21 June 2018
[50-18]

Approval report – Application A1153

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

Food Standards Australia New Zealand (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) 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.

On 15 February 2018, FSANZ made a call for submissions on a draft variation to the Australia New Zealand Food Standards Code (the Code) together with the call for submissions and food technology/safety assessment documents. FSANZ received six submissions.

FSANZ approved the draft variation on 7 June 2018. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 18 June 2018.

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 which informed the assessment of this Application are available on the FSANZ website:

SD1 Food technology and safety assessment

Executive summary

AB Enzymes GmbH (AB Enzymes) applied 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 (GM) strain of *Trichoderma reesei* containing a xylanase gene isolated from *Thermopolyspora flexuosa* (endo-1,4-β-xylanase) as a processing aid (enzyme).

The enzyme breaks down cell walls in plant-based foods, which results in improved quality and production efficiencies. The enzyme's technological function is to depolymerise arabinoxylans during the manufacture and/or processing of bakery products, cereal products, grain, cereal based beverages (including beer) and potable alcohol.

FSANZ has completed a food technology and safety assessment and concluded that there are no public health and safety issues associated with using endo-1,4-β-xylanase as a processing aid (enzyme) and that the enzyme's use as a processing aid in the quantity and form proposed was technologically justified.

The enzyme is appropriately classified as a processing aid since the enzyme performs its technological purpose during processing and/or manufacture of food only.

Food produced using endo-1,4-β-xylanase must carry the labelling statement 'genetically modified' where novel protein is present. Denaturation of the enzyme protein does not alter the status of the food as being genetically modified.

With the exception of alcohol distilled from wheat, foods this enzyme is used in must comply with the mandatory declaration requirement for the presence of cereals containing gluten (which includes wheat).

FSANZ has therefore prepared a draft variation to 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 good manufacturing practice (GMP).

1 Introduction

1.1 The applicant

The applicant was AB Enzymes GmbH (AB Enzymes), an industrial biotech company that specialises in developing and manufacturing enzyme preparations for industrial applications, including food grade enzymes.

1.2 The application

FSANZ received the Application on 31 August 2017.

The Application sought an amendment to the Australia New Zealand Food Standards Code (the Code) to permit the use of endo-1,4-β-xylanase from a GM 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. This helps reduce viscosity in the food and makes food processing easier.

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 no longer provide a technological purpose in the final food.

Paragraph 1.1.1—10(6)(c) 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 list the permitted processing aids. 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 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 purpose in the final food for sale.

Schedule 18 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 GM 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.

1.3.1 International standards

Individual countries regulate the use of enzymes differently to the Code. The enzyme has been approved for use in food production in France and the USA. Codex Alimentarius does not establish standards for processing aids or for enzymes.

There are internationally recognised specifications for enzymes. These enzyme specifications are established by Joint FAO/WHO Expert Committee on Food Additives (JECFA 2006) and the Food Chemicals Codex (Food Chemicals Codex 2014).

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 was assessed under the general procedure.

1.6 Decision

The draft variation proposed during assessment was approved without change. The approved draft variation is at Attachment A. The variation takes effect on the date of 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.

2 Summary of findings following the call for submissions

2.1 Summary of submissions

FSANZ called for submissions on a proposed draft variation on 15 February 2018. Six submissions were received from:

- the New Zealand Food and Grocery Council
- the Ministry for Primary Industries (New Zealand)
- the Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources
- AB Enzymes
- South Australia Health
- a private individual.

Four submissions supported the application (New Zealand Food and Grocery Council, Ministry for Primary Industries, and Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources, South Australia Health). Some submissions raised issues, which are summarised in Table 1.

Table 1: Summary of issues raised in submissions

Issue	Raised by	FSANZ response
The truncated endo-1,4-β-xylanase can be found in nature and meets subsection 1.5.2-4(5), such that the 'genetically modified' labelling statement on final foods is not required.	AB Enzymes	The truncated xylanase is not a natural transcript of the gene nor is it the result of a gene variant. The truncation is due to a deletion of part of the gene sequence resulting in the expression of a shorter protein. This means that the end product (being endo-1, 4- β-xylanase) is not found in nature and considered to be protein engineered. Protein engineered enzymes require labelling as 'genetically modified' where the novel protein remains in the final food. Labelling requirements for GM food are set out in Standard 1.5.2 Food produced using gene technology of the Code.
All gene technology must be regulated and labelled. The Gene Technology Act 2000 defines Gene Technology as, 'any technique for the modification of genes or other genetic material'. It must be regulated as we have a right to know what we are eating and make choices about what we eat.	Private individual	The Gene Technology Act 2000 does not apply to food. Requirements for GM food are set out in the Code and are given legal effect through the Australian State and Territory Food Acts and the New Zealand Food Act. FSANZ is proposing to apply the same regulatory approach that applies to all approved GM foods in Australia and New Zealand. Food produced using this endo-1,4-β-xylanase enzyme must carry the 'genetically modified' labelling statement where novel protein is present. This helps consumers make an informed choice about the food they purchase and consume. For further detail on labelling requirements refer to section 2.3.1.

Issue	Raised by	FSANZ response
In general support of the application. For the food categories this enzyme is permitted in (and included in the draft variation), the terms are not defined in the Code i.e. 'bakery products, cereal products, grain, cereal based beverages (including beer) and potable alcohol.' Terms not defined in the Code (Standard 1.1.2) make interpretation and enforcement difficult.	South Australia Health	This Application is not the vehicle to consider a change to the Code's structure and use of definitions. In terms of the draft variation in issue, FSANZ does not see a need to provide a prescriptive, all-inclusive definition detailing what is and what is not a 'bakery product' etc for the purposes of this one processing aid permission. These terms are already present and undefined in the Code (see, for example, Schedules 15, 17, and 22). Where definitions are provided (e.g., definition of 'dairy products'), these definitions are only illustrative (i.e. 'dairy products' includes …) and are not prescriptive. In the absence of a definition, these terms generally have their accepted and ordinary meaning. FSANZ is unaware of any evidence of a problem with this approach to date. Nor has any other jurisdiction raised this as an issue.
New Zealand Food and Grocery Council support combining processing aid and food additive applications into a streamlined application, assessment and approval process.	New Zealand Food and Grocery Council	This issue is broader and not specific to only this application. FSANZ considers that Part 3, Division 1 of the *Food Standards Australia New Zealand Act 1991* details the requirements for accepting, assessing and approving applications, including statutory timeframes. FSANZ must manage applications submitted to FSANZ in accordance with its statutory requirements.

2.2 Risk assessment

FSANZ completed a safety assessment and concluded there are no public health and safety issues associated with the use of endo-1,4-β-xylanase from *T. reesei* as a food processing aid. Endo-1,4-β-xylanase was not genotoxic *in vitro*, and caused no adverse effects in a sub-chronic toxicity study in rats. The enzyme does not have the characteristics of a food allergen and is unlikely to pose an allergenicity concern. 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.

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

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

2.3 Risk management

On the basis of the conclusions of the risk assessment, a draft variation to permit the use of this processing aid was considered. The cost benefit considerations concluded that the direct and indirect benefits that would arise from permitting the use of this enzyme as a processing aid most likely outweigh the costs arising from that permission being granted

Based on the risk assessment, cost benefit considerations and consideration of submissions, FSANZ's decision was to approve the draft variation to the Code.

Other risk management issues on labelling requirements and the difference in draft variation sought for this application are provided below.

2.3.1 Labelling requirements

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. This is in accordance with paragraphs 1.2.4—3(2)(d) and (e) in Standard 1.2.4 (Information requirements – statement of ingredients).

The general exemption for labelling processing aids will apply to foods produced using this enzyme as a processing aid. However, labelling requirements described in sections 2.3.1.1 and 2.3.1.2 below may trigger the need for a mandatory 'genetically modified' labelling statement or a declaration of certain substances.

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) provides that labelling requirements for genetic modification 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 to 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.

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*. Denaturation of the enzyme protein does not alter the status of the food as being genetically modified. Consequently, the labelling statement 'genetically modified' will apply where novel protein remains in food produced using this endo-1,4-β-xylanase enzyme. The labelling statement will need to be made in conjunction with the name of the processing aid.

2.3.1.2 Declaration of certain substances

The powdered form of the endo-1,4-β-xylanase enzyme contains a wheat-based carrier, 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 (Information requirements – warning statements, advisory statements and declarations).

This enzyme is intended for use in the manufacture and/or processing of bakery products, grain, cereal-based beverages (including beer) and potable alcohol. With the exception of

alcohol distilled from wheat, these foods will 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 1.2.1—9 of Standard 1.2.1).

2.3.2 Difference in draft variation prepared and that sought by the application

The Application sought a draft variation for permission of the enzyme in section S18—4(5). This would have permitted the endo-1,4-β-xylanase for any technological function in any food. This was not consistent with the Application and information that FSANZ assessed.

For this reason, the draft variation for permission of the enzyme will be listed in subsection S18—9(3) where the technological purpose and use is limited to depolymerisation of arabinoxylans during the manufacture and/or processing of bakery products, cereal products, grain, cereal based beverages (including beer), and potable alcohol. This is consistent with the Application and supporting information that FSANZ assessed.

The applicant confirmed they did not wish to withdraw their Application.

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. The call for submissions was notified via the Food Standards Notification Circular, media release, FSANZ's social media tools and Food Standards News.

The process by which FSANZ considers standards development matters is open, accountable, consultative and transparent. Public submissions were called to obtain the view of interested parties on issues raised by the application and the impacts of regulatory options.

Every submission on this assessment was considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application. The draft variation has been considered taking into account public comments received from the call for submissions.

2.5 FSANZ Act assessment requirements

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

The Office of Best Practice Regulation (OBPR) 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.

However, notwithstanding 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)). Approving the application is the only proposed measure that has been considered against the status quo.

The purpose of this consideration is to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo. 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.

Consideration of costs and benefits from approving the application

Table 2: Approving the Application

Sector	Costs or benefits to sector
Consumers	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 improved quality that become available due to the use of enzyme by Australian and New Zealand manufacturers and access to internationally manufactured products using the enzyme. It is also possible that the prices for some products may be reduced.
Industry	The enzyme works by breaking down cell walls in plant-based foods, which results in improved quality and production efficiencies which in turn can provide a benefit to food manufacturers in terms of profits and/or competitive advantage to conventionally manufactured products. 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 degree by a wider range of international products using this enzyme being able to access the Australian/New Zealand market. Use by industry is voluntary, therefore it will only be used where industry believe a net benefit exists above using existing manufacturing processes.
Governments	There may be some minor costs to government in terms of monitoring and compliance in that regulators will need to be made aware that this is now a permitted processing aid. There are no other costs or benefits to governments associated with this option.

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

FSANZ is required to consider whether other measures (available to FSANZ or not) would be more cost-effective than a food regulatory measure developed or varied as a result of the application (s29(2)(c)). FSANZ is of the view that no other realistic food regulatory measures exist beyond the consideration of approving or not approving the Application.

2.5.1.3 Any relevant New Zealand standards

There are no 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 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 completed a food technology and safety assessment (SD1), which was summarised in section 2.2. The safety assessment concluded there are no public health and safety issues 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 a specific technological purpose in certain food.

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

The labelling requirements for permitting endo-1,4-β-xylanase (EC 3.2.1.8) sourced from *T. reesei* are discussed in Section 2.3.1 – Labelling requirements.

2.5.2.3 The prevention of misleading or deceptive conduct

No issues were identified in regard to misleading or deceptive conduct.

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ has used the best available scientific evidence to complete 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 and FSANZ also considered other information relevant to the Application.

- **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 standards in section 1.3.1 of this report.

- **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.

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

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

- **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.

FSANZ has determined that permitting endo-1,4-β-xylanase (EC 3.2.1.8) from a GM 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 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 27 November 2017).

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

Attachments

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

Food Standards (Application A1153 – Endo xylanase from *Trichoderma reesei* as a Processing Aid) Variation

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

Dated [To be completed by Standards Management Officer]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

Name

This instrument is the *Food Standards (Application 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-ß-xylanase, protein engineered variant, (EC 3.2.1.8) from *Trichoderma reesei,* containing the gene for endo-1,4-ß-xylanase isolated from *Thermopolyspora flexuosa*	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

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.

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 approved 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 GM 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. Permitted use is at levels of GMP.

3. Documents incorporated by reference

The variations to a food regulatory measure does not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1153 included one round of public consultation following an assessment and the preparation of a draft variation to the Code and assessment report. The call for submissions (public consultation) started on 15 February 2018 for a six-week period.

The Office of Best Practice Regulation, in a letter dated 24 November 2010 (reference 12065), provided a standing exemption from the need to develop a Regulatory Impact Statement for Applications relating to processing aids. 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.

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 will permit the use of 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. The technological function is for the depolymerisation of arabinoxylans during the manufacture and/or processing of the following types of food at levels of GMP,

(a) bakery products;
(b) cereal products;
(c) grain;
(d) cereal based beverages (including beer); and
(e) potable alcohol.