

2 June 2015
[10–15]

Approval Report – Application A1098

Serine Protease (Chymotrypsin) as a Processing Aid

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Novozymes Australia Pty Ltd to approve a new enzyme, serine protease (chymotrypsin), sourced from a genetically modified strain of *Bacillus licheniformis* containing the genes for chymotrypsin from *Nocardioopsis prasina* as a processing aid.

On 16 January 2015, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received three submissions.

FSANZ approved the draft variation on 20 May 2015. The Australia and New Zealand Ministerial Forum on Food Regulation¹ (Forum) was notified of FSANZ's decision on 26 May 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
1.3.1 <i>International Standards</i>	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
2.3.1 <i>Enzyme nomenclature</i>	5
2.3.2 <i>Labelling</i>	5
3 IMPACT ANALYSIS	6
4 DECISION	6
5 RISK COMMUNICATION	6
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>	7
6.1.3 <i>Any relevant New Zealand standards</i>	7
6.1.4 <i>Any other relevant matters</i>	7
6.2 SUBSECTION 18(1).....	7
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
7 TRANSITIONAL ARRANGEMENTS FOR CODE REVISION	9
8 REFERENCES	9
ATTACHMENT A – APPROVED DRAFT VARIATION TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i>	11
EXPLANATORY STATEMENT	13
ATTACHMENT B – APPROVED DRAFT VARIATION TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE (COMMENCING 1 MARCH 2016)</i>	15
EXPLANATORY STATEMENT	17

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/A1098SerineProtease-ChymotrypsinPA.aspx>

SD1 Risk and technical assessment report (at Approval)

Executive summary

Novozymes Australia Pty Ltd submitted an Application seeking permission for a new enzyme, serine protease (chymotrypsin specificity, EC 3.4.21.1), sourced from a genetically modified strain of *Bacillus licheniformis* containing the genes for chymotrypsin from *Nocardioopsis prasina*. The Applicant claims the purpose of using the enzyme is the hydrolysis of peptide bonds in proteins to produce smaller proteins and peptides of smaller length with various functionalities. Enzyme treatment is an alternative approach to acid and alkaline hydrolysis and heat treatment to produce protein hydrolysates.

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 existing *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 in the existing Code. Standard 1.3.3 is replicated in the revised Code. The relevant provisions in that version of the Code are in Schedule 18.

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 may be present in the final food but would be inactive and susceptible to digestion like other dietary proteins. FSANZ further concluded that in the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) 'not specified' is appropriate. A dietary exposure assessment was therefore not required.

The evidence presented to support the proposed uses provided adequate assurance that the enzyme, in the form described in the Application 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. Therefore the assessment considered that the enzyme should be permitted to be used as a processing aid.

The approved enzyme name was determined to be "chymotrypsin" as this is consistent with the International Union of Biochemistry and Molecular Biology naming system.

No novel DNA or novel protein is present in the final food, therefore there are no labelling requirements for use of this enzyme as a processing aid in the production of food.

The FSANZ Board has approved draft variations to the Table to clause 17 of Standard 1.3.3 of the existing Code and to Schedule 18 of the revised Code. These approved variations permit a serine protease (chymotrypsin), sourced from a genetically modified strain of *B. licheniformis* containing genes for chymotrypsin from *N. prasina*, as a new processing aid.

FSANZ received three submissions on the draft variation following the call for submissions, with all submitters supporting the draft variation. No issues were raised.

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 Application was received by FSANZ on 30 July 2014.

The purpose of the Application was to seek permission for the enzyme, serine protease (chymotrypsin specificity, EC 3.4.21.1) to be used as a processing aid in producing food. The Application stated that the enzyme can be used for the partial or extensive hydrolysis of various animal and vegetable proteins such as casein, whey, gluten, and proteins from soy, corn, rice, peas, lentils, meat and fish. Hydrolysis of peptide bonds in proteins produces smaller proteins and peptides of smaller length. These protein hydrolysates are then used as ingredients in different types of food and beverage products. Enzyme treatment is an alternative approach to acid and alkaline hydrolysis and heat treatment to produce protein hydrolysates.

The enzyme preparation is produced from a genetically modified microorganism, *B. licheniformis* containing the genes for chymotrypsin from *N. prasina*. During production of the enzyme preparation, the source organism is removed through filtration.

Once the desired degree of hydrolysis is obtained in the production of protein hydrolysates, the food is subjected to a heat treatment to denature the enzyme, making it inactive with no function in the final food.

1.3 The current Standard

Enzymes used in producing and manufacturing 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 producing 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 there are no permissions for the enzyme serine protease (chymotrypsin) or enzymes with the EC number 3.4.21.1 in the Code. *B. licheniformis* is the host microorganism for a number of other permitted enzymes in the Code.

Standard 1.3.3 is replicated in the revised Code. The relevant provisions in that version of the Code are in Schedule 18.

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 FAO/WHO Expert Committee on Food Additives (JECFA 2006) and the Food Chemicals Codex (U.S. Pharmacopeial Convention 2014).

The enzyme preparation has been approved for use in food production in Denmark, France (Legifrance.gouv.fr 2015a, Legifrance.gouv.fr 2015b) and Mexico (COFEPRIS 2014). In Brazil, protease from *N. prasina* expressed in *B. licheniformis* is permitted for use in the production of foods (ANVISA 2014). JECFA positively evaluated the enzyme preparation at its 76th meeting in 2012. JECFA prepared a safety assessment (JECFA 2012a), a summary evaluation (JECFA 2012b), a Chemical and Technical Assessment (JECFA 2012c) and specifications (JECFA 2012d) for the enzyme preparation.

1.4 Reasons for accepting Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the FSANZ Act
- it related to a matter that warranted the variation of a food regulatory measure.

1.5 Procedure for assessment

The Application was assessed under the General Procedure.

2 Summary of the findings

2.1 Summary of issues raised in submissions

Three submissions were received—two were from government departments (one Australian; one New Zealand) and one was from a food technology association. No issues were raised in submissions. The draft variation to Standard 1.3.3 was supported by all submitters.

Submitters were satisfied that the use of the enzyme is technologically justified and that there were no public health or safety concerns identified during FSANZ's safety assessment of the enzyme preparation and donor/host microorganisms. Additionally, the usefulness of the enzyme for control and yield of protein hydrolysates was identified.

2.2 Risk assessment

There are no public health and safety issues associated with using the enzyme preparation, containing serine protease (chymotrypsin) produced by genetically modified (GM) *B. licheniformis*, as a food processing aid. This conclusion was based on 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 may be present in the final food but would be inactive.
- Bioinformatic analysis 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 NOAEL was 500 mg Total Organic Solids (TOS) per kg body weight per day, the highest dose tested.
- The enzyme preparation was not genotoxic *in vitro*.

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. A dietary exposure assessment was therefore not required.

Minor modifications were made to the Risk and technical assessment report (SD1) following the Call for Submissions to clarify the nomenclature for the production organism.

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. The enzyme preparation meets international specifications for enzyme preparations used in the production of food.

2.3 Risk management

The risk assessment conclusions provided evidence that there were no safety risks from the use of this enzyme as intended. As processing aids require permissions in the Code, the risk management options available to FSANZ were to approve or reject the draft variation to the Code.

Additionally, as discussed below, the risk management evaluation considered the appropriate enzyme nomenclature and the applicability of the labelling provisions in the Code.

2.3.1 Enzyme nomenclature

The nomenclature used in the French legislation is "Protéase à résidu sérine issue d'une souche génétiquement modifiée de *Bacillus licheniformis* (RH) contenant le gène codant la protéase de *Nocardiopsis prasina*" (Legifrance.gouv.fr 2015b) that translates to "Serine protease derived from a genetically modified *Bacillus licheniformis* (HR) containing the gene encoding the protease from *Nocardiopsis prasina* strain" (Legifrance.gouv.fr 2015a). The nomenclature used in the JECFA assessments is "serine protease (chymotrypsin)" (JECFA 2012a).

FSANZ noted that the International Union of Biochemistry and Molecular Biology (IUBMB), the internationally recognised authority for enzyme nomenclature, uses the name "Chymotrypsin" for enzymes with an EC number of EC 3.4.21.1 (IUBMB 2014). FSANZ used the IUBMB name of "Chymotrypsin" for the drafting for the Code (see Attachment A).

2.3.2 Labelling

Processing aids are, in most cases, exempt from the requirement to be declared in the statement of ingredients in accordance with subclause 3(d) of Standard 1.2.4 – Labelling of Ingredients of the existing Code (paragraphs 1.2.4-3(2)(d) and (e) of the revised 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 4(1)(d) of Standard 1.5.2 – Food produced using Gene Technology of the existing Code (paragraph 1.5.2-4(1)(b) of the revised 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 subclause 4(1) of Standard 1.5.2 of the existing Code (amended definition in subsection 1.5.2.4(5) of the revised 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 may 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, no novel DNA or novel protein is present in the final food and therefore there are no labelling requirements for use of this enzyme as a processing aid in the production of food.

3 Impact analysis

FSANZ undertook a limited impact analysis for this Application and concluded that permitting the use of the serine protease (chymotrypsin) sourced from a genetically modified strain of *B. licheniformis* as a food processing aid had benefits to the various sectors of the food industry, including manufacturers of protein hydrolysates. These benefits are higher yields of soluble proteins and peptides, milder process conditions, reduced amounts of salts used and better control of peptide profile so more tailored functions can be provided. There were no costs to different stakeholders that overrode these benefits. There were 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 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 Standard 1.3.3.

4 Decision

The draft variation to permit a new enzyme, chymotrypsin (EC 3.4.21.1), sourced from a genetically modified strain of *B. licheniformis* containing the gene for chymotrypsin from *N. prasina* as a processing aid, as proposed following assessment, was approved without change (see Attachment A). As a consequence, a draft variation to Schedule 18 of the revised Code was also approved (see Attachment B).

The approved draft variation to Standard 1.3.3 of the existing Code takes effect on gazettal.

The approved draft variation to Schedule 18 of the revised Code takes effect on 1 March 2016, which is the date on which the revised Code comes into effect.

The approved draft variations are at Attachments A and C. The explanatory statements are at Attachment B and D respectively. 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 the Application was considered and reviewed by FSANZ staff. All comments are valued and contribute to the rigour of our assessment.

FSANZ called for public comment between 16 January 2015 and 2 March 2015 after assessing the Application. All three submissions that were received supported the draft variation.

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 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 Regulation. 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.

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 above.

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

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

6.1.4 Any other relevant matters

Other relevant matters are considered below.

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 serine protease (chymotrypsin), sourced from a genetically modified strain of *B. licheniformis* as a processing aid.

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

No issues were identified. The labelling requirements for processing aids are discussed in Section 2.3.2 – Labelling.

6.2.3 The prevention of misleading or deceptive conduct

There were 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, France, Brazil and Mexico. It had also been assessed as safe by JECFA.

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

The enzyme preparation was claimed to provide advantages in the production and profile of protein hydrolysates that can be added to a variety of food products. 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 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 was therefore appropriate that the local Australian and New Zealand food industries had access to the same enzyme preparation which may have benefits to industry and consumers.

- **any written policy guidelines formulated by the Ministerial Council²**

The Ministerial Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*³ 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 determined that permitting the use of the enzyme serine protease (chymotrypsin), sourced from a genetically modified strain of *B. licheniformis* as a processing aid was consistent with the specific order policy principles for 'Technological Function'.

7 Transitional arrangements for Code Revision

FSANZ has completed a review of the Code undertaken under Proposal P1025⁴ 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). The current Code will also be repealed on this date. The approved variation at Attachment B varies the revised Code on 1 March 2016 to ensure that the revised Code is consistent with the current Code as amended by the variation at Attachment A.

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/e156580045c8232da081e2d10ee53f37/Resolu%25C3%25A7%25C3%25A3o%2BRDC%2Bn.%2B53-2014_Lista%2Bde%2Benzimas.pdf%3FMOD%3DAJPERES&prev=search. Accessed 6 March 2015

COFEPRIS (2014) Adiciones Al Anexo Vi Enzimas.
<http://translate.google.com.au/translate?hl=en&sl=es&u=http://www.cofepris.gob.mx/AZ/Documents/Aditivos/AnexoVI.pdf&prev=search>. Accessed 6 March 2015

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>

² Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

³ <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

⁴ <http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx>

Legifrance.gouv.fr (2015a) Order of 19 October 2006 on the use of processing aids in the manufacture of certain foodstuffs.

http://translate.googleusercontent.com/translate_c?depth=1&hl=en&prev=/search%3Fq%3Dfrench%2BOrder%2Bof%2B19%2BOctober%2B2006%2Bvenenatum%26biw%3D1536%26bih%3D875&rurl=translate.google.com.au&sl=fr&u=http://www.legifrance.gouv.fr/affichTexte.do%3FcidTexte%3DLEGITEXT000020667468&usq=ALkJrhjh44Huuxku-TY5yEij6TjZVcFUTQ. Accessed 6 March 2015

Legifrance.gouv.fr (2015b) Order of 19 October 2006 on the use of processing aids in the manufacture of certain foodstuffs.

<http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000271061&dateTexte=>. Accessed 6 March 2015

JECFA (2006) General specifications and considerations for enzyme preparations used in food processing. <http://www.fao.org/docrep/009/a0691e/A0691E03.htm>. Accessed 6 March 2015

JECFA (2012a) Serine protease (chymotrypsin) from *Nocardiosis prasina* expressed in *Bacillus licheniformis*. In: Safety evaluation of certain food additives (prepared by the seventy-sixth meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA)). 67 ed, World Health Organization, Geneva, p. 39–49

JECFA (2012b) Evaluation of certain food additives: seventy-sixth report of the Joint FAO/WHO Expert Committee on Food Additives. 974. World Health Organization, Geneva.

http://apps.who.int/iris/bitstream/10665/77752/1/WHO_TRS_974_eng.pdf. Accessed 6 March 2015

JECFA (2012c) Serine protease (chymotrypsin) from *Nocardiosis prasina* expressed in *Bacillus licheniformis*: Chemical and Technical Assessment.

http://www.fao.org/fileadmin/user_upload/agns/pdf/CTA_Serine_Protease_Chymotrypsin_IM_Final.pdf. Accessed 6 March 2015

JECFA (2012d) Serine protease with chymotrypsin specificity from *Nocardiosis prasina* expressed in *Bacillus licheniformis*. 13. Geneva.

<http://www.fao.org/ag/agn/jecfa-additives/specs/monograph13/additive-530-m13.pdf>. Accessed 6 March 2015

U.S.Pharmacopeial Convention (2014) Food Chemicals Codex.

<http://www.usp.org/food-ingredients/food-chemicals-codex>. Accessed 6 March 2015

Attachments

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

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



Food Standards (Application A1098 – Serine Protease (Chymotrypsin) 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 A1098 – Serine Protease (Chymotrypsin) 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 inserting in the Table to clause 17 in alphabetical order

“

Chymotrypsin EC 3.4.21.1	<i>Bacillus licheniformis</i> , containing the gene for chymotrypsin isolated from <i>Nocardiopsis prasina</i>
-----------------------------	---

”

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.

The Authority accepted Application A1098 which seeks to approve a new enzyme, serine protease (chymotrypsin), sourced from a genetically modified strain of *Bacillus licheniformis* containing the genes for chymotrypsin from *Nocardiopsis prasina* as a processing aid. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft Standard.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation⁵, 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 chymotrypsin produced by a genetically modified microorganism, *B. licheniformis* containing the gene for serine protease (chymotrypsin) from *N. prasina*. This requires an addition to the Table to clause 17 (Permitted enzymes of microbial origin) in Standard 1.3.3 – Processing Aids. The nomenclature for the enzyme for inclusion in Standard 1.3.3 was determined as “chymotrypsin” as this is consistent with the IUBMB naming system.

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 A1098 included one round of public consultation following an assessment and the preparation of a draft Standard and associated report. Submissions were called for on 16 January 2015 for approximately 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.

⁵ 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 clause 17 of Standard 1.3.3. The new entry will permit the use of chymotrypsin (EC 3.4.21.1) from a genetically modified form of the microorganism *B. licheniformis*, containing the genes for chymotrypsin from *N. prasina*, as a processing aid in the production of food.

Attachment B – Approved draft variation to the *Australia New Zealand Food Standards Code* (commencing 1 March 2016)



Australia New Zealand Food Standards Code – Transitional Variation 2015 (Application A1098 – Serine Protease (Chymotrypsin) as a Processing Aid (Enzyme))

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 *Australia New Zealand Food Standards Code – Transitional Variation 2015 (Application A1098 – Serine Protease (Chymotrypsin) as a Processing Aid (Enzyme))*

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 to the *Australia New Zealand Food Standards Code*

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

SCHEDULE

[1] **Schedule 18** is varied by inserting in the table to subsection S18—4(5), in alphabetical order

“

Chymotrypsin (EC 3.4.21.1)

Bacillus licheniformis, containing the gene for chymotrypsin isolated from *Nocardiopsis prasina*

”

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).

FSANZ had completed a review of the Code undertaken under Proposal P1025⁶ in order to improve the Code's clarity and legal efficacy. A revised Code has been approved and will commence on 1 March 2016. It will replace the existing Code, which will be repealed on that date.

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 A1098 which seeks to approve an enzyme, serine protease (chymotrypsin), sourced from a genetically modified strain of *Bacillus licheniformis* containing the genes for chymotrypsin from *Nocardioopsis prasina* as a processing aid.

The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation to Standard 1.3.3 of the existing Code.

The Authority has also approved a draft variation to Schedule 18 of the revised Code to ensure that, on 1 March 2016, the revised Code is consistent with the existing Code as amended by the draft variation.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation⁷, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the draft variation.

Section 94 of the FSANZ Act specifies that 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. Commencement

The approved variation to the revised Code takes effect on 1 March 2016. This is the date on which the existing Code is repealed and the revised Code comes into effect.

3. Purpose

The Authority has approved chymotrypsin (EC 3.4.21.1) produced by a genetically modified microorganism, *B. licheniformis* containing the gene for serine protease (chymotrypsin) from *N. prasina*. This requires the addition of a new entry into the table to subsection S18—4(5) in Schedule 18 of the revised Code. The nomenclature for the enzyme for inclusion in Standard 1.3.3 was determined as 'chymotrypsin' as this is consistent with the IUBMB naming system.

⁶ <http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx>

⁷ convening as the Australia and New Zealand Food Regulation Ministerial Council

4. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1098 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 16 January 2015 for approximately a six-week consultation period.

A Regulation Impact Statement was not required because the Application is likely to have a minor but beneficial impact on business and individuals.

6. 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.

7. Variation

Item [1] of the Schedule to the Variation amends Schedule 18 of the revised Code by inserting a new entry into the table to subsection S18—4(5).

The new entry permits the use of chymotrypsin (EC 3.4.21.1) sourced from a genetically modified strain of *Bacillus licheniformis* containing the genes for chymotrypsin from *Nocardiopsis prasina* as a processing aid in the production of food.