

25 July 2014
[14–14]

Call for submissions – Application A1096

Xylanase from *Bacillus licheniformis* as a Processing Aid (Enzyme)

FSANZ has assessed an Application made by Novozymes Australia Pty Ltd to approve a genetically modified strain of *Bacillus licheniformis* as a source for the enzyme xylanase for use in the bread-making industry and has prepared a draft food regulatory measure including updating the nomenclature of other enzymes. 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 is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker 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) 5 September 2014

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
CANBERRA BC ACT 2610
AUSTRALIA
Tel +61 2 6271 2222

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6143
NEW ZEALAND
Tel +64 4 978 5630

Table of Contents

EXECUTIVE SUMMARY	2
1 INTRODUCTION	3
1.1 THE APPLICANT	3
1.2 THE APPLICATION.....	3
1.3 THE CURRENT STANDARD.....	3
1.3.1 <i>International Standards</i>	3
1.4 REASONS FOR ACCEPTING APPLICATION	4
1.5 PROCEDURE FOR ASSESSMENT	4
2 SUMMARY OF THE ASSESSMENT	4
2.1 RISK ASSESSMENT	4
2.2 RISK MANAGEMENT	5
2.2.1 <i>Labelling considerations</i>	5
2.2.2 <i>Consequential drafting</i>	6
2.3 RISK COMMUNICATION.....	6
2.3.1 <i>Consultation</i>	6
2.3.2 <i>World Trade Organization (WTO)</i>	7
2.4 FSANZ ACT ASSESSMENT REQUIREMENTS	7
2.4.1 <i>Section 29</i>	7
2.4.2 <i>Subsection 18(1)</i>	9
2.4.3 <i>Subsection 18(2) considerations</i>	9
3 DRAFT VARIATION	10
3.1 TRANSITIONAL ARRANGEMENTS.....	11
4 REFERENCES	11
ATTACHMENT A – DRAFT VARIATIONS TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i>	12
ATTACHMENT B – DRAFT EXPLANATORY STATEMENT.....	14

Supporting document

The following document which informed the assessment of this Application are available on the FSANZ website at

<http://www.foodstandards.gov.au/code/applications/Pages/A1096XylanaseasaPA.aspx>

SD1 Risk and Technical Assessment Report

Executive summary

Novozymes Australia Pty Ltd submitted an Application seeking permission for a new enzyme for use in the baking industry. This new enzyme is a protein engineered variant of the enzyme, endo-1,4- β -xylanase, sourced from a genetically modified strain of *Bacillus licheniformis*. The Applicant claims the purpose of using the enzyme is to improve production processes in the baking industry by facilitating dough handling and improving the characteristics of the final bread.

Enzymes used in the production and manufacture of food are considered processing aids and are regulated by Standard 1.3.3 – Processing Aids in the *Australia New Zealand Food Standards Code* (the Code). Permitted enzymes of microbial origin are listed in the Table to clause 17 of Standard 1.3.3.

FSANZ's risk assessment concluded that there are no public health and safety issues associated with the use of the enzyme preparation as a food processing aid. Residual enzyme is expected to be present in the final food but would be inactive and susceptible to digestion like any other dietary protein. It was further 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.

The evidence presented to support the proposed uses 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 preparation meets international purity specifications.

The enzyme protein of this preparation differs by one amino acid to that found in nature. Because no evidence has been provided or located that the enzyme protein is identical to that found in nature, the enzyme protein would be considered novel in relation to the definition in Standard 1.5.2 – Food Produced using Gene Technology.

If novel protein were to remain in the final food, then food produced using the enzyme preparation would be required to be labelled 'genetically modified' in conjunction with the name of the processing aid. It is the responsibility of food manufacturers who use the enzyme preparation to determine if any residual enzyme or inactivated enzyme breakdown products remain in the final food and label the food correctly.

FSANZ, therefore proposes draft variations to permit a protein engineered variant of the enzyme, endo-1,4- β -xylanase, sourced from a genetically modified strain of *Bacillus licheniformis* as a new processing aid.

FSANZ also proposes changes to Standard 1.3.3 to update the name of this enzyme when derived from different permitted bacterial sources to make it consistent with current scientific enzyme nomenclature. This will amend the enzyme name 'Hemicellulose endo-1,4- β -xylanase' to 'endo-1,4-beta-xylanase'; both have the same EC number of 3.2.1.8. FSANZ decided to replace the ' β ' symbol with the term 'beta' in the nomenclature for the new enzyme entries since Greek symbols in the Code are not always correctly written when the Code is viewed using certain types of electronic platforms.

1 Introduction

1.1 The Applicant

The Applicant is Novozymes Australia Pty Ltd, a biotechnology company specialising in supplying enzymes to the food industry.

1.2 The Application

The purpose of the Application is to seek permission for a protein engineered variant of the enzyme, endo-1,4- β -xylanase. The microbial source of the enzyme is a genetically modified strain of *Bacillus licheniformis*. The Applicant claims the purpose of using the enzyme is to improve production processes in the baking industry by facilitating dough handling and improving the characteristics of the final bread.

In the Application it is suggested that an advantage of the genetically modified source organism is that genes have been removed which encode for unwanted proteases and peptides as well as the ability to sporulate. The lack of these side activities represents improvements in stability and purity of activity of the produced enzyme preparation.

1.3 The current Standard

Enzymes used in the production and manufacture of food are considered processing aids. Only those processing aids listed in Standard 1.3.3 – Processing Aids in the *Australia New Zealand Food Standards Code* (the Code) are permitted to be used in the production of food sold in Australia and New Zealand. Permitted enzymes of microbial origin are listed in the Table to clause 17 of Standard 1.3.3.

Currently, hemicellulase endo-1,4- β -xylanase is a permitted enzyme in the Table to clause 17 with a number of permitted microbial sources. This enzyme has the same Enzyme Commission (EC) number (3.2.1.8) as the enzyme referred to in this Application as endo-1,4- β -xylanase. *B. licheniformis* or genetically modified strains of this organism are not permitted microbial sources for this enzyme.

1.3.1 International Standards

Codex Alimentarius does not list 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, including those produced from genetically modified microbial sources. These enzyme specifications are provided by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Food Chemicals Codex.

The Application contained a copy of a letter, dated 11.09.2013, from the Danish Veterinary and Food Administration within the Ministry of Food, Agriculture and Fisheries, noting that endo-1,4- β -xylanase was acceptable to be used for baking.

The Applicant self-assessed that the same enzyme preparation is Generally Recognized as Safe (GRAS) and provided a dossier to the US Food and Drug Administration (USFDA) as GRAS Notice No. GRN 000472¹. The USFDA responded in a letter dated 10 December 2013² to indicate that it did not have any questions regarding the company's determination that the enzyme preparation was considered GRAS for the proposed purpose of use in baking.

The Brazilian regulatory agency (National Health Surveillance Agency, in Portuguese, Agência Nacional de Vigilância Sanitária, ANVISA) have evaluated the dossier of the enzyme preparation and similar to the USA, considered that it was safe for use in baking. However, an amendment to the positive list of approved enzymes had not been updated at the time of submission of the current Application to FSANZ in March 2014. The Applicant had expected this to occur in early 2014.

The Applicant has also submitted a dossier to Health Canada in May 2013 for their assessment, which is currently being reviewed.

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 might be developed as a food regulatory measure.

1.5 Procedure for assessment

The Application is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Risk assessment

There are no public health and safety issues associated with the use of the protein engineered variant of the enzyme, endo-1,4- β -xylanase sourced from a genetically modified strain of *Bacillus licheniformis* as a food processing aid on the basis of the following considerations:

- The production organism is not toxigenic, pathogenic or sporogenic and is absent in the final enzyme preparation proposed to be used as a food processing aid. Further, *B. licheniformis* has a history of safe use as the production organism for a number of enzyme processing aids that are already permitted in the Code.
- Residual enzyme is expected to be present in the final food but would be inactive and susceptible to digestion like any other dietary protein.
- Bioinformatic analysis³ indicated that the enzyme has no biologically relevant homology to known protein allergens or toxins.

¹

http://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=472&sort=GRN_No&order=DESC&startrow=1&type=basic&search=472

² <http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm382201.htm>

³ Bioinformatic analysis is the application of computer programmes for searching large protein-datasets on a statistical basis so that results are interpreted in a biologically meaningful manner.

- The enzyme caused no observable effects at the highest tested doses in a 90-day toxicity study in rats. The No Observed Adverse Effect Level (NOAEL) was 1020 mg TOS⁴/kg bodyweight per day, the highest dose tested.
- The enzyme preparation was not genotoxic *in vitro*.
- Orthologous⁵ xylanases from a range of other sources have been approved as processing aids by FSANZ and are permitted to be used in the manufacture of food.

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

The evidence presented to support the proposed uses 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 preparation meets international purity specifications.

2.2 Risk management

As processing aids require permissions in the Code the only risk management options available to FSANZ are to approve or reject the request to amend the Code. The risk assessment conclusions provide evidence that there are no safety risks from the use of this enzyme as intended. The regulatory options analysed in section 2.4.1.1 take account of the safety of the enzyme preparation. However, there are some labelling matters related to the Application that do require consideration and future management.

2.2.1 Labelling considerations

2.2.1.1 *Mandatory allergen declaration*

Wheat flour is used as a carrier to formulate and standardise the enzyme preparations. Therefore, the use of the enzyme preparation would trigger labelling provisions for the mandatory declaration of cereals containing gluten within clause 4 of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations. It is noted, however, that the enzyme is intended to be used in the baking industry where the primary ingredients are cereals containing gluten.

2.2.1.2 *'Genetically modified' statement*

Under current requirements in the Code, processing aids are, in most cases, exempt from the requirement to be declared in the statement of ingredients (paragraph 3(d) of Standard 1.2.4 – Labelling of Ingredients). However subclause 4(1)(d) of Standard 1.5.2 – Food produced using Gene Technology overrides this exemption when novel DNA and/or novel protein from the processing aid remains present in the final food. In such cases, the name of the processing aid must be declared on the label of the food in conjunction with the statement 'genetically modified'.

⁴ Total Organic Solids

⁵ Orthologous enzymes are those enzymes expressed by genes that evolved in different species from a common ancestral gene.

Novel DNA and/or novel protein is defined in subclause 4(1) of Standard 1.5.2 to mean *DNA or a 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 which has not been produced using gene technology.*

The Applicant notes that the enzyme protein of this preparation differs by one amino acid to that found in nature. The Application states that ‘the change could occur naturally because it is insignificant compared to the variation of native xylanases from strains within the *Bacillus licheniformis* species and because there is evidence that the specific change occurs in nature’. However, there is no actual evidence provided in the Application that the enzyme protein is identical to that found in nature. Therefore, the enzyme protein would be considered novel in relation to the definition.

If novel protein were to remain in the final food, then food produced using the protein engineered variant of the enzyme, endo-1,4- β -xylanase sourced from genetically modified *Bacillus licheniformis* would be required to be labelled ‘genetically modified’. Clause 5 of Standard 1.5.2 states that the ‘genetically modified’ statement must be used in conjunction with the name of the genetically modified food, ingredient or processing aid. It is the responsibility of food manufacturers who use the enzyme preparation to determine if any residual enzyme or inactivated enzyme breakdown products remain in the final food and label the food correctly.

2.2.2 Additional drafting related to enzyme nomenclature

FSANZ notes that the International Union of Biochemistry and Molecular Biology (IUBMB), the internationally recognised authority for enzyme nomenclature, uses the name endo-1,4- β -xylanase⁶ for enzymes with an EC number of 3.2.1.8. This enzyme, sourced from several different host organisms, is listed as hemicellulase endo-1,4- β -xylanase in the Code. FSANZ therefore proposes to change the name of the enzyme in the Code to be consistent with current scientific nomenclature and with the proposed addition of the enzyme which is the subject of this Application. These additional changes were not requested by the Applicant.

It is therefore proposed to change the name of the enzyme in the Table to clause 17 of Standard 1.3.3 from:

hemicellulase endo-1,4- β -xylanase (EC 3.2.1.8)
to
endo-1,4-beta-xylanase (EC 3.2.1.8).

Because Greek symbols in the Code are not always correctly written when the Code is viewed using certain types of electronic platforms, FSANZ decided to replace the ‘ β ’ symbol with the written term ‘beta’ in the nomenclature for the new enzyme entries.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ’s standards development process.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application.

⁶ International Union of Biochemistry and Molecular Biology (IUBMB) Enzyme Nomenclature, EC 3.2.1.8, <http://www.chem.qmul.ac.uk/iubmb/enzyme/EC3/2/1/8.html> Accessed 31/3/14

Every submission on an application or proposal is considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

FSANZ has developed and applied a basic communication strategy to this Application. All calls for submissions are notified via the Food Standards Notification Circular, media release, FSANZ's social media tools and Food Standards News.

The process by which FSANZ considers standard development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the Application and the impacts of regulatory options.

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

The Applicant, individuals and organisations that make submissions on this Application will be notified at each stage of the assessment. Subscribers and interested parties are also notified via email about the availability of reports for public comment.

If the draft variation to the Code is approved by the FSANZ Board, that decision will be notified to the Legislative and Governance Forum on Food Regulation (the Forum). If the decision is not subject to a request for a review, the Applicant and stakeholders including the public will be notified of the gazettal of the variation to the Code in the national press and on the FSANZ website.

2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards and amending the Code to approve a protein engineered variant of the enzyme endo-1,4- β -xylanase sourced from genetically modified *B. licheniformis* is unlikely to have a significant effect on international trade. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

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

2.4.1 Section 29

2.4.1.1 Cost benefit analysis

FSANZ is required to consider the impact of various regulatory and non-regulatory options on all sectors of the community, especially relevant stakeholders who may be affected by this Application. The benefits and costs associated with the proposed amendments to the Code have been analysed using regulatory impact principles. The level of analysis is commensurate with the nature of the Application and significance of the impacts.

Two regulatory options were considered:

- (1) prepare a draft variation to Standard 1.3.3 to permit the use of a protein engineered variant of endo-1,4- β -xylanase produced from a genetically modified *B. licheniformis* source organism as a processing aid
- (2) reject the Application.

The Office of Best Practice Regulation, in a letter dated 24 November 2010 (reference 12065), provided a standing exemption from the need to assess if a Regulation Impact Statement is required for applications relating to processing aids as they are machinery in nature and their use is voluntary. However, FSANZ has undertaken a limited impact analysis.

A consideration of the costs and benefits of the regulatory options is not intended to be an exhaustive, quantitative economic analysis of the options and, in fact, most of the effects that are considered cannot be assigned a dollar value.

Rather, the assessment seeks to highlight the qualitative effects of criteria that are relevant to each option. These criteria are deliberately limited to those involving broad areas such as trade, consumer information and compliance.

Option 1 – Prepare a draft variation to Standards 1.3.3

Sector	Costs or benefits to sector
Consumers	There should be no measurable impact or costs on consumers, but there may be improved characteristics in the final bread which may be a benefit to consumers. If there is any residual novel protein in the final product, labelling will be a benefit and assist consumers to make an informed choice in their future purchases of bread.
Industry	There are specific benefits to the baking industries for this option to improve both dough handling and the characteristics of the final bread. Australian and New Zealand bread manufacturers will benefit from having an alternative enzyme, which is claimed to be the latest technical development for use in baking and is permitted in some other countries. There is industry interest in investigating the use of the enzyme once it is permitted. Costs could arise from the requirement to label a food treated with this enzyme as 'genetically modified', if novel protein from this enzyme is present in the final food. However the use of this enzyme is voluntary and therefore this cost is not one which is imposed directly by the approval of the enzyme.
Governments	There are no costs or benefits to governments associated with this option.

Option 2 – Reject the Application

Sector	Costs or benefits to sector
Consumers	There are no benefits or costs to consumers of this option.
Industry	There are no benefits to industry from this option. However, there are likely to be costs by not allowing industry the option to use new current improved technology to ensure the final quality of their products like their international competitors are able to do.
Governments	There are no benefits or costs to governments for this option.

The direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the Application outweigh the costs to the community, Government or industry that would arise from the development or variation of the food regulatory measure. Therefore, the preferred option is to prepare a draft variation to Standard 1.3.3.

2.4.1.2 Other measures

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

2.4.1.3 Any relevant New Zealand standards

Standard 1.3.3 applies to New Zealand and there are no relevant New Zealand only Standards.

2.4.1.4 Any other relevant matters

There are no other relevant matters.

2.4.2. Subsection 18(1)

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

2.4.2.1 Protection of public health and safety

FSANZ has undertaken a safety assessment (SD1) and concluded that there are no public health and safety concerns related to permitting a genetically modified source organism as a source for a protein engineered variant of the enzyme endo-1,4- β -xylanase.

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

In accordance with existing labelling provisions, food produced using this enzyme preparation would have to be labelled as 'genetically modified' if it contains novel DNA or novel protein (see Section 2.2.1.2).

2.4.2.3 The prevention of misleading or deceptive conduct

No issues were identified for this Application relevant to this objective.

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ has used the best available scientific evidence to conduct the risk analysis which is provided in SD1 – the Risk and Technical Assessment Report. The Applicant submitted a dossier of scientific studies as part of their Application. Other technical information including scientific literature was also used in assessing the Application.

- **the promotion of consistency between domestic and international food standards**

There are no Codex Alimentarius Standards for enzymes. However, it is noted that for use in baking the enzyme is permitted in Denmark, has been self-assessed and notified as Generally Recognized as Safe (GRAS) in the United States and evaluated as safe for use in Brazil.

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

The enzyme source is an alternative source for an already permitted enzyme, but it has been permitted for use in other countries so competitive forces may operate in relation to costs and performance. There has been an expression of support from the local baking industry who wish to evaluate the performance of the enzyme preparation. The food industry will make their own economic decisions, taking account of costs and benefits of the new source of an already permitted enzyme to determine if it is of benefit to their business.

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

The enzyme preparation has been permitted, and is being evaluated, in other countries. It is therefore appropriate that the local Australian and New Zealand baking industries have access to the same enzyme preparation which may have benefits to the industry.

- **any written policy guidelines formulated by the Ministerial Council⁷**

The Addition to Food of Substances other than Vitamins and Minerals⁸ 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 has determined that permitting the use of a protein engineered variant of the enzyme endo-1,4-- β -xylanase sourced from a genetically modified strain of *B. licheniformis* as a processing aid is consistent with the specific order policy principles for 'Technological Function'.

3 Draft variation

The draft variation is at Attachment A. The draft variation 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 Legislative Instruments.

⁷ Now known as the Legislative and Governance Forum on Food Regulation

⁸ <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

3.1 Transitional arrangements

3.1.1 *Transitional arrangements for Code Revision*

FSANZ is reviewing the Code in order to improve its clarity and legal efficacy. This review is being undertaken through Proposal P1025 – details of which are on the FSANZ website⁹. FSANZ released a draft revision of the Code for public comment in May 2013. The draft revision has changed the Code's structure and format. A further draft revision of the Code and call for submissions has been released recently.

The FSANZ Board is expected to consider P1025 and the proposed changes to the Code in late 2014. If approved, it is expected that the new Code will commence in 2015 and will repeal and replace the current Code. The new Code will then need to be amended to incorporate any outstanding changes made to the current Code, including the variations at Attachment A.

4 References

Compendium of Food Additive Specifications – General specifications and considerations for enzyme preparations used in food processing. Joint FAO/WHO Expert Committee on Food Additives (JECFA). FAO Food and Nutrition Monograph 3, 67th session, (2006), online to current version
http://www.fao.org/ag/agn/jecfa-additives/docs/enzymes_en.htm

Food Chemicals Codex (8th edition, 2012) Enzyme Preparations, United States Pharmacopoeia

Attachments

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

⁹ <http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx>

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



Food Standards (Application A1096 – Xylanase from *Bacillus licheniformis* as a Processing Aid (Enzyme)) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard 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.

1 Name

This instrument is the *Food Standards (Application A1096 – Xylanase from Bacillus licheniformis as a Processing Aid (Enzyme)) Variation*.

2 Variation to Standards 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] Standard 1.3.3 is varied by

[1.1] inserting in the Table to clause 17 in alphabetical order

“

Endo-1,4-beta-xylanase EC 3.2.1.8	<i>Aspergillus niger</i> <i>Aspergillus oryzae</i> <i>Aspergillus oryzae</i> , containing the gene for Endo-1,4-beta-xylanase isolated from <i>Aspergillus aculeatus</i> <i>Aspergillus oryzae</i> , containing the gene for Endo-1,4-beta-xylanase isolated from <i>Thermomyces lanuginosus</i> <i>Bacillus amyloliquefaciens</i> <i>Bacillus subtilis</i> <i>Humicola insolens</i> <i>Trichoderma reesei</i>
Endo-1,4-beta-xylanase, protein-engineered variant EC 3.2.1.8	<i>Bacillus licheniformis</i> , containing the gene for Endo-1,4-beta-xylanase isolated from <i>Bacillus licheniformis</i>

”

[1.2] omitting from the Table to clause 17

“

Hemicellulase endo-1,4-β-xylanase EC 3.2.1.8	<i>Aspergillus niger</i> <i>Aspergillus oryzae</i> <i>Aspergillus oryzae</i> , containing the gene for Endo-1,4-β-xylanase isolated from <i>Aspergillus aculeatus</i> <i>Aspergillus oryzae</i> , containing the gene for Endo-1,4-β-xylanase isolated from <i>Thermomyces lanuginosus</i> <i>Bacillus amyloliquefaciens</i> <i>Bacillus subtilis</i> <i>Humicola insolens</i> <i>Trichoderma reesei</i>
---	---

”

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 A1096 which seeks to approve a genetically modified strain of *Bacillus licheniformis* as a source for a protein engineered variant of the enzyme endo-1,4- β -xylanase for use in the bread-making industry. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared draft variations to the Code.

2. Purpose

The Authority has proposed that a protein engineered variant of endo-1,4- β -xylanase produced by a genetically modified *B. licheniformis* be permitted. This requires an addition to the Table to clause 17 (Permitted enzymes of microbial origin) in Standard 1.3.3 – Processing Aids.

A further amendment to this Table is proposed to ensure the current scientific nomenclature is also applied to the enzyme when derived from other permitted sources. That is, the current entry for hemicellulase endo-1,4- β -xylanase is replaced by the term endo-1,4- β -xylanase.

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 A1096 will include one round of public consultation following an assessment and the preparation of draft variations and associated reports. A call for submissions (including the draft variations) will occur for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variations to Standard 1.3.3 are likely to have a minor impact on business and individuals.

5. Statement of compatibility with human rights

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

6. Variation

Permissions for the new enzyme, being the protein engineered variant of endo-1,4-beta-xylanase sourced from a genetically modified form of the microorganism *Bacillus licheniformis* has been added into the Table to clause 17 of Standard 1.3.3.

The current accepted scientific common name of the enzyme is as noted above (i.e. endo-1,4- β -xylanase), which has been updated from the name currently listed in the Table for the same enzyme. Therefore changes were also made to replace the enzyme name 'Hemicellulose endo-1,4- β -xylanase' with 'endo-1,4-beta-xylanase'; both with the same EC number of 3.2.1.8.

FSANZ decided to replace the ' β ' symbol with the written term 'beta' in the nomenclature for the new enzyme entries since Greek symbols in the Code are not always correctly written when the Code is viewed using certain types of electronic platforms.