

16 January 2015
[01–15]

Call for submissions – Application A1098

Serine Protease (Chymotrypsin) as a Processing Aid (Enzyme)

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 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) 27 February 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:

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

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

Table of Contents

EXECUTIVE SUMMARY	2
1 INTRODUCTION	3
1.1 THE APPLICANT	3
1.2 THE APPLICATION.....	3
1.3 THE CURRENT STANDARD.....	3
1.3.1 <i>International Standards</i>	3
1.4 REASONS FOR ACCEPTING APPLICATION	4
1.5 PROCEDURE FOR ASSESSMENT	4
2 SUMMARY OF THE ASSESSMENT	4
2.1 RISK ASSESSMENT	4
2.2 RISK MANAGEMENT	5
2.2.1 <i>Enzyme nomenclature</i>	5
2.2.2 <i>Labelling</i>	5
2.3 RISK COMMUNICATION.....	6
2.3.1 <i>Consultation</i>	6
2.3.2 <i>World Trade Organization (WTO)</i>	6
2.4 FSANZ ACT ASSESSMENT REQUIREMENTS	6
2.4.1 <i>Section 29</i>	7
2.4.2 <i>Subsection 18(1)</i>	8
2.4.3 <i>Subsection 18(2) considerations</i>	9
3 DRAFT VARIATION	10
3.1 TRANSITIONAL ARRANGEMENTS.....	10
3.1.1 <i>Transitional arrangements for Code Revision</i>	10
4 REFERENCES	10
ATTACHMENT A – DRAFT VARIATION TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i>	12
ATTACHMENT B – DRAFT EXPLANATORY STATEMENT.....	14

Supporting document

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

<http://www.foodstandards.gov.au/code/applications/Pages/A1098SerineProtease-ChymotrypsinPA.aspx>.

SD1 Risk and Technical Assessment Report

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 *Nocardiopsis 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 *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.

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 provides adequate assurance that the enzyme, in the form and prescribed amounts, is technologically justified and has been demonstrated to be effective in achieving its stated purpose. The enzyme preparation meets international purity specifications.

FSANZ, therefore proposes draft variations to permit a serine protease (chymotrypsin), sourced from a genetically modified strain of *Bacillus licheniformis* containing genes for chymotrypsin from *Nocardiopsis prasina*, as a new processing aid. The nomenclature for the enzyme is consistent with the International Union of Biochemistry and Molecular Biology (IUBMB) naming system, the internationally recognised authority for enzyme nomenclature.

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, serine protease (chymotrypsin specificity, EC 3.4.21.1) as a processing aid to be used in producing food. The Application states 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, *Bacillus licheniformis* containing the genes for chymotrypsin from *Nocardiopsis 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 (ComLaw 2014a).

Currently there are no permissions for the enzyme serine protease (chymotrypsin) or enzymes with the EC number 3.4.21.1 in the Code. *Bacillus licheniformis* is the host microorganism for a number of other permitted enzymes in the Code.

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 2014) and Mexico (COFEPRIS 2014). In Brazil, protease from *Nocardiopsis 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 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

Application A1098 seeks approval for the use of a new enzyme, a serine protease (chymotrypsin), sourced from a genetically modified strain of *B. licheniformis* containing genes for chymotrypsin from *N. prasina*, as a processing aid. The stated purpose of this enzyme, namely production of peptides and smaller proteins with different functionalities via the partial or extensive hydrolysis of animal or vegetable proteins, is clearly articulated in the Application. The enzyme preparation meets international purity specifications for enzymes used in the production of food.

This risk assessment has considered the technological suitability of serine protease (chymotrypsin) as a food processing aid and the potential hazards of the production microorganism.

Based on the information supplied by the Applicant, FSANZ concludes that serine protease (chymotrypsin) fulfils its intended technological function. It is effective as a processing aid in producing peptides and smaller proteins at the level of proposed use.

There are no public health and safety issues associated with using the enzyme preparation as a food processing aid. This conclusion is 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 is concluded that, in the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) 'not specified' is appropriate. A dietary exposure assessment is therefore not required.

For further details on the risk assessment, refer to the Risk and Technical Assessment report (Supporting Document 1).

2.2 Risk management

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

2.2.1 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 2014) 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 2014). The nomenclature used in the JECFA assessments is "serine protease (chymotrypsin)" (JECFA 2012).

FSANZ notes 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 has used the IUBMB name of "Chymotrypsin" for the drafting for the Code (see Attachment A).

2.2.2 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. However, labelling requirements do apply where novel DNA and/or novel protein from the processing aid remains in the final food as per subclause 4(1)(d) of Standard 1.5.2 – Food produced using Gene Technology (ComLaw 2014b). In such cases, the name of the processing aid must be declared on the label of the food in conjunction with the statement 'genetically modified'.

Novel DNA and/or novel protein is defined in subclause 4(1) of Standard 1.5.2 to mean *DNA or a protein which, as a result of the use of gene technology, is different in chemical sequence or structure from DNA or protein present in counterpart food which has not been produced using gene technology*. FSANZ has taken 'counterpart food' in relation to enzymes to mean enzymes found in nature (naturally occurring enzymes).

As no genetically modified production organism is present in the final enzyme preparation (see section 2.1 above), no novel DNA remains in the enzyme preparation or in the final food. Although residual enzyme protein may be present in the final food, the enzyme is identical to that enzyme which is found in nature. Consequently, the residual enzyme protein 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.

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.

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 (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 serine protease (chymotrypsin) sourced from a genetically modified strain of *B. licheniformis* 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 Standard 1.3.3 to permit the use of serine protease (chymotrypsin), sourced from a genetically modified strain of *B. licheniformis* containing genes for chymotrypsin from *N. prasina* as a processing aid
- (2) reject the Application.

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

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

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

Option 1 – Prepare a draft variation to Standard 1.3.3

Sector	Costs or benefits to sector
Consumers	There should be no measurable impact or costs on consumers, but there may be improved characteristics and efficiencies in the manufacture of protein hydrolysates which may be a benefit to consumers.
Industry	There are benefits to the food industry in using serine protease (chymotrypsin) compared to acid and alkaline hydrolysis as well as heat treatment to produce protein hydrolysates. These are: <ul style="list-style-type: none">• higher yields of soluble proteins and peptides• milder process conditions• reduced amounts of salts used• better control of peptide profile so provide more tailored functions.
Governments	There are no costs or benefits to governments associated with this option.

Option 2 – Reject the Application

Sector	Costs or benefits to sector
Consumers	There are no benefits or costs to consumers of this option.
Industry	There are no benefits to industry from this option. However, there are likely to be costs by not giving industry the option to use new current improved technology to expand the market for new innovative hydrolysed protein products that can be used in a wide variety of food products.
Governments	There are no benefits or costs to governments for this option.

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

2.4.1.2 Other measures

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

2.4.1.3 Any relevant New Zealand standards

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

2.4.1.4 Any other relevant matters

There are no other relevant matters.

2.4.2 Subsection 18(1)

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

2.4.2.1 Protection of public health and safety

FSANZ has undertaken a safety assessment (SD1) and concluded that there are no public health and safety concerns related to permitting the enzyme serine protease (chymotrypsin), sourced from a genetically modified strain of *B. licheniformis* 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.

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 Risk and Technical Assessment Report. The Applicant submitted a dossier of scientific studies as part of their Application. Other technical information including scientific literature was also used in assessing the Application.

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

There are no Codex Alimentarius Standards for enzymes. However, this enzyme is permitted for use in Denmark, France, Brazil and Mexico. It has also been assessed as safe by JECFA.

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

The enzyme preparation is claimed to provide advantages in the production and profile of protein hydrolysates that can be added to a variety of food products. 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**

There are no fair trading aspects to this Application.

- **any written policy guidelines formulated by the Ministerial Council¹**

The Ministerial Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*² 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 serine protease (chymotrypsin), sourced from a genetically modified strain of *B. licheniformis* as a processing aid is consistent with the specific order policy principles for ‘Technological Function’.

¹ Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

² <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

3 Draft variation

The draft variation is at Attachment A. The variation is intended to take effect on gazettal. Explanation of the nomenclature used in the drafting is provided in section 2.2.1.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislative Instruments.

3.1 Transitional arrangements

3.1.1 Transitional arrangements for Code Revision

FSANZ is reviewing the Code in order to improve its clarity and legal efficacy. This review is being undertaken through Proposal P1025 – details of which are on the FSANZ website³. FSANZ released a draft revision of the Code for public comment in May 2013. The draft revision has changed the Code's structure and format. A further draft revision of the Code and call for submissions was released in July 2014.

The FSANZ Board approved the proposed changes to the Code in December 2014. If approved by the Forum, the new Code will commence in March 2016 and will repeal and replace the current Code. The new Code will then need to be amended to incorporate any outstanding changes made to the current Code, including the variations at Attachment A if not rejected by the Forum.

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. Accessed 14 November 2014

COFEPRIS (2014) Adiciones Al Anexo Vi Enzimas. <http://translate.google.com.au/translate?hl=en&sl=es&u=http://www.cofepris.gob.mx/Paginas/MapaDeSitio.aspx&prev=search>. Accessed 14 November 2014

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>

IUBMB (2014) EC 3.4.21.1. <http://www.enzyme-database.org/query.php?ec=3.4.21.1>

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

JECFA (2012a) Serine protease (chymotrypsin) from *Nocardioopsis 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

³ <http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx>

Expert Committee on Food Additives. 974. World Health Organization, Geneva.
http://apps.who.int/iris/bitstream/10665/77752/1/WHO_TRS_974_eng.pdf

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

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>

Legifrance.gouv.fr (2014a) 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 23 September 2014a

Legifrance.gouv.fr (2014b) 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 November 2014b

U.S.Pharmacopeial Convention (2014) Food Chemicals Codex.
<http://www.usp.org/food-ingredients/food-chemicals-codex>

Attachments

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

Attachment A – 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>
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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 A1098 which seeks to approve a new enzyme, serine protease (chymotrypsin), sourced from a genetically modified strain of *Bacillus licheniformis* as a processing aid. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation to the Code.

2. Purpose

The Authority has proposed that the enzyme, serine protease (chymotrypsin), sourced from a genetically modified strain of *Bacillus licheniformis* containing genes for chymotrypsin from *Nocardiopsis prasina*, is permitted as a processing aid. This requires an addition to the Table to clause 17 of Standard 1.3.3 (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 other enzyme naming in the Code. The nomenclature is consistent with the International Union of Biochemistry and Molecular Biology (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 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 Standard 1.3.3 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 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.