas (see section 2.5.1.1). In addition, it meets international specifications for enzyme preparations – 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, this enzyme is already permitted in several countries. 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.

Ultimately, the food industry will make their own economic decisions, taking into account the costs and benefits of using the new enzyme, to determine if it is of benefit to their particular business.

- **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](#)<sup>3</sup> 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 this endo-1,4-beta-xylanase as a processing aid in the manufacture of bakery and other cereal-based products, including cereal-based beverages is consistent with these specific order policy principles for 'Technological Function'.

### 3 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 (2017) 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 Pharmacopoeial Convention, Rockville, MD. <http://publications.usp.org/>

### Attachments

- A. Approved 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)

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<sup>3</sup> <http://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Substances-other-than-Vitamins-and-Minerals>

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



### Food Standards (Application A1174 – Xylanase from *Trichoderma reesei* 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 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 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) sourced from <i>Trichoderma reesei</i> containing the endo-1,4-beta-xylanase gene from <i>Aspergillus niger</i> .	For use in the manufacture of bakery and other cereal-based products, including cereal-based beverages	GMP
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## **Attachment B – Explanatory statement**

### **1. Authority**

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

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

The Authority accepted Application A1174, which seeks permission to use endo-1,4-beta-xylanase from a genetically modified strain of *Trichoderma reesei* as a processing aid in the manufacture of bakery products and other cereal-based products, including cereal-based beverages. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation to the Code.

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 an amendment to 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 genetically modified strain of *Trichoderma reesei* as a processing aid in the manufacture of bakery and other cereal-based products, including cereal-based beverages.

### **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 (11<sup>th</sup> 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 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. Submissions were called for on 24 September 2019 for a six-week consultation period.



The Office of Best Practice Regulation (OBPR) granted the Authority 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 processing aid 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) sourced 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 the manufacture of bakery and other cereal-based products, including cereal-based beverages.

A condition of the permission is that the maximum permitted level or amount that may be used must be consistent with good manufacturing practice.

## Attachment C – Draft variation to the Australia New Zealand Food Standards Code (Call for Submissions)



### Food Standards (Application A1174 – Xylanase from *Trichoderma reesei* 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 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 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) 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