

2 October 2015
[24–15]

Approval Report – Application A1107

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

Food Standards Australia New Zealand (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.

On 19 June 2015, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received three submissions.

FSANZ approved the draft variation on 17 September 2015. The Australia and New Zealand Ministerial Forum on Food Regulation¹ (Forum) was notified of FSANZ's decision on 1 October 2015.

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	3
1.1 THE APPLICANT	3
1.2 THE APPLICATION	3
1.3 THE CURRENT STANDARD	3
1.4 REASONS FOR ACCEPTING APPLICATION	4
1.5 PROCEDURE FOR ASSESSMENT	4
2 SUMMARY OF THE FINDINGS	4
2.1 SUMMARY OF ISSUES RAISED IN SUBMISSIONS	4
2.2 RISK ASSESSMENT	4
2.3 RISK MANAGEMENT	5
3 IMPACT ANALYSIS	6
4 DECISION	7
5 RISK COMMUNICATION	7
6 FSANZ ACT ASSESSMENT REQUIREMENTS	7
6.1 SECTION 29.....	7
6.1.1 <i>Cost benefit analysis</i>	7
6.1.2 <i>Other measures</i>	8
6.1.3 <i>Any relevant New Zealand standards</i>	8
6.1.4 <i>Any other relevant matters</i>	8
6.2 SUBSECTION 18(1)	8
6.2.1 <i>Protection of public health and safety</i>	8
6.2.2 <i>The provision of adequate information relating to food to enable consumers to make informed choices</i>	8
6.2.3 <i>The prevention of misleading or deceptive conduct</i>	8
6.3 SUBSECTION 18(2) CONSIDERATIONS	8
8 REFERENCES	9
ATTACHMENT A – APPROVED DRAFT VARIATION TO THE REVISED <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i> (COMMENCING 1 MARCH 2016)	11
ATTACHMENT B – EXPLANATORY STATEMENT	13

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-BacillusSubtilisPA.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 Applicant claimed the purpose of using the enzyme is the hydrolysis of asparagine to reduce the risk of acrylamide formation in various foods during manufacture. 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 current *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 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, was technologically justified and had 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 when this enzyme is used as a processing aid in producing 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) was consistent with the International Union of Biochemistry and Molecular Biology (IUBMB) naming system, the internationally recognised authority for enzyme nomenclature. The name was also consistent with the Code as asparaginase is a currently permitted enzyme from two different microbial sources.

FSANZ prepared a draft variation to the revised Code to permit a new microbial source of the enzyme asparaginase (EC 3.5.1.1), sourced from a genetically modified strain of *B. subtilis* containing the gene for a thermo-tolerant asparaginase from *P. furiosus*. A call for submissions was publically released in June 2015. All three submitters supported the draft variation, including two Government enforcement agencies.

FSANZ, therefore, prepared a variation to permit asparaginase, sourced from a genetically modified strain of *B. subtilis* containing the gene for asparaginase from *P. furiosus*, as a processing aid. With the Applicant’s agreement, the prepared variation is only for the revised Code which comes into operation on 1 March 2016, as it was felt unnecessary to amend the current Code which will be replaced at that 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 was 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 stated that the enzyme is used to hydrolyse asparagine to aspartic acid and ammonia to reduce the risk of acrylamide formation 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 provide a public health benefit. FSANZ has website information on acrylamide².

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 to produce and manufacture 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.

² FSANZ fact sheet on acrylamide and food, 2014,
<http://www.foodstandards.gov.au/consumer/chemicals/acrylamide/Pages/default.aspx>

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. However, there are internationally recognised specifications for enzymes, including those produced from genetically modified microbial sources. These enzyme specifications are provided by the Joint Food and Agricultural Organization/World Health Organization 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 was assessed under the General Procedure.

2 Summary of the findings

2.1 Summary of issues raised in submissions

No issues were raised in responses to the Call for Submissions document, which was released for comment between 19 June and 31 July 2015. All submitters supported permitting the enzyme asparaginase (EC 3.5.1.1) sourced from *B. subtilis* containing the gene for asparaginase from *P. furiosus* as a processing aid to be used in producing food.

2.2 Risk assessment

There were no public health and safety issues associated with using 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 was noted that JECFA allocated an acceptable daily intake (ADI) “not specified” for asparaginase from both *A. 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 was concluded that in the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) ‘not specified’ was appropriate for asparaginase from *B. subtilis*. 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, was 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).

2.3 Risk management

The risk assessment conclusions provided 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 was to approve or reject the request to amend the Code. Other risk management options available for this Application were related to labelling and enzyme nomenclature which are discussed below.

2.3.1 Enzyme nomenclature

FSANZ noted 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 for this enzyme.

2.3.2 Labelling considerations

2.3.2.1 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 in 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 in 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 using this enzyme as a processing aid in the production of food.

2.3.2.2 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 in 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 2013³ 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)⁴ 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.

3 Impact analysis

FSANZ undertook a limited impact analysis for this Application and concluded that permitting the use of asparaginase sourced from a genetically modified strain of *B. subtilis* containing the gene for asparaginase from *P. furiosus* as a food processing aid had benefits to the various sectors of the food industry. These included manufacturers of breakfast cereals, potato-based products and green coffee beans. These benefits are potentially lower levels of acrylamide formed during processing. There were no costs to different stakeholders that overrode these benefits. There were no benefits in rejecting the Application.

³ FoodDrinkEurope, 2014. FoodDrinkEurope Acrylamide Toolbox 2013-.
http://www.fooddrinkeurope.eu/uploads/publications_documents/AcrylamideToolbox_2013.pdf
Accessed 21 May 2015

⁴ 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

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 outweighed 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 was to prepare a draft variation to the Code.

4 Decision

The variation to the revised Code is at Attachment A and is intended to take effect on 1 March 2016.

An 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.

5 Risk communication

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

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

The process by which FSANZ considers 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 FSANZ Board considered the draft variation taking into account public comments received from the 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.

The FSANZ Board's decision has been notified to the Australia and New Zealand Ministerial Forum on Food Regulation⁵ (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.

6 FSANZ Act assessment requirements

6.1 Section 29

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 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. The analysis is described in section 3.

⁵ Convening as the Australia and New Zealand Food Regulation Ministerial Council

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.

6.1.3 Any relevant New Zealand standards

Schedule 18 of the revised Code applies in New Zealand and there are no relevant New Zealand-only Standards.

6.1.4 Any other relevant matters

There are no other relevant matters.

6.2 Subsection 18(1)

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

6.2.1 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.

6.2.2 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 2.3.2 above.

6.2.3 The prevention of misleading or deceptive conduct

There are no issues identified with this Application relevant to this objective.

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 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 was 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 had been an expression of support from the local food industry for the Application to amend the Code to include this enzyme. The food industry businesses will make their own commercial 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 had been permitted and assessed as safe in other countries. It is therefore appropriate that 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 Council⁶**

The Ministerial Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*⁷ 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 had 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'.

8 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/156580045c8232da081e2d10ee53f37/Resolu%25C3%25A7%25C3%25A3o%2BRDC%2Bn.%2B532014_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 Code*: 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>

⁶ Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

⁷ <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

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

Attachment A – Approved 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

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)	<i>Aspergillus niger</i> <i>Aspergillus oryzae</i>
---------------------------	---

”

and inserting

“

Asparaginase (EC 3.5.1.1)	<i>Aspergillus niger</i> <i>Aspergillus oryzae</i> <i>Bacillus subtilis</i> , containing the gene for asparaginase isolated from <i>Pyrococcus furiosus</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 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.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation⁸, 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 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 included one round of public consultation following an assessment and the preparation of a draft Standard and associated report. Submissions were called for on 19 June 2015 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.

⁸ 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

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.