

16 December 2014
[26–14]

Approval Report – Application A1096

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

Food Standards Australia New Zealand (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.

On 25 July 2014, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received seven submissions.

FSANZ approved the draft variation on 4 December 2014. The Australia and New Zealand Ministerial Forum on Food Regulation¹ (Forum) was notified of FSANZ's decision on 15 December 2014.

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

¹ convening as the Australia and New Zealand Food Regulation Ministerial Council

Table of Contents

EXECUTIVE SUMMARY	2
1 INTRODUCTION.....	4
1.1 THE APPLICANT.....	4
1.2 THE APPLICATION.....	4
1.3 THE CURRENT STANDARD	4
1.4 REASONS FOR ACCEPTING APPLICATION.....	5
1.5 PROCEDURE FOR ASSESSMENT	5
2 SUMMARY OF THE FINDINGS	5
2.1 SUMMARY OF ISSUES RAISED IN SUBMISSIONS.....	5
2.2 RISK ASSESSMENT.....	8
2.3 RISK MANAGEMENT.....	8
2.3.1 <i>Labelling considerations</i>	9
2.3.2 <i>Additional drafting related to enzyme nomenclature</i>	10
2.4 DECISION.....	10
2.5 RISK COMMUNICATION	10
2.5.1 <i>Consultation</i>	10
2.6 FSANZ ACT ASSESSMENT REQUIREMENTS.....	11
2.6.1 <i>Section 29</i>	11
2.6.2 <i>Subsection 18(1)</i>	12
2.6.3 <i>Subsection 18(2) considerations</i>	12
3 TRANSITIONAL ARRANGEMENTS.....	13
3.1 TRANSITIONAL ARRANGEMENTS FOR CODE REVISION.....	13
4 REFERENCES.....	14
ATTACHMENT A – APPROVED DRAFT VARIATIONS TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i>	15
ATTACHMENT B – EXPLANATORY STATEMENT.....	17
ATTACHMENT C – DRAFT VARIATION TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i> IN MARCH 2015 FOLLOWING P1025.....	19

Supporting document

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

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

SD1 Risk and Technical Assessment Report (at Approval)

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. A change to the amino acid sequence in the native protein was made in order to slightly change the specificity of the enzyme to increase the production of oligosaccharides with a positive effect on the dough handling properties. In dough handling, reducing the risk of stickiness is very important, and the new enzyme results in a dough that is less sticky and thereby easier to handle than dough produced with other permitted xylanase enzymes.

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' was 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, was technologically justified and had 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 a xylanase found in nature. No direct evidence has been provided or located that the enzyme protein is 'present in counterpart food', which has been taken to be native xylanase enzymes. The enzyme protein has therefore been considered novel protein due to the definition in Standard 1.5.2 – Food produced using Gene Technology. Therefore, any enzyme remaining in food, even if inactivated or denatured, would require labelling as 'genetically modified' due to the labelling requirements in Standard 1.5.2.

FSANZ approved 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 approved changes to Standard 1.3.3 to update the name of this enzyme when derived from bacterial sources different to that which is the subject of this Application to make it consistent with current scientific enzyme nomenclature. This amended 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 replaced 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.

FSANZ received seven submissions on the draft variation following the call for submissions, with five submitters supporting the draft variation and two opposing it. An issue that was raised related to whether the enzyme was 'novel protein' and therefore would trigger labelling in relation to the genetic modification if it remained in the final food. Issues raised in opposition to the Application related to concerns about safety of genetically modified organisms (GMOs), concern that only industries involved in the production and supply of GMOs benefit from their approval and not the community including consumers. Other reasons for opposing the Application include the view that the organic classification of other companies will be at risk, and that stronger labelling is required if the enzyme is approved. Responses to the issues are provided in the Report.

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. A change to the amino acid sequence in the native protein was made in order to slightly change the specificity of the enzyme to increase the production of oligosaccharides with a positive effect on the dough handling properties. In dough handling, reducing the risk of stickiness is very important, and the new enzyme results in a dough that is less sticky and thereby easier to handle than dough produced with other permitted xylanase enzymes.

The Application stated 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 have a standard 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 (US FDA) as GRAS Notice No. GRN 000472². The US FDA responded in a letter dated 10 December 2013³ 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), has evaluated the dossier of the enzyme preparation and like the US FDA, considered that it was safe for use in baking. The Applicant provided update information after the Application was submitted that the enzyme was added to the positive list of approved enzymes in October 2014⁴. The enzyme has also been approved for use in Canada⁵ and Mexico⁶, again after the Application was submitted.

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 was assessed under the General Procedure.

2 Summary of the findings

2.1 Summary of issues raised in submissions

The issues raised in submissions have been reviewed and addressed by FSANZ in Table 1. The report has been amended, as deemed necessary, following these submissions.

The main issues raised in submissions are summarised as:

- Determining that the enzyme is 'novel protein' and therefore requires labelling if it remains in final food.

² http://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=472&sort=GRN_No&order=DESC&startrow=1&type=basic&search=472

³ <http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm382201.htm>

⁴ Brazil, 2014, Resolução da Diretoria Colegiada – RDC Nº 53, de 07 de Outubro de 2014 (Board Resolution – RDC No. 53, of 7 October 2014) Provides on the list of enzymes, food additives and vehicles authorised in enzyme preparations for use in the production of foods in general, The Board of the National Health Surveillance Agency.

http://portal.anvisa.gov.br/wps/wcm/connect/e156580045c8232da081e2d10ee53f37/Resolu%C3%A7%C3%A3o+RDC+n.+53_2014_Lista+de+enzimas.pdf?MOD=AJPERES, accessed 11 November 2014

⁵ Health Canada, 2014, List of permitted food enzymes, X.1 xylanases, <http://hc-sc.gc.ca/fn-an/securit/addit/list/5-enzymes-eng.php>, accessed 11 November 2014

⁶ Mexico 2014, Lista positiva actualizada 01072014 AnexoVI, Comisión Federal para la Protección contra Riesgos Sanitarios (Federal Commission for the Protection against Sanitary Risk (COFEPRIS)) Adiciones Al Anexo VI Enzimas (Food additive regulations pertaining to enzymes).

<http://www.cofepris.gob.mx/AZ/Documents/Aditivos/AnexoVI.pdf>, (not yet updated on line) accessed 11 November 2014

- Opposition to approving the draft variation: safety concerns; philosophical grounds that GM technology only benefits the GM companies and not the community, in particular consumers; potential contamination of organic status of other companies; and a request for much tougher labelling requirements if the enzyme is permitted.
- Concern that the labelling requirements for the enzyme should be clearly ascertained and stated in the Report.

Table 1: Summary of issues

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>That the xylanase enzyme of this Application, derived from <i>B. licheniformis</i> should not be considered 'novel protein'. The reason for this view is that the small change (one amino acid difference) in the protein sequence is negligible compared to the natural variation that occurs in native xylanases, let alone the smaller subset of xylanases sourced from <i>B. licheniformis</i>. Evidence was also provided that the specific change introduced in the specific enzyme of the Application does occur in nature.</p>	<p>The Applicant, Novozymes A/S</p>	<p>FSANZ notes the extra information that the Applicant has provided to support their claim that this particular xylanase should not be considered to be novel protein. However, it is clear that the deliberate introduction of an additional amino acid into the primary amino acid sequence of this enzyme has conferred a functional advantage over its naturally occurring counterpart enzyme. Since the Applicant was unable to provide direct evidence that this particular amino acid sequence is present in any xylanases found in nature, FSANZ has concluded that it is not identical to a protein present in counterpart food (i.e. enzymes found in nature) and therefore is a novel protein requiring labelling under Standard 1.5.2.</p>
<p>The development of genetically modified organisms (GMOs) is only to benefit the companies licenced to produce and sell such products; it is not to benefit the broader community, including consumers.</p>	<p>An individual</p>	<p>As explained in the cost/benefit section in the Call for Submissions, consumers and food manufacturers using these organisms will also benefit if the Application is permitted by improving characteristics in the final bread and during handling prior to baking.</p>
<p>There are no long term safety studies on the effect of GMOs on the human body. Use of GMOs also threatens organic producers where GMOs could contaminate their organic products and threaten their organic classification. If the enzyme is permitted then very prominent labelling should be required for bread produced using the enzyme and strong fines should be imposed on products that don't comply.</p>	<p>An individual</p>	<p>FSANZ's Risk and Technical Assessment Report (SD1) has investigated the safety of both the final enzyme preparation as well as the genetically modified source organism and has found there are no safety concerns for public health and safety. It is unlikely the use of the enzyme preparation during bread manufacture will impact on any other organic producer as the production will be performed in the manufacturer's premises. If this is a risk appropriate segregation processes would need to be followed as part of normal production operations. Furthermore, organic producers are responsible for sourcing food ingredients which are consistent with their organic status. Changes to the policy of food produced using gene technology are outside the scope of the Application. The current labelling requirements pertinent to this Application are noted in section 2.3.1.2 of the Report.</p>
<p>The labelling requirements for the GMO processing aid (enzyme) needs to be ascertained and advised clearly in the report.</p>	<p>Food Technology Association of Australia</p>	<p>The labelling requirements for the genetically modified enzyme are detailed in section 2.3.1.2 of the Report.</p>

2.2 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 analysis⁷ indicated that the enzyme has no biologically relevant homology to known protein allergens or toxins.
- 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 TOS⁸/kg bodyweight per day, the highest dose tested.
- The enzyme preparation was not genotoxic *in vitro*.
- Orthologous⁹ 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.

2.3 Risk management

As processing aids require permissions in the Code and labelling requirements for genetically modified organisms are specified in standard 1.5.2, 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 2.6.1.1 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.

⁷ 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.

⁸ Total Organic Solids

⁹ Orthologous enzymes are those enzymes expressed by genes that evolved in different species from a common ancestral gene.

2.3.1 Labelling considerations

2.3.1.1 Mandatory allergen declaration

Clause 4 of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations states that cereals containing gluten and their products (for example, wheat), must be declared on the label when present as a processing aid or component of a processing aid. The enzyme preparation uses wheat flour as a solid carrier, to both formulate and standardise the preparation. Therefore, the use of wheat flour in the enzyme preparation triggers this labelling requirement.

The enzyme preparation is proposed to be used in the baking industry whose ingredients are gluten containing cereals which themselves trigger these labelling requirements. Consumers wishing to eliminate gluten containing foods from their diet will already be aware of the gluten status of these bakery products and so using this enzyme preparation will not change the purchasing behaviour of such products by consumers concerned about gluten.

2.3.1.2 ‘Genetically modified’ labelling 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 ‘where novel DNA and/or novel protein from the processing aid or food additive remains present in the food to which it has been added’. In such cases, clause 5 of Standard 1.5.2 requires the name of the processing aid must be declared on the label of the food in conjunction with the statement ‘genetically modified’.

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*. FSANZ has taken counterpart food in relation to enzymes to mean enzymes found in nature (naturally occurring enzymes).

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 [amino acid, i.e. two leucine amino acids next to each other] change occurs in nature’. However, the Applicant has not provided evidence that the change does occur in counterpart food (enzymes found in nature). As noted in the explanation in Table 1, the insertion of the extra amino acid produces a functional advantage in the enzyme which, to date, has not been observed in other xylanases. Therefore, FSANZ has concluded that the enzyme is considered to be a novel protein.

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.

2.3.2 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 -xylanase¹⁰ 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. The Applicant was notified of this change and had no objections.

The name of the enzyme in the Table to clause 17 of Standard 1.3.3 was changed 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 displayed 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.

2.4 Decision

The draft variation as proposed following assessment was approved without change. The variation takes effect on gazettal.

The approved draft variation is at Attachment A. The 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.

2.5 Risk communication

2.5.1 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. Every submission on the Application was considered and reviewed by FSANZ staff, who examined the issues identified and prepared a response (see Table 1). All comments are valued and contribute to the rigour of our assessment.

FSANZ called for public comment between 25 July 2014 and 5 September 2014 after assessing the Application. Seven submissions were received, along with one late submission which supported the Application. Five submissions supported the Application though the issue of labelling requirements due to novel protein potentially remaining in the final food was raised as an issue specifically by the Applicant. The Application was supported by two jurisdictions and two industry groups along with the Applicant. Two individuals were opposed to the Application. The issues raised in the submissions have been addressed in Table 1.

¹⁰ 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

FSANZ developed and applied a basic communication strategy to this Application. All calls for submissions were notified via the FSANZ 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 were called to obtain the views of interested parties on issues raised by the Application and the impacts of regulatory options.

The FSANZ Board considered the draft variation taking into account public comments received from the Call for Submissions.

The Applicant, individuals and organisations that made 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.

The FSANZ Board's decision has been notified to the Australia and New Zealand Ministerial Forum on Food Regulation¹¹. If the decision is not subject to a request for a review by Ministers, the Applicant and stakeholders will be notified of the gazettal of the variation to the Code in the national press and on the FSANZ website.

2.6 FSANZ Act assessment requirements

2.6.1 Section 29

2.6.1.1 Cost benefit analysis

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

However, FSANZ undertook a limited impact analysis for this Application. FSANZ concluded that permitting the use of the protein engineered variant of the enzyme, endo-1,4- β -xylanase sourced from a genetically modified strain of *B. licheniformis* as a food processing aid has benefits to the baking industry. These benefits are improvements in the dough handling and the characteristics of the final bread. Improvements in the characteristics of the final bread are also benefits for consumers. There are no costs to different stakeholders that override these benefits. There are no benefits in rejecting the Application.

FSANZ concluded that 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.

2.6.1.2 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.

¹¹ convening as the Australia and New Zealand Food Regulation Ministerial Council

2.6.1.3 Any relevant New Zealand standards

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

2.6.1.4 Any other relevant matters

These are considered below.

2.6.2 Subsection 18(1)

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

2.6.2.1 Protection of public health and safety

FSANZ undertook 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.

2.6.2.2 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 2.3.1.2).

2.6.2.3 The prevention of misleading or deceptive conduct

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

2.6.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ used the best available scientific evidence 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 is no Codex Alimentarius Standard 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 of America 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 commercial 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**

There are no fair trading aspects to this Application.

- **any written policy guidelines formulated by the Ministerial Council¹².**

The Addition to Food of Substances other than Vitamins and Minerals¹³ 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 Transitional arrangements

3.1 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 website¹⁴. 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 was released in July 2014.

The FSANZ Board approved the proposed changes to the Code in December 2014 and that decision has since been notified to Ministers. If Ministers do not request a review of the Board's decision, the new Code is expected commence in March 2016 and will repeal and replace the current Code. The new Code will then need to be amended to incorporate any outstanding changes made to Chapters 1 and 2 of the current Code,

¹² Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

¹³ <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

¹⁴ <http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx>

The amendment to the new Code resulting from Application A1096 is provided at Attachment C.

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. Approved draft variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement
- C. Draft variation to the *Australia New Zealand Food Standards Code* in March 2015 following P1025

Attachment A – Approved draft variation 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 – 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 variations to the Code.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation¹⁵, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislative Instruments Act 2003*.

2. Purpose

The Authority has approved a protein engineered variant of endo-1,4- β -xylanase produced by a genetically modified *B. licheniformis* as a processing aid. 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 name endo-1,4-beta-xylanase.

3. Documents incorporated by reference

The variations 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 included one round of public consultation following an assessment and the preparation of a draft Standard and associated report. Submissions were called for on 25 July 2014 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 but beneficial impact on business and individuals.

¹⁵ convening as the Australia and New Zealand Food Regulation Ministerial Council

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 displayed when the Code is viewed using certain types of electronic platforms.

Attachment C – Draft variation to the *Australia New Zealand Food Standards Code* in March 2015 following P1025

Background

FSANZ is reviewing the *Australian New Zealand Food Standards Code* in order to improve its clarity and legal efficacy. This review is being undertaken through Proposal P1025. 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. The draft instrument below reflects those changes. A further draft revision of the Code and call for submissions was released in July 2014.

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, such as the variations to Standard 1.3.3 proposed by A1096. This is the rationale for the draft variation below.

This draft variation is provided for background only. Its content and structure may change as P1025 progresses.

Draft instrument

Food Standards Code—Variation

Made under the *Food Standards Australia New Zealand Act 1991*

1 Name of instrument

This instrument is the *Food Standards Australia New Zealand Code — Revocation and Transitional Variation 2015 (No. 1)*.

2 Commencement

This instrument commences on the day after it is registered.

3 Variation of Schedule 18

Schedule 1 varies the *Australia New Zealand Food Standards Code* – Schedule 18– Processing Aids.

Schedule 1 Variation of Schedule 18

(section 4)

[1] Insert in S18-4(5) 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>

”

[2] Omit from S18-4(5)

“

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>
--	---

”