FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

19 June 2015
[12–15]

Call for submissions – Application A1107

Asparaginase from *Bacillus subtilis* as a Processing Aid (Enzyme)

FSANZ has assessed an Application made by Novozymes Australia Pty Ltd to permit the use of a new microbial source for asparaginase sourced from a genetically modified strain of *Bacillus subtilis* for use in food production to reduce the risk of acrylamide formation and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at information for submitters.

All submissions on applications and proposals will be published on our website. We will not publish material that 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) 31 July 2015

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

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

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

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Supporting document

The following document which informed the assessment of this Application is available on the FSANZ website at http://www.foodstandards.gov.au/code/applications/Pages/A1107-Asparaginase-BacillusSubtillisPA.aspx

SD1 Risk and Technical Assessment Report

Executive summary

Novozymes Australia Pty Ltd submitted an Application seeking permission for a new microbial source of the enzyme asparaginase (EC 3.5.1.1), sourced from a genetically modified strain of *Bacillus subtilis* containing the gene for a thermo-tolerant asparaginase from *Pyrococcus furiosus*. The purpose of using the enzyme is the potential reduction in the formation of acrylamide in some foods. Acrylamide is a contaminant formed during heat processing of some food for which there is public health and safety concern. These food groups are specifically, but not exclusively, breakfast cereals, various potato based products and green coffee beans.

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 subsection S18—4(5) in Schedule 18 of the revised Code (the Table to clause 17 of Standard 1.3.3 of the current Code).

After undertaking a risk assessment, FSANZ has concluded that there are no public health and safety issues associated with using the enzyme preparation as a food processing aid. Residual enzyme may be present in the final food but would be inactive and susceptible to digestion like other dietary proteins. FSANZ also 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 provided 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. Food manufacturers will need to perform their own efficacy testing to determine the appropriate production conditions to optimise acrylamide reduction for their food products and production facilities and to ensure acrylamide formation is reduced. The enzyme preparation meets international purity specifications.

No novel DNA or novel protein is present in the final food, therefore there are no genetically modified labelling requirements for use of this enzyme as a processing aid in the production of food. The mandatory declaration of soybean or wheat products would be required if these are present in the final food as a component of the enzyme (soybean meal or starch hydrolysates made from wheat starch may be used during the production of the enzyme preparation). The nomenclature for the enzyme (asparaginase) is consistent with the International Union of Biochemistry and Molecular Biology (IUBMB) naming system, the internationally recognised authority for enzyme nomenclature. The name is also consistent with the Code as asparaginase is a currently permitted enzyme from two different microbial sources.

FSANZ therefore proposes draft variations to permit asparaginase, sourced from a genetically modified strain of *B. subtilis* containing the gene for asparaginase from *P. furiosus*, as a processing aid. The proposed draft variations are only for the revised Code since it comes into operation on 1 March 2016, and it was felt unnecessary to amend the current Code which will be replaced at that time. Gazettal is expected to be close to this time.

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 the enzyme asparaginase (EC 3.5.1.1) sourced from *Bacillus subtilis* containing the gene for asparaginase from *Pyrococcus furiosus* as a processing aid to be used in producing food. The Application states that the enzyme is used to hydrolyse asparagine to aspartic acid and ammonia to reduce the formation of acrylamide during food manufacture. Examples of food applications are breakfast cereals, potato crisps (chips), potato products and green coffee beans. Acrylamide is formed when asparagine and reducing sugars react at temperatures above 120°C. Acrylamide is a public health and safety contamination issue so any methods and processes to reduce its formation in food is a public health benefit. FSANZ has a fact sheet on acrylamide[1].

The enzyme preparation is produced from a genetically modified microorganism, *B. subtilis* containing the gene for asparaginase from *P. furiosus*. During production of the enzyme preparation, the source organism is removed through filtration.

The Applicant reported that the enzyme is largely heat inactivated by excessive heat treatment during food manufacturing processes such as the roasting of coffee beans and the extrusion and toasting of breakfast cereal. Guidelines for time and temperature to achieve enzyme inactivation were provided in the Application.

1.3 The current Standard

Enzymes used in the production and manufacture of food sold in Australia and New Zealand are considered processing aids (Standard 1.3.3 of both the current and revised *Australia New Zealand Food Standards Code* (the Code)). Only those enzymes listed in Schedule 18 – Processing Aids in the revised Code are permitted to be used in producing food sold in Australia and New Zealand. Permitted enzymes of microbial origin are listed in the table to subsection S18—4(5) in Schedule 18 of the revised Code (the Table to clause 17 of Standard 1.3.3 of the current Code (ComLaw 2014a)).

Currently, asparaginase (EC number 3.5.1.1) is a permitted enzyme in the table to subsection S18—4(5) with two listed sources: *Aspergillus niger* and *Aspergillus oryzae*. *B. subtilis* is the host microorganism for several other permitted enzymes in the Code (i.e. α-acetolactate decarboxylase, α-Amylase, β-amylase, endo-1,4-beta xylanase, β-glucanase, hemicellulase multicomponent enzyme, maltogenic α-amylase, metalloproteinase, pullulanase, and serine proteinase). *P. furiosus* is not listed in the Schedule as a host microorganism or as a gene donor.

1.3.1 International Standards

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

[1] FSANZ fact sheet on acrylamide and food, 2014, http://www.foodstandards.gov.au/consumer/chemicals/acrylamide/Pages/default.aspx

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 2006) and the Food Chemicals Codex (Food Chemicals Codex 2014).

The enzyme preparation has been approved for use in food production in Denmark, the United States of America (US FDA 2014), Brazil (ANVISA 2014) and Mexico (COFEPRIS 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 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 asparaginase enzyme preparation, containing asparaginase produced by genetically modified *B. subtilis* strain MOL2940, as a food processing aid because:

- The production organism *B. subtilis* 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. subtilis* 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 analysis indicated that the enzyme has no biologically relevant homology to known protein allergens or toxins.

- The enzyme preparation 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 1.207 g TOS (Total Organic Solids)/kg bodyweight/day, the highest dose tested.

- The enzyme preparation was not genotoxic *in vitro*.

It is noted that JECFA allocated an acceptable daily intake (ADI) “not specified” for asparaginase from both *Aspergillus oryzae* expressed in *A. oryzae* (JECFA 2007) and *A. niger* expressed in *A. niger* (Mueller et al. 2009). Based on the reviewed toxicological data, it is concluded that in the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) ‘not specified’ is appropriate for asparaginase from *B. subtilis.* A dietary exposure assessment is 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 to be effective in achieving its stated purpose. The enzyme preparation meets international purity specifications for enzymes used in the production of food.

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

2.2 Risk management

The risk assessment conclusions provide evidence that there are no safety risks from the use of this enzyme as intended. As processing aids require permissions in the Code, the main risk management option available to FSANZ is to approve or reject the request to amend the Code. Other risk management options available for this Application are related to labelling and enzyme nomenclature which are discussed below. The regulatory options analysed in section 2.4.1.1 take account of the safety of the enzyme preparation.

2.2.1 Enzyme nomenclature

FSANZ notes that the International Union of Biochemistry and Molecular Biology (IUBMB), the internationally recognised authority for enzyme nomenclature, uses the name "asparaginase" for enzymes with an EC number of 3.5.1.1 (IUBMB 2015). This is the name used in the Standard and will be used for this enzyme.

2.2.2 Labelling considerations

2.2.2.1 Genetically modified labelling

Processing aids are, in most cases, exempt from the requirement to be declared in the statement of ingredients in accordance with paragraphs 1.2.4—3(2)(d) and (e) of the revised Code (subclause 3(d) of Standard 1.2.4 – Labelling of Ingredients of the current Code). However, labelling requirements do apply where novel DNA and/or novel protein from the processing aid remains in the final food as per paragraph 1.5.2—4(1)(b) of the revised Code (paragraph 4(1)(d) of Standard 1.5.2 – Food produced using Gene Technology of the current Code). In such cases, the statement 'genetically modified' must be declared on the label of the food in conjunction with the reference to the processing aid. Novel DNA and/or novel protein is defined in the amended definition in subsection 1.5.2—4(5) of the revised Code (subclause 4(1) of Standard 1.5.2 of the current Code).

As the source organism that is genetically modified is not present in the final enzyme preparation (the source organism is removed through filtration), no novel DNA remains in the enzyme preparation or in the final food. Although residual protein from the enzyme preparation is expected to be present in the final food, the enzyme protein is identical to enzymes found in nature. Consequently, the residual protein from the enzyme preparation is not considered to be novel protein for the purposes of genetically modified labelling. Therefore, as no novel DNA or novel protein is present in the final food, there are no genetically modified labelling requirements for use of this enzyme as a processing aid in the production of food.

2.2.2.2 Mandatory declaration of certain substances

Soybean meal and starch hydrolysates (which may be produced from wheat starch) are potential raw material sources that may be used in the fermentation process during the production of the enzyme preparation.

The presence of these soybean or wheat products in the final food as a component of the enzyme preparation would require mandatory declaration in accordance with section 1.2.3—4 of the revised Code (clause 4 of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations of the current Code).

2.2.3 International acrylamide reduction strategies

International food regulators are working with industry to reduce acrylamide levels in foods. New farming and processing techniques are being investigated to produce lower levels of acrylamide, for example, lowering cooking temperatures, using enzymes that reduce acrylamide formation and obtaining raw materials with lower reducing sugar levels.

FoodDrinkEurope produced an updated Acrylamide Toolbox in 2013[2] to help the food industry use methods to minimise the formation of acrylamide in their processed food. It specifically mentions using asparaginase in food processing, with the understanding that regulatory approval is first required.

The Codex Committee on Contaminants in Food (CCCF) developed a Codex Code of Practice for the Reduction of Acrylamide in Food (CAC/RCP 67-2009)[3] which was adopted and published in 2009. This document highlights the potential use of the enzyme asparaginase to reduce asparagine and hence acrylamide formation in food, specifically potato products made from potato dough and cereal-based products.

The availability of a new thermo-tolerant asparaginase for use in the food industry is in keeping with acrylamide formation mitigation strategies.

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. Every submission 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.

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[2] FoodDrinkEurope, 2014. FoodDrinkEurope Acrylamide Toolbox 2013-. http://www.fooddrinkeurope.eu/uploads/publications_documents/AcrylamideToolbox_2013.pdf Accessed 21 May 2015

[3] Codex Alimentarius, 2009, Codex Code of Practice for the Reduction of Acrylamide in Food (CAC/RCP 67-2009), at http://www.codexalimentarius.org/download/standards/11258/CXP_067e.pdf Accessed 21 May 2015

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 Australia and New Zealand Ministerial Forum on Food Regulation[4] (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 members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards. Amending the Code to allow asparaginase sourced from a genetically modified strain of *B. subtilis* as a permitted processing aid (enzyme) is unlikely to have a significant effect on international trade as the enzyme preparation complies with international specifications for food enzymes written by JECFA and the Food Chemicals Codex (9th Edition). Therefore, a notification to WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 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 the Code to permit the use of asparaginase sourced from a genetically modified strain of *B. subtilis* containing the gene for asparaginase from *P. furiosus* 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.

[4] Convening as the Australia and New Zealand Food Regulation Ministerial Council

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 public health and safety benefits (reduction in acrylamide) and any costs related to the options.

Option 1 – Prepare a draft variation to the Code

Sector	Costs or benefits to sector
Consumers	Potential reduction in the amount of acrylamide in some foods. There is considerable concern with respect to public health and safety with levels of acrylamide formed in some foods.
Industry	There are benefits to the food industry in using thermo-tolerant asparaginase. These are an option to reduce the level of acrylamide formation during food manufacture, particularly where a greater degree of thermo-tolerance is required.
Governments	There are no costs or benefits to governments associated with this option. There are public health benefits to reducing the formation of acrylamide in some foods.

Option 2 – Reject the Application

Sector	Costs or benefits to sector
Consumers	There is the possible detriment that technology available to reduce acrylamide in some foods will not be used.
Industry	There are no benefits to industry from this option. However, there are likely to be costs by not allowing industry the use of one option to reduce the potential formation of acrylamide in a variety of food products by using thermo-tolerant asparaginase. There are a range of different options and technologies that industry can use to reduce the formation of acrylamide; use of the asparaginase enzyme is one of them (see section 2.2.3).
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. There are public health benefits to measures that reduce the formation of acrylamide in some foods (i.e. the use of this asparaginase enzyme during the processing of certain foods). Therefore, the preferred option is to prepare a draft variation to the revised Code.

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

Schedule 18 of the revised Code applies in 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 the enzyme asparaginase sourced from a genetically modified strain of *B. subtilis* as a processing aid.

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

No issues have been identified. The labelling requirements for processing aids are discussed in Section 2.2.2 – Labelling considerations.

2.4.2.3 The prevention of misleading or deceptive conduct

There are no issues identified with 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 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, this enzyme is permitted for use in Denmark, the United States of America, Brazil and Mexico.

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

The enzyme preparation is claimed to provide advantages in reducing acrylamide formation in a variety of food products due to the thermo-tolerant nature of the enzyme compared to other asparaginases. There has been an expression of support from the local food industry for the Application to amend the Code to include this enzyme.

The food industry will make their own economic decisions, taking account of costs and benefits of using a new enzyme preparation to determine if it is of benefit to their business.

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

The enzyme preparation has been permitted and assessed as safe in other countries. It is therefore appropriate that the local Australian and New Zealand food industries have access to the same enzyme preparation which may have benefits to industry and consumers.

- **any written policy guidelines formulated by the Ministerial Council**[5]

The Ministerial Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*[6] 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 the enzyme asparaginase sourced from a genetically modified strain of *B. subtilis* as a processing aid is consistent with the specific order policy principles for 'Technological Function'.

3 Draft variation

The proposed draft variations are only for the revised Code which comes into operation on 1 March 2016. As gazettal is expected to be close to this time, it was felt unnecessary to amend the current Code, which will be replaced at that time.

The draft variation to the revised Code is at Attachment A and the related draft explanatory statement is at Attachment B. The variation is intended to take effect on 1 March 2016.

An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislative Instruments (FRLI).

3.1 Transitional arrangements

3.1.1 Transitional arrangements for Code Revision

FSANZ has completed a review of the Code undertaken under Proposal P1025[7] in order to improve its clarity and legal efficacy. Following approval of the revision and Ministerial consideration, the new Code will commence on 1 March 2016 (following gazettal on 10 April 2015 and registration on the Federal Register of Legislative Instruments).

[5] Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)
[6] http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx
[7] http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx

The current Code will also be repealed on this date. The draft variation at Attachment A varies the revised Code on 1 March 2016.

4 References

ANVISA (2014) Collegiate Directorate of Resolution - RDC No. 53 of 07 of October 2014. http://translate.google.com.au/translate?hl=en&sl=pt&u=http://portal.anvisa.gov.br/wps/wcm/connect/e156580045c8232da081e2d10ee53f37/Resolu%25C3%25A7%25C3%25A3o%2BRDC%2Bn.%2B53_2014_Lista%2Bde%2Benzimas.pdf%3FMOD%3DAJPERES&prev=search.

COFEPRIS (2014) Adiciones Al Anexo VI Enzimas (19 September 2014). http://www.cofepris.gob.mx/AZ/Documents/Aditivos/AnexoVI.pdf

ComLaw (2014a) *Australia New Zealand Food Standards Cod*e: Standard 1.3.3 – Processing Aids. http://www.comlaw.gov.au/Series/F2008B00616

ComLaw (2014b) *Australia New Zealand Food Standards Code*: Standard 1.5.2 - Food Produced Using Gene Technology. http://www.comlaw.gov.au/Series/F2008B00628

IUBMB (2015) EC 3.5.1.1. http://www.enzyme-database.org/query.php?ec=3.5.1.1

JECFA (2006) General specifications and considerations for enzyme preparations used in food processing. http://www.fao.org/docrep/009/a0691e/A0691E03.htm

Food Chemicals Codex 9th Edition (2014), The United States Pharmacopeia, United States Pharmacopeial Convention, Rockville, MD. http://www.usp.org/food-ingredients/food-chemicals-codex

US FDA (2014) Agency Response Letter GRAS Notice No. GRN 000476. http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm396395.htm

Attachments

A. Draft variation to the revised *Australia New Zealand Food Standards Code* (commencing 1 March 2016)
B Draft Explanatory Statement

Attachment A – Draft variation to the revised *Australia New Zealand Food Standards Code* (commencing 1 March 2016)

Food Standards (Application A1107 – Asparaginase from *Bacillus subtilis* as a Processing Aid (Enzyme)) Variation

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 2 of the 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.

1 Name of instrument

This instrument is the *Food Standards (Application A1107 – Asparaginase from* Bacillus subtilis *as a Processing Aid (Enzyme)) Variation*.

2 Commencement

This instrument commences on 1 March 2016 immediately after the commencement of Standard 5.1.1 – Revocation and transitional provisions — 2014 Revision.

3 Variation of Schedules

The Schedule varies a Schedule in the *Australia New Zealand Food Standards Code*.

Schedule

[1] Schedule 18 is varied by omitting from the table to section S18—4(5)

“

Asparaginase (EC 3.5.1.1)	*Aspergillus niger* *Aspergillus oryzae*

”

and inserting

“

Asparaginase (EC 3.5.1.1)	*Aspergillus niger* *Aspergillus oryzae* *Bacillus subtilis*, containing the gene for asparaginase isolated from *Pyrococcus furiosus*

”

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 A1107 which seeks to permit the use of a new microbial source for asparaginase sourced from a genetically modified strain of *Bacillus subtilis* for use in food production to reduce the risk of acrylamide formation. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation.

2. Purpose

The Authority has proposed that the enzyme asparaginase, sourced from a genetically modified strain of *B. subtilis* containing the gene for asparaginase from *Pyrococcus furiosus,* is permitted as a processing aid. This requires an addition to the table to subsection S18—4(5) in Schedule 18.

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 A1107 will include one round of public consultation following an assessment and the preparation of a draft Standard and associated report. A call for submissions (including the draft variation) will occur for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variation to Schedule 18 is 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

The variation inserts a new entry into the Table to subsection S18—4(5) in Schedule 18. The new entry will permit the use of asparaginase (EC 3.5.1.1) from a genetically modified form of the microorganism *B. subtilis*, containing the gene for asparaginase from *P. furiosus*, as a processing aid in the production of food.