

15 February 2018
[38-18]

Call for submissions – Application A1153

Endo-1,4- β -xylanase from *Trichoderma reesei* as a processing aid (enzyme)

FSANZ has assessed an Application from AB Enzymes to permit the use of endo-1,4- β -xylanase (EC 3.2.1.8) as a processing aid (enzyme). The enzyme is obtained from a genetically modified strain of *Trichoderma reesei* (*T. reesei*) expressing a xylanase gene from *Thermopolyspora flexuosa* (*T. flexuosa*) for use in the manufacture and/or processing of bakery products, cereal products, grain, cereal based beverages (including beer) and potable alcohol. FSANZ 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 application number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 29 March 2018

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:

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Supporting document

The following document which informed the assessment of this Application is available on the FSANZ website:

SD1 [Food technology and safety assessment](#)

Executive summary

AB Enzymes GmbH (AB Enzymes) submitted an Application to amend the *Australia New Zealand Food Standards Code* (the Code) to permit the use of endo-1,4- β -xylanase from a genetically modified strain of *T. reesei* containing a xylanase gene isolated from *T. flexuosa* (endo-1,4- β -xylanase) as a processing aid (enzyme).

The enzyme works by breaking down cell walls in plant-based foods, which results in improved quality and production efficiencies. It will be used to depolymerise arabinoxylans during the manufacture and/or process bakery products, cereal products, grain, cereal based beverages (including beer) and potable alcohol.

Enzymes used to produce and manufacture food are considered processing aids. Permitted processing aids are listed in Schedule 18 of the Code.

The safety assessment concluded that there are no public health and safety issues associated with using endo-1,4- β -xylanase as a processing aid (enzyme).

The food technology assessment concluded that the enzyme's use as a processing aid in the quantity and form proposed is technologically justified. It is appropriately classified as a processing aid since the enzyme performs its technological purpose during processing and/or manufacture of food only. The proposed maximum permitted level is good manufacturing practice (GMP).

The enzyme also complies with internationally accepted enzyme identification, chemical and microbiological specifications.

FSANZ has therefore prepared a draft variation to the table to subsection S18—9(3) in Schedule 18 of the Code to permit the use of endo-1,4- β -xylanase as a processing aid (enzyme) for a specific technological purpose in certain foods, at levels of GMP.

1 Introduction

1.1 The Applicant

The Applicant is AB Enzymes, an industrial biotech company that specialises in developing, manufacturing and supplying enzyme preparations for industrial applications. This includes food grade enzymes.

1.2 The Application

The purpose of the Application is to amend the Code to permit the use of endo-1,4- β -xylanase from a genetically modified strain of *T. reesei* containing a xylanase gene isolated from *T. flexuosa* (endo-1,4- β -xylanase) as a processing aid.

Endo-1,4- β -xylanase benefits food manufacturers and processors by breaking down cell walls in plant-based foods, which results in improved quality and production efficiencies.

The technological purpose of endo-1,4- β -xylanase is to depolymerise arabinoxylans during the manufacture and/or processing of bakery products, cereal products, grain, cereal based beverages (including beer) and potable alcohol.

1.3 The current standard

Enzymes used in food manufacturing and/or processing are considered processing aids as although they may be present in the final food, they are no longer providing a technological purpose in the final food.

Paragraph 1.1.1—10(6)(c) of the *Australia New Zealand Food Standards Code* (the Code) provides that a food for sale must not have, as an ingredient or a component, a substance that is used as a processing aid, unless expressly permitted.

Standard 1.3.3 and Schedule 18 of the Code list the permitted processing aids. Enzymes of microbial origin permitted to be used as processing aids are listed in the table to subsection S18—4(5) or in the table to subsection S18—9(3). The table to subsection S18—9(3) lists those substances, including enzymes, that are permitted to be used as processing aids for specific technological purposes.

Section 1.1.2—13 of the Code defines the expression ‘used as a processing aid.’ That definition imposes requirements 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.

Schedule 18 of the Code currently contains permissions for endo-1,4- β -xylanase (EC 3.2.1.8) used as a processing aid for various technological purposes. However, endo-1,4- β -xylanase (EC 3.2.1.8) from a genetically modified strain of *T. reesei* containing a xylanase gene isolated from *T. flexuosa* is not listed in Schedule 18. Therefore, its use as a processing aid is currently not permitted.

1.4 International standards

The enzyme has been approved for use in food production in France and the USA.

The Codex Alimentarius does not establish Standards for processing aids or for enzymes. Individual countries regulate the use of enzymes differently to the Code.

There are internationally recognised specifications for enzymes. These enzyme specifications are established by JECFA (2006) and the Food Chemicals Codex (Food Chemicals Codex 2014).

1.5 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 warranted the variation of a food regulatory measure.

1.6 Procedure for assessment

The Application is being assessed under the General Procedure.

2 Summary of the assessment

2.2 Food technology and safety assessment

2.2.1 Food technology assessment

The food technology assessment concluded that the use of the enzyme as a processing aid in the quantity and form proposed is technologically justified. It is appropriately classified as a processing aid since the enzyme performs its technological purpose during processing and/or manufacture of food. The proposed maximum permitted level is GMP.

The enzyme meets the internationally accepted enzyme identification (EC 3.2.1.8), and accepted chemical and microbiological specifications.

For further details on the food technology assessment refer to the Food technology and safety assessment (SD1).

2.2.2 Safety assessment

There are no public health and safety concerns associated with the use of endo-1,4- β -xylanase as a food processing aid, because:

- The production organism *T. reesei* is not toxigenic or pathogenic and is absent in the final enzyme preparation proposed to be used as a food processing aid. Further, *T. reesei* has a long history of safe use as the production organism for a number of enzyme processing aids that are already permitted in the Code.
- Endo-1,4- β -xylanase from *T. reesei* was not mutagenic or genotoxic *in vitro*.
- The no observable adverse effect level (NOAEL) in a 13-week repeat dose oral toxicity study in rats was the highest dose tested and corresponds to 1000 mg/kg bw/day or 940 mg total organic solids (TOS)/kg bw/day. This is more than 2000-fold higher than the Applicant's estimate of an individual's theoretical maximal daily intake (0.41 mg TOS/kg bw/day) based on the proposed uses, as stated in the Application.
- Endo-1,4- β -xylanase from *T. reesei* does not have the characteristics of a potential food allergen and ingestion of any residual endo-1,4- β -xylanase in food is unlikely to pose an allergenicity concern.

FSANZ has reviewed the toxicological data and concluded that in the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) for endo-1,4- β -xylanase 'not specified' is appropriate. A dietary exposure assessment was therefore not required.

For further details on the safety assessment refer to the Food technology and safety assessment (SD1).

2.3 Risk management

The risk management options available to FSANZ, after assessment, were to reject the Application or to prepare a draft variation to amend the Code to permit the enzyme's used as processing aid, imposing any appropriate conditions.

The food technology and safety assessment concluded that there were no public health and safety concerns associated with using endo-1,4- β -xylanase as a processing aid in the manner proposed in the Application and that its use as a processing aid in the quantity and form proposed is technologically justified.

For this reason, the appropriate risk management option was to prepare a draft variation to amend the Code to permit the use of endo-1,4- β -xylanase, protein engineered variant (EC 3.2.1.8) from *T. reesei*, containing a gene for endo-1,4- β -xylanase isolated from *T. flexuosa*, as a processing aid.

The Application requested listing the permission for the enzyme in the provisions of the Code that would have permitted the enzyme's use for any technological purpose and in any food. This was not consistent with the risk assessment which assessed the enzyme only for the technological purpose stated in the Application. For this reason the permission for the enzyme will be listed in subsection S18—9(3), with the technological purpose as the depolymerisation of arabinoxylans during the manufacture and/or processing of bakery products, cereal products, grain, cereal based beverages (including beer); and potable alcohol. After notification, the Applicant has confirmed that they had no objection to this approach

In the absence of any concerns identified in the food technology and safety assessment, the permitted level is at good manufacturing practice (GMP).

2.3.1 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.

The safety assessment concluded that using the enzyme preparation poses no risk to public health and safety. Therefore, no additional labelling requirements are required in this case. The general exemption for processing aids will apply to foods produced using this particular enzyme as a processing aid.

2.3.1.1 Labelling requirements for food produced using gene technology

Standard 1.5.2, outlines provisions for labelling of foods produced using gene technology. Although processing aids are not normally subject to labelling on the final food, subsection 1.5.2—4(1) indicates that labelling requirements apply for processing aids where novel DNA and/or novel protein from the processing aid remains present in the final food.

Subsection 1.5.2—4(5) defines novel DNA and/or novel protein:

novel DNA and **novel protein** mean DNA or protein which, as a result of the use of gene technology, is different in chemical sequence or structure from DNA or protein present in counterpart food that has not been produced using gene technology, other than protein that:

- (a) is *used as a processing aid or *used as a food additive; and
- (b) has an amino acid sequence that is found in nature.

The safety assessment notes that the enzyme expressed by *T. reesei* is a truncated protein that differs in sequence to the native protein found in *T. flexuosa* (refer to section 3.4.1 of Supporting Document 1). If approved, food produced using this endo-1,4- β -xylanase enzyme would be required to be labelled 'genetically modified' in conjunction with the name of the processing aid where novel protein remains in the final food.

2.3.1.2 Declaration of certain substances

The powdered form of the endo-1,4- β -xylanase enzyme contains a wheat-based carrier, which makes up approximately 95.5% of the enzyme preparation. If wheat is present in a food for retail sale or food sold to a caterer, it must be declared in accordance with section 1.2.3—4 of Standard 1.2.3, which requires that food bear or be accompanied by warning statements, advisory statements and declarations in certain circumstances.

This enzyme is intended for use in the manufacture and/or processing of bakery products (e.g. breads, biscuits, cakes and tortillas), grain, cereal based beverages (including beer) and potable alcohol. With the exception of alcohol distilled from wheat, these foods would have to comply with the mandatory declaration requirement for the presence of cereals containing gluten (which includes wheat). In the case where bakery products are made without gluten containing cereals, a 'gluten-free' claim can only be made subject to the food meeting the conditions set out in Schedule S4—3. For example the food must not contain detectable gluten.

If the food is unpackaged, the allergen information must be displayed in connection with the display of the food or provided to the purchaser on request (section 1.2.9 of Standard 1.2.1).

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 of this Application.

The draft variation in this Application will be considered for approval by the FSANZ Board taking into account public comments received from this call for submissions.

2.4.2 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.

Amending the Code to permit endo-1,4- β -xylanase for use as a processing aid is unlikely to have a significant effect on international trade as the enzyme meets international specifications for food enzymes. 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.

2.5 FSANZ Act assessment

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:

2.5.1 Section 29 of the FSANZ Act considerations

2.5.1.1 Cost benefit considerations

Objectives for cost benefit consideration

The objective of this consideration is to determine whether consumers, industry and government are likely to benefit from a change to the status quo by accepting the Application.

Accepting the application would mean varying schedule 18 to permit the use of endo-1,4- β -xylanase (EC 3.2.1.8) from a genetically modified strain of *T. reesei* expressing a modified xylanase gene from *T. flexuosa* as a processing aid (enzyme) for use in certain foods.

As FSANZ can approve or reject the Application under S21 of the FSANZ Act, approving the Application is the only proposed measure that has been considered against the status quo (i.e. rejecting the Application).

FSANZ can conclude there is no other practical food regulatory measure aside from accepting or remaining with the status quo (i.e. rejecting the application).

Standing exemption from FSANZ completing a regulatory impact statement

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for the approval of additional processing aids (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting additional processing aids is a minor, deregulatory change and their use is voluntary. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

Despite that exemption, the FSANZ Act requires FSANZ to consider whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the consumers, government or industry (S.29 (2)(a)). FSANZ is also required to consider whether other measures (available to the Authority or not) would be more cost-effective than a food regulatory measure developed or varied as a result of the application (s29(2)(c)).

Costs and benefits

The consideration of the costs and benefits is not intended to be an exhaustive, quantitative economic analysis of the proposed measures. The considerations/assessment sought to highlight the likely benefits and costs of changing from the status quo by accepting the Application.

Table 1 Proposed food regulatory measure – accept the Application

Sector	Costs or benefits to sector
Consumers	<p>The use of the enzyme as a processing aid in the manner proposed will not pose a health or safety risk for consumers. Consumers may benefit from the choice of additional food products and better quality that become available due to the use of the enzyme by Australian and New Zealand manufacturers and access to products manufactured using enzyme that are currently manufactured overseas.</p> <p>Prices for products the enzyme is used in may be reduced.</p>
Industry	<p>The enzyme works by breaking down cell walls in plant-based foods, which results in improved quality and production efficiencies and can provide a benefit (in terms of product and/or competitive advantage) to food manufacturers.</p> <p>The enzyme has already been permitted for use overseas. Permission to use the enzyme as a processing aid will enable Australia/New Zealand food manufacturers to access and use a product assessed as safe that is available to their overseas competitors. This will improve their capacity to compete in overseas markets. This will be offset to some extent by a wider variety of enzymes for Australia/New Zealand food manufacturers.</p> <p>Use by industry is voluntary, therefore it will only be used where industry believe a net benefit exists above using existing manufacturing processes.</p>
Governments	<p>There may be some costs to government in terms of monitoring and compliance in that regulators will need to be made aware this is now a permitted processing aid - enzyme. There are no other costs or benefits to governments associated with this option.</p>

Conclusions from cost benefit considerations

The direct and indirect benefits that would arise from permitting the use of this particular enzyme as a processing aid most likely outweigh the costs arising from that permission being granted.

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 variation of a food regulatory measure as a result of the Application. See discussion above.

2.5.1.3 Any relevant New Zealand standards

Standards 1.1.1, 1.1.2 and 1.3.3; and Schedule 18 from the Code apply in both Australia and New Zealand. There are no other relevant New Zealand standards.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2. Subsection 18(1)

FSANZ has 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 has completed a safety assessment (SD1) which is summarised in section 2.2.2. The safety assessment concluded there are no public health and safety concerns in permitting endo-1,4- β -xylanase (EC 3.2.1.8) sourced from *T. reesei*, containing a modified xylanase gene from *T. flexuosa*, as a processing aid for use in certain food applications.

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

No issues have been identified. The labelling requirements relating to permitting endo-1,4- β -xylanase (EC 3.2.1.8) sourced from *T. reesei* are discussed in Section 2.3.2 – Labelling considerations.

2.5.2.3 The prevention of misleading or deceptive conduct

There are no issues for preventing misleading or deceptive conduct in this Application.

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

2.5.3.1 The need for standards to be based on risk analysis using the best available scientific evidence

FSANZ has used the best available scientific evidence to conduct the food technology and safety assessment (SD1). The Applicant submitted supporting information (including scientific studies, product information and relevant literature) as part of their Application. FSANZ also considered other information relevant to the Application.

2.5.3.2 The promotion of consistency between domestic and international food standards

There are no Codex Alimentarius standards for enzymes. However, this enzyme is permitted for use in France and the USA. It also meets international specifications in section 1.4.

2.5.3.3 The desirability of an efficient and internationally competitive food industry

Permitting this enzyme provides the Applicant and food manufacturers and processors with the opportunity to obtain improved quality and production efficiencies in the production and manufacture of certain foods.

2.5.3.4 The promotion of fair trading in food

FSANZ did not identify any relevant issues relating to this consideration.

2.5.3.5 Any written policy guidelines formulated by the Forum on Food Regulation

The Ministerial Policy Guideline for [Addition to Food of Substances other than Vitamins and Minerals](#)¹ 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, and
- no nutrition, health or related claims are to be made in regard to the substance.

FSANZ has determined that permitting endo-1,4- β -xylanase (EC 3.2.1.8) from a genetically modified strain of *T. reesei* containing a xylanase gene isolated from *T. flexuosa* as a processing aid for use in certain food applications is consistent with the Ministerial Policy Guideline and the specific order principles for 'Technological Function'.

3 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

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

4 References

[Food Chemicals Codex 9th Edition \(2014\)](#), The United States Pharmacopeia, United States Pharmacopeial Convention, Rockville, MD. (Accessed November 2017).

IUBMB (2017) International Union of Biochemistry and Molecular Biology (IUBMB) Enzyme Nomenclature. [Enzyme Nomenclature for EC 3.2.1.8](#) (Accessed 27th November 2017).

JECFA (2006) [General specifications and considerations for enzyme preparations](#), used in food processing. (Accessed 24th November 2017).

Attachments

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

¹ <http://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Substances-other-than-Vitamins-and-Minerals>

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



Food Standards (Application A1153 – Endo xylanase from *Trichoderma reesei* as a Processing Aid) 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 Name and Position of Delegate

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 A1153 – Endo xylanase from Trichoderma reesei as a Processing Aid) 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-β-xylanase, protein engineered variant, (EC 3.2.1.8) from <i>Trichoderma reesei</i> , containing the gene for endo-1,4-β-xylanase isolated from <i>Thermopolyspora flexuosa</i>	For depolymerisation of arabinoxylans during the manufacture and/or processing of the following types of food: (a) bakery products; (b) cereal products; (c) grain; (d) cereal based beverages (including beer); and (e) potable alcohol	GMP
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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 A1153 which seeks to permit the use of endo-1,4- β -xylanase (EC 3.2.1.8) from *T. reesei*, containing a modified xylanase gene from *T. flexuosa* as a processing aid. The technological purpose is for the depolymerisation of arabinoxylans during the manufacture and/or processing of bakery products, cereal products, grain, cereal based beverages (including beer); and potable alcohol. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation to the Code.

2. Purpose

The purpose of the draft variation is to amend the Code to permit the use of endo-1,4- β -xylanase (EC 3.2.1.8) from a genetically modified strain of *T. reesei* containing a xylanase gene isolated from *T. flexuosa* as a processing aid. The technological purpose is for the depolymerisation of arabinoxylans during the manufacture and/or processing of bakery products, cereal products, grain, cereal based beverages (including beer); and potable alcohol.

3. Documents incorporated by reference

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

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1153 will include one round of public consultation following an assessment and the preparation of a draft variation to the Code and associated assessment summary.

The Office of Best Practice Regulation, in a letter dated 24 November 2010 (reference 12065), provided a standing exemption from a full cost benefit analysis and Regulatory Impact Statement for Applications relating to processing aids. This is because processing aids are no longer providing a technological purpose in the final food and are mostly or completely removed during food manufacture and/or processing. Their use is also voluntary (i.e. non mandatory).

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

Item [1] inserts a new entry into the table to subsection S18-9(3) in Schedule 18 of the Code.

The new entry would permit the use of the enzyme, endo-1,4- β -xylanase, protein engineered variant (EC 3.2.1.8) from *T. reesei* containing the gene for endo-1,4- β -xylanase isolated from *T. flexuosa* as a processing aid in food for the technological purpose specified in that permission.