

12 April 2018
[43-18]

Call for submissions – Application A1146

Thermolysin as a Processing Aid

FSANZ has assessed an Application made by Amano Enzyme Inc., to amend Schedule 18 of the *Australia New Zealand Food Standards Code* (the Code) to permit the use of thermolysin, a food enzyme of microbial origin, as a processing aid in the manufacture and/or processing of proteinaceous foods 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 we accept as confidential, 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) 24 May 2018

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

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au. Hard copy submissions may be sent to one of the following addresses:

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Supporting document

The following document which informed the assessment of this Application is available on the FSANZ website at: [A1146 Thermolysin as a Processing Aid](#).

SD1 Risk and technical assessment report

Executive summary

Amano Enzyme Inc. (Amano), has applied to amend Schedule 18 of the Australia New Zealand Food Standards Code (the Code) to permit the use of a new enzyme, thermolysin (EC 3.4.24.27), sourced from *Anoxybacillus caldiproteolyticus* as a processing aid.

The enzyme will be used to manufacture or process foods including dairy, egg, meat, fish, yeast, protein products and flavourings. Thermolysin converts proteins and peptides in various foods, resulting in the improvement of physiological properties (foaming ability, emulsifying ability, heat stability, viscosity) and organoleptic properties (taste and flavour).

Based on toxicological data, FSANZ has concluded that in the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) 'not specified' is appropriate. Therefore there is no need for a dietary exposure assessment.

Tuna protein from the culture medium may be present in thermolysin-treated foods at low levels. There is no established threshold for allergenic responses to fish proteins such that exposure to even low amounts of tuna protein is potentially hazardous to individuals with an allergy to that food. Risk management measures are indicated for the protection of individuals with allergy to that food. If fish is present in a food for sale, including when present as a processing aid or an ingredient or component of a processing aid, it is required to be declared under section 1.2.3—4 of Standard 1.2.3.

FSANZ is satisfied that using thermolysin as a processing aid in the way specified in the Application is technologically justified. FSANZ also concludes that, as thermolysin performs its technological purpose during the manufacture and/or processing of food only, it is appropriately categorised as a processing aid rather than a food additive.

Thermolysin also complies with the internationally accepted Joint Expert Committee on Food Additives (JECFA) specifications for chemical and microbiological purity. Enzymes used to produce and manufacture food are considered processing aids. Permitted processing aids are listed in Standard 1.3.3 and Schedule 18 of the Code.

FSANZ has therefore prepared a draft variation to the table to subsection S18—9(3) in Schedule 18 of the Code to permit the use of thermolysin as a processing aid (enzyme) for a specific technological purpose in certain foods, at maximum permitted level in accordance with GMP.

1 Introduction

1.1 The Applicant

The Applicant is Amano Enzyme Inc. (Amano), a company that produces specialty enzymes for the food industry, pharmaceuticals and diagnostic medicines.

1.2 The Application

The Applicant seeks an amendment Schedule 18 of the Australia New Zealand Food Standards Code (the Code) to permit the use of a new enzyme, thermolysin (protease - EC 3.4.24.27) sourced from *Anoxybacillus caldiproteolyticus* (*A. caldiproteolyticus*) as a processing aid. The processing aid is intended for use in the manufacture and/or processing of dairy, egg, meat, fish, yeast, protein products and in the flavouring production industry.

Thermolysin, converts the substrate proteins and peptides in various proteinaceous foods, resulting in the improvement of physiological properties (foaming ability, emulsifying ability, heat stability, viscosity) and organoleptic properties (taste and flavour).

1.3 The current Standard

Enzymes used to process and manufacture food are considered processing aids as although they may be present in the final food, they are no longer providing a technological purpose in that final food.

Paragraph 1.1.1—10(6)(c) of the Code provides that a food for sale must not have, as an ingredient or a component, a substance that is used as a processing aid, unless expressly permitted.

Standard 1.3.3 and Schedule 18 of the Code list the permitted processing aids. Enzymes of microbial origin permitted to be used as processing aids are listed in the table to subsection S18—4(5) or in the table to subsection S18—9(3). The table to subsection S18—4(5) lists enzymes that may be used as a processing aid to perform *any* technological purpose. The table to subsection S18—9(3) lists those substances, including enzymes, that are only permitted to be used as processing aids for *specific* technological purposes.

There are no current permissions in Schedule 18 for thermolysin sourced from *A. caldiproteolyticus*.

1.3.1 International Standards

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

However, there are internationally recognised specifications for enzymes. These enzyme specifications are provided by the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 2006) and the Food Chemicals Codex (Food Chemicals Codex, 2015).

The Applicant notes that the following national and international standards are relevant to the current application:

- Protease is listed on the Food Additive Index of CODEX General Standard for Food Additives (GSFA) (INS: 1101(i)). Also, this food enzyme, thermolysin (a protease), complies with the internationally accepted JECFA specifications for chemical and microbiological purity of food enzymes (FAO/WHO, 2006).

- Protease sourced from *A. caldiproteolyticus* (listed under its former name; *Geobacillus stearothermophilus*) is approved in France¹.

1.4 Reasons for accepting Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2); and
- it related to a matter that warranted the variation of 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 and technical assessment

FSANZ has conducted an assessment of the public health and safety risks associated with the enzyme preparation containing thermolysin produced by *A. caldiproteolyticus* strain TP-7, as a food processing aid and concluded:

- the production organism is not toxigenic or pathogenic. Further, *A. caldiproteolyticus* has a long history of safe use overseas as the production organism for a number of enzyme processing aids.
- under the recommended conditions of use, thermolysin is inactivated by heating, so there is no enzyme activity remaining in the final product.
- bioinformatics analysis indicated that thermolysin has no biologically relevant homology to known food protein allergens.
- the thermolysin preparation caused no observable effects at the highest tested doses in a 91-day repeated dose toxicity study in rats. The NOAEL for the thermolysin concentrate was determined to be 1000 mg/kg bw/day for Sprague Dawley rats. Assuming a Total Organic Solids (TOS) concentration of 42.2% in thermolysin powder, this dose level is equivalent to 422 mg TOS/kg bw/day.
- the enzyme was not genotoxic or mutagenic in a mouse micronucleus assay or a chromosomal aberration assay carried out in Chinese hamster lung fibroblasts.
- Tuna protein from the culture medium may be present in thermolysin-treated foods at low levels. There is no established threshold for allergenic responses to fish proteins such that exposure to even low amounts of tuna protein in thermolysin-treated foods is potentially hazardous to individuals with an allergy to that food. Risk management measures are indicated for the protection of this sensitive subpopulation.

Based on the reviewed toxicological data, FSANZ 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.

¹ <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000271061&dateTexte=#LEGIARTI000023482902>

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

2.2 Risk management considerations

The risk management options available to FSANZ, after assessment, were to reject the Application or to prepare a draft variation to amend the Code to permit the enzyme's use as processing aid, imposing any appropriate conditions.

These options are considered in section 2.4.1.1 and take account of the safety of the enzyme preparation. Other risk management issues relate to enzyme nomenclature and labelling as discussed below.

The risk assessment conclusions are based on evidence that there are no safety risks for the general population, however there may exist a potential hazard for consumers sensitive to fish protein. The use of this enzyme in the manner proposed in the Application and that its use as a processing aid in the quantity and form proposed is technologically justified.

2.2.1 Source microorganism and enzyme nomenclature

The Code does not normally identify microorganisms at the strain level. However, if the draft variation is approved, the Code would specifically refer to thermolysin sourced from *Anoxybacillus caldiproteolyticus* strain TP-7. The basis for listing as such is that the safety data provided by the Applicant referred only to their own TP-7 strain of *A. caldiproteolyticus*.

Information about the identity of the enzyme provided by the Application has been verified using the appropriate internationally accepted reference for enzyme nomenclature, the International Union of Biology and Molecular Biology (IUBMB 2016). The accepted IUBMB name is thermolysin, for enzymes with an EC² number 3.4.24.27 (see SD1).

2.2.2 Labelling considerations

As a general rule, processing aids are 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 Standard 1.2.4.

The risk assessment concludes that the use of the enzyme preparation containing thermolysin sourced from *A. caldiproteolyticus* strain TP-7 poses no risk to public health and safety for the general population. Therefore, the generic exemption from declaration of processing aids in the statement of ingredients will apply to foods containing this processing aid and no additional labelling requirements are proposed.

The Code requires the mandatory declaration of certain known allergens. Fish (Tuna) products are used in the fermentation media. If fish is present in a food for sale, including when present as a processing aid or an ingredient or component of a processing aid, it is required to be declared under section 1.2.3—4 of Standard 1.2.3.

² EC: Enzyme Commission, internationally recognised number that provides a unique identifier for the enzyme

2.2.3 Risk management conclusion

As processing aids require permissions in the Code, the main risk management option available to FSANZ is to either reject the application to amend the Code; or approve the application to amend the Code and impose any conditions that may be appropriate.

Taking into account the risk assessment, the enzyme nomenclature and labelling considerations, the risk management conclusion is to permit thermolysin (EC 3.4.24.27) sourced from *A. caldiproteolyticus* strain TP-7.

The permitted technological purpose of thermolysin will be to catalyse the hydrolysis of peptide bonds during the manufacture and/or processing of the following types of food:

- (a) dairy
- (b) egg
- (c) meat
- (d) fish
- (e) protein
- (f) yeast, and
- (g) flavouring.

During the reaction between thermolysin and proteinaceous foods, low molecular weight peptides and some free amino acids are generated, which is explained in the Application. These reactions help to improve taste and flavour, but are not by means of generated monosodium glutamate (MSG).

Amano confirms that enzymes such as thermolysin from bacteria do not have peptidase activity and therefore, rarely produce amino acids. FSANZ concluded that that thermolysin does not increase the amount of free glutamates (MSG) when used as a processing aid (see SD1, section 2.1).

In the absence of any public health or safety concerns identified by the risk assessment to the general population, addition will be in accordance with GMP.

2.2.4 Differences between what the Applicant requested and FSANZ's risk management conclusion

FSANZ's risk management conclusion and the Applicant's request differs in two ways.

First, the Applicant sought to amend Schedule 18 of the Code to permit the use of an enzyme, thermolysin (protease), sourced from *Anoxybacillus caldiproteolyticus* (*A. caldiproteolyticus*) (EC 3.4.24.27). However, the safety data submitted by the Applicant was only for thermolysin sourced from one particular strain of *Anoxybacillus caldiproteolyticus* (i.e., *Anoxybacillus caldiproteolyticus* strain TP-7). FSANZ therefore only assessed thermolysin sourced from that particular strain.

Second, the Applicant had asked for thermolysin to be listed in table to subsection S18—4(5), which would have permitted the enzyme's use for *any* technological purpose. This was not consistent with the risk assessment, which assessed the enzyme only for the technological purpose stated in the Application i.e. to catalyse the hydrolysis of peptide bonds during the manufacture and/or processing of dairy, egg, meat, fish, yeast, protein products and in flavouring production. For this reason, the permission for the enzyme will be listed in the table to subsection S18—9(3) of the Code instead.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ 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. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application.

The draft variation will be considered for approval by the FSANZ Board taking into account public comments received from this call for submissions.

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 for processing aids or enzymes.

Also, amending the Code to approve the enzyme thermolysin, sourced from *A. caldiproteolyticus* strain TP-7, as a processing aid is unlikely to have a significant effect on international trade as the enzyme preparation complies with international specifications for food enzymes provided by JECFA (JECFA, 2006) and the Food Chemicals Codex (9th Edition) (Food Chemicals Codex, 2015).

Therefore, a notification to the 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

Objectives for cost benefit consideration

The objective of this consideration is to determine whether consumers, industry and government are likely to benefit from a change to the status quo by accepting the Application.

Accepting the application would mean varying schedule 18 to permit the use of the enzyme thermolysin, sourced from *A. caldiproteolyticus* strain TP-7 as a processing aid in certain foods.

As FSANZ can prepare a draft variation or reject the Application under section 30 of the FSANZ Act, preparing a draft variation to permit the enzyme's use as a processing aid is the only proposed measure that has been considered against the status quo (i.e. rejecting the Application).

FSANZ can conclude there is no other practical food regulatory measure aside from accepting or remaining with the status quo (i.e. rejecting the application).

Standing exemption from FSANZ completing a regulatory impact statement

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for the approval of additional processing aids (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting additional processing aids is a minor, deregulatory change and their use is voluntary. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

Despite that exemption, the FSANZ Act requires FSANZ to consider whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the consumers, government or industry (section 29(2)(a)). FSANZ is also required to consider whether other measures (available to the Authority or not) would be more cost-effective than a food regulatory measure developed or varied as a result of the application (section 29(2)(c)).

Costs and benefits

The consideration of the costs and benefits is not intended to be an exhaustive, quantitative economic analysis of the proposed measures. The considerations/assessment sought to highlight the likely benefits and costs of changing from the status quo by accepting the Application.

Table 1 Proposed food regulatory measure – accept the Application

Sector	Costs or benefits to sector
Consumers	<p>The use of the enzyme as a processing aid in the manner proposed will not pose a health or safety risk for consumers. Consumers may benefit from the choice of additional (and better quality) food products that become available due to the use of the enzyme by Australian and New Zealand manufacturers and access to products manufactured using enzyme that are currently manufactured overseas.</p> <p>Prices for products the enzyme is used in may be reduced.</p>
Industry	<p>Thermolysin improves textural and physiochemical (foamability, emulsification, heat stability, viscosity) and organoleptic (taste and flavour) properties of foods. This can provide a benefit in terms of product and/or competitive advantage, to food manufacturers.</p> <p>The enzyme has already been permitted for use in France. Permission to use the enzyme as a processing aid will enable Australia/New Zealand food manufacturers to access and use a product assessed as safe that is available to their overseas competitors. This will improve their capacity to compete in overseas markets. This will be offset to some extent by a wider variety of enzymes for Australia/New Zealand food manufacturers.</p> <p>Use by industry is voluntary, therefore it will only be used where industry believe a net benefit exists above using existing manufacturing processes.</p>
Governments	<p>There may be some costs to government in terms of monitoring and compliance in that regulators will need to be made aware this is now a permitted processing aid - enzyme. There are no other costs or benefits to governments associated with this option.</p>

Conclusions from cost benefit considerations

The direct and indirect benefits that would arise from permitting the use of this particular enzyme as a processing aid most likely outweigh the costs arising from that permission being granted.

2.4.1.2 Other measures

FSANZ considers that there are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed as a result of this Application. See discussion above.

2.4.1.3 Any relevant New Zealand standards

Standards 1.1.1 and 1.3.3; and Schedule 18 from the Code apply in both Australia and New Zealand. There are no relevant New Zealand only Standards.

2.4.1.4 Any other relevant matters

Other relevant matters are covered below.

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 concluded that there are no public health and safety risks to the general population. Fish (Tuna) products are used in the fermentation media. Fish protein has no allergenic threshold, therefore may pose a risk to vulnerable populations sensitive to it.

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

The labelling requirements for the thermolysin are discussed in Section 2.2.2 above. The existing labelling requirements in the Code, including the mandatory declaration of certain allergens when present as a processing aid or an ingredient or component of a processing aid, are considered to be appropriate for the permitted use of thermolysin in foods.

2.4.2.3 The prevention of misleading or deceptive conduct

No issues have been 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 used the best available scientific evidence to conduct the risk assessment 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 processing aids or enzymes. However, there are internationally recognised specifications for enzymes. These enzyme specifications are provided by the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 2006) and the Food Chemicals Codex (Food Chemicals Codex, 2015).

The enzyme preparation containing thermolysin sourced from *A. caldiproteolyticus* (listed under its former name; *Geobacillus stearothermophilus*) is permitted for use in France.

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

Permission to use the enzyme as a processing aid will enable Australia/New Zealand food manufacturers to access and use a product assessed as safe that is available to their overseas competitors. This will improve their capacity to compete in overseas markets. See discussion at Section 2.4.1 above.

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

The thermolysin enzyme preparation has been assessed as safe and is permitted for use in France. It is therefore appropriate that the local Australian and New Zealand food industries can also benefit by gaining permission to use this same enzyme preparation.

- **any written policy guidelines formulated by the Ministerial Council**³

The Ministerial Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*⁴ 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 with regard to the substance.

FSANZ considers that permitting the use of the enzyme preparation containing thermolysin, from *A. caldiproteolyticus* strain TP-7 as a processing aid for the stated technological purpose is consistent with the Ministerial Policy Guideline and the specific order policy principles for 'Technological Function'.

3 Draft variation

The draft variation to the revised Code is at Attachment A and is intended to take effect on the date of gazettal.

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 Legislation.

Attachments

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

³ Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

⁴ [Policy guidelines formulated by the Ministerial Council](#)

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



Food Standards (Application A1146 – Thermolysin from *Anoxybacillus caldiproteolyticus* 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 variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[Insert Name and Position of Delegate]

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 A1146 – Thermolysin from A. caldiproteolyticus as a Processing Aid (Enzyme)) Variation*.

2 Variation to a standard 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] **Schedule 18** is varied by inserting in the table to subsection S18—9(3), in alphabetical order

Substance	Technological Purpose and food	Maximum permitted level (mg/kg)
Thermolysin (EC 3.4.24.27) sourced from <i>Anoxybacillus caldiproteolyticus</i> strain TP-7	To catalyse the hydrolysis of peptide bonds during the manufacture and/or processing of the following types of food: (a) dairy; (b) egg; (c) meat; (d) fish; (e) protein; (f) yeast; and (g) flavouring	GMP

”

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 A1146 thermolysin, from Amano which seeks to amend Schedule 18, of the Code to permit the use of a new enzyme, thermolysin (EC⁵ number 3.4.24.27) sourced from *A. caldiproteolyticus* strain TP-7, as a processing aid.

The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation.

2. Purpose

The purpose of the draft variation is to amend the table to subsection S18—9(3) of the Code to permit the use of the enzyme, thermolysin (EC 3.4.24.27) sourced from *A. caldiproteolyticus* strain TP-7, as a processing aid in food at a maximum permitted level in accordance with Good Manufacturing Practice and for the technological purposes specified in that permission.

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 A1146 will include one round of public consultation following an assessment, and the preparation of a draft amendment to the Code and associated assessment summary.

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

Item [1] inserts a new entry into the table to subsection S18-9(3) in Schedule 18 of the Code.

⁵ EC: Enzyme Commission, internationally recognised number that provides a unique identifier for the enzyme

The effect of the new entry would be to permit the use of thermolysin (EC 3.4.24.27) sourced from *A. caldiproteolyticus* strain TP-7 as a processing aid in food for the following technological purpose: to catalyse the hydrolysis of peptide bonds during the manufacture and/or processing of dairy, egg, meat, fish, protein, yeast, and flavouring. The permission includes the condition that the maximum permitted amount used as a processing aid must be consistent with Good Manufacturing Practice (as defined by section 1.1.2—2(3) of the Code).