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

25 September 2025
360-25

Approval report – Application A1288

Thermolysin from *Anoxybacillus caldiproteolyticus* Rokko as a processing aid

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Food Standards Australia New Zealand (FSANZ) has assessed an application submitted by IFF Australia Pty Ltd (trading as Danisco Australia Pty Ltd) to amend the Australia New Zealand Food Standards Code to permit the use of the enzyme thermolysin (EC 3.4.24.27) sourced from a Rokko strain of *Anoxybacillus caldiproteolyticus* as a processing aid. The enzyme can be used for protein hydrolysis in the manufacture and/or processing of dairy foods, eggs, meat and fish, protein concentrates and isolates, yeast and in beer brewing.

On 22 May 2025 FSANZ sought submissions on a draft variation and published an associated report. FSANZ received three submissions.

FSANZ approved the draft variation on 17 September 2025. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 25 September 2025.

This report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

[1] Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation.

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Supporting document

The following document which informed the assessment of this application is available on the Application A1288 page on the FSANZ website[2]:

SD1 Risk and technical assessment report (unchanged at approval)

The published submissions from the call for submissions can be found on the Application A1288 Consultation Hub page.

[2] https://www.foodstandards.gov.au/food-standards-code/applications/a1288-thermolysin-anoxybacillus-caldiproteolyticus-rokko

Executive summary

IFF Australia Pty Ltd (trading as Danisco Australia Pty Ltd) applied to Food Standards Australia New Zealand (FSANZ) to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of the enzyme thermolysin (EC 3.4.24.27) sourced from a Rokko strain of *Anoxybacillus caldiproteolyticus* as a processing aid.

Thermolysin helps break down proteins during the manufacture and/or processing of dairy foods, eggs, meat and fish, protein concentrates and isolates, yeast and in beer brewing.

Thermolysin from *A. caldiproteolyticus* Rokko has been used as a processing aid in some countries for more than 10 years.

The enzyme is used in a way that is technologically justified and does not perform a technological function in the food for sale, therefore functioning as a processing aid for the purposes of the Code. There are existing identity and purity specifications for the enzyme in the Code when added to food in accordance with the Code or sold for use in food.

A risk assessment did not identify any public health and safety concerns associated with thermolysin sourced from *A. caldiproteolyticus Rokko* under the proposed use conditions. *A. caldiproteolyticus* has been previously assessed by FSANZ and a different strain of the organism already has permission in the Code for the production of thermolysin as a processing aid.

Wheat and soy are used in the manufacturing process to produce thermolysin from *A. caldiproteolyticus* Rokko and therefore may be present in the final enzyme preparation. Declaration requirements in the Code for wheat and soy may apply if they are present in a food for sale that is manufactured using this processing aid.

Following assessment, FSANZ prepared a draft variation to the Code and called for submissions on that draft variation on 22 May 2025, with a six-week consultation period. FSANZ received three submissions; two supported the draft variation and one was neutral.

Based on this information and other relevant considerations outlined in this report, FSANZ has approved the draft variation proposed at the call for submissions.

The approved draft variation will amend the table to subsection S18—9(3) of the Code by listing the enzyme, thermolysin (EC 3.4.24.27) sourced from *A. caldiproteolyticus* Rokko, and its proposed technological purpose, in that table. The table to subsection S18—9(3) lists substances (including enzymes) permitted to be used as processing aids for specific technological purposes. The technological purpose of this enzyme will be protein hydrolysis in the manufacture and/or processing of dairy foods, eggs, meat and fish, protein concentrates and isolates, yeast and in beer brewing. That permission will be subject to the condition that the enzyme must be used in accordance with Good Manufacturing Practice.

The effect of the approved draft variation will be to permit the proposed use of thermolysin (EC 3.4.24.27) sourced from *A. caldiproteolyticus* Rokko as a processing aid in accordance with the Code.

1 Introduction

1.1 The applicant

The applicant is IFF Australia Pty Ltd, trading as Danisco Australia Pty Ltd. The company is a manufacturer and marketer of food ingredients, food additives and food processing aids.

1.2 The application

The purpose of the application was to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of the enzyme thermolysin (EC 3.4.24.27) produced by *Anoxybacillus caldiproteolyticus* Rokko (formerly classified as *Geobacillus caldoproteolyticus*) as a processing aid. The enzyme can be used for protein hydrolysis in the manufacture and/or processing of dairy foods, eggs, meat and fish, protein concentrates and isolates, yeast and in beer brewing.

Thermolysin converts the substrate proteins in various proteinaceous foods into protein fragments of various lengths, peptides and free amino acids, resulting in improvements in flavour and physical properties, increased yields (e.g. extracts) and processing efficiencies.

The applicant has indicated that the enzyme is to be used in accordance with Good Manufacturing Practice (GMP).[3]

1.3 The current Standard

Australian and New Zealand food laws require food for sale to comply with relevant requirements in the Code. The requirements relevant to this application are summarised below.

1.3.1 Permitted use

Paragraph 1.1.1—10(6)(c) of the Code provides that food for sale cannot contain, as an ingredient or component, a substance used as a processing aid unless the use of that substance as a processing aid is expressly permitted by the Code. Section 1.1.2—13 provides that a substance 'used as a processing aid' in relation to a food is a substance used during the course of processing that meets all of the following conditions:

- it is used to perform a technological purpose during the course of processing
- it does not perform a technological purpose in the food for sale, and
- it is a substance listed in Schedule 18 or identified in section S16—2 as an additive permitted at GMP.

Enzymes of microbial origin permitted to be used as processing aids are listed in the table to

[3] GMP is defined in section 1.1.2—2 of the Code as follows: ***GMP*** *or* ***Good Manufacturing Practice****, with respect to the addition of substances used as food additives and substances used as processing aids to food, means the practice of:*
(a) limiting the amount of substance that is added to food to the lowest possible level necessary to accomplish its desired effect; and
(b) to the extent reasonably possible, reducing the amount of the substance or its derivatives that:
*(i) remains as a *component of the food as a result of its use in the manufacture, processing or packaging; and*
(ii) is not intended to accomplish any physical or other technical effect in the food itself;
(c) preparing and handling the substance in the same way as a food ingredient.

subsection S18—4(5) or table to subsection S18—9(3) of Schedule 18, depending on whether a technological purpose has been specified. Enzymes of microbial origin listed in the table to subsection S18—4(5) are permitted for use as a processing aid to perform any technological purpose if the enzyme is derived from the corresponding source specified in the table. The table to subsection S18—9(3) lists those substances, including enzymes derived from particular sources, that are permitted to be used as processing aids for specific technological purposes in relation to:

- if a food is specified—that food, or
- if no food is specified—any food.

Additionally, paragraph 1.3.3—11(c) specifies that the substance may only be used as a processing aid if it is not present in the food at greater than the maximum permitted level for that substance indicated in the table to section S18—9.

Thermolysin from *A. caldiproteolyticus* Rokko is not listed in the table to subsection S18—9(3) nor elsewhere in Schedule 18, and so this enzyme is not currently a permitted processing aid for use in food processing.

1.3.2 Identity and purity requirements

Paragraph 1.1.1—15(1)(b) of the Code requires substances used as processing aids in food to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code when added to food in accordance with the Code or sold for use in food.

Subsection S3—2(1) of the Code incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications and the United States Pharmacopeial Convention Food Chemicals Codex. These include general specifications for enzyme preparations used in food processing for identity and purity parameters.

1.3.3 Labelling requirements

Subsection 1.1.1—10(8) provides that food for sale must comply with all relevant labelling requirements in the Code.

Paragraphs 1.2.4—3(2)(d) and (e) exempt processing aids from the requirement to be declared in the statement of ingredients, unless other requirements apply.

Division 3 of Standard 1.2.3 requires declarations of certain foods (e.g. allergens) on the label of food for sale, unless an exemption applies. If the declaration relates to a processing aid, it must be made in the statement of ingredients and must include the required name[4] for the food which is to be declared in conjunction with the words ‘processing aid’. If the requirement for a statement of ingredients does not apply, the required name must be declared on the label of the food for sale. If a food for retail sale is not required to bear a label, the required name must be displayed in connection with the display of the food or provided to the purchaser on request. If food sold to a caterer is not required to bear a label, the required name must be provided to the caterer with the food.

[4] ***Required name***, of a particular food, means the name declared by section 1.2.3—5 as the required name for that food for the purposes of Division 3 of Standard 1.2.3 (see subsection 1.1.2—2(3)).

1.4 International standards

1.4.1 International

In developing food regulatory measures, FSANZ must have regard to the promotion of consistency between domestic and international food standards. In terms of food safety, the relevant international standard setting body is the Codex Alimentarius Commission (Codex).

In contrast to food additives, there is no Codex 'general standard' for processing aids. However, as noted in section 1.3.2 above, there are internationally recognised specifications for enzyme preparations established by JECFA and Food Chemicals Codex.

Additionally, there is a Codex guideline, *Guidelines on Substances used as Processing Aids* (CAC/GL 75-2010), which sets out general principles for the safe use of substances used as processing aids, including that substances used as processing aids shall be used under conditions of GMP.

1.4.2 Overseas regulations

Thermolysin from *A. caldiproteolyticus* Rokko has been self-affirmed as Generally Recognized as Safe (GRAS) in the USA. It has been authorised/approved for use in France, Denmark, China and Mexico. Protease from *Geobacillus stearothermophilus* (*A. caldiproteolyticus*) is approved in Japan[5].

1.5 Reasons for accepting application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), and
- it related to a matter that warranted the variation of a food regulatory measure.

1.6 Procedure for assessment

The application was assessed under the General Procedure in accordance with the FSANZ Act.

1.7 Decision

Following assessment, FSANZ prepared a draft variation proposing to amend the Code to permit the use of this thermolysin enzyme (EC 3.4.24.27) produced by *A. caldiproteolyticus* Rokko.

Under that draft variation, the enzyme would be permitted to be used as a processing aid for protein hydrolysis in the manufacture and/or processing of dairy foods, eggs, meat and fish, protein concentrates and isolates, yeast and in beer brewing.

For the reasons outlined in this report and after consideration of submissions received during the consultation period, FSANZ approved the draft variation without change. The approved variation takes effect on gazettal and is at Attachment A.

[5] https://nihsfl.z11.web.core.windows.net/koteisyoD/10/en/FA052500_Protease_10EN.pdf

The related 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.

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions on a draft variation to the Code from 22 May 2025 to 3 July 2025. Three submissions were received (see Table 1 below).

The submissions are publicly available on the FSANZ website Application A1288 Consultation Hub page.

Table 1: Summary of issues

Issue	Raised by	FSANZ response
Submitter supports the use of enzyme processing aids in beer brewing and distilled alcohol production. Submitter notes there are a considerable number of approved and commercially available enzymes for use in brewing (and therefore whisky production). However, submitter does not support the use of any enzymes in the production of spirits labelled as 'New Zealand Single Malt Whisky'. based on product authenticity/ brand identity. Specifically, whisky labelled as 'New Zealand Single Malt Whisky' denotes that it is very restrictive in the process that can be used in manufacturing. No additional enzymes may be added or used beyond what is already naturally occurring in the grain. The prohibition on the use of added enzymes is similar to that in the UK for Scotch Whisky.	Distilled Spirits Aotearoa (NZ) Inc.	FSANZ acknowledges the submitter's comments regarding the use of enzymes in the production of 'New Zealand Single Malt Whisky'. However, the approved draft variation does not permit thermolysin enzyme (EC 3.4.24.27) from this source to be used as a processing aid in the production of alcoholic spirits such as whisky.
Supportive of application	New Zealand Food Safety	Noted.
Is neither supportive nor unsupportive. They are unable to provide a full opinion, stating they have not read the full assessment and draft measure.	Individual (JT)	Noted.

2.2 Food technology assessment

FSANZ undertook a food technology assessment to determine whether the processing aid achieves its technological purpose as described in the application (see SD1).

The food technology assessment concluded:

- the proposed use of thermolysin was consistent with its function and that of proteases generally, with reaction products being protein fragments of various lengths, peptides and free amino acids
- thermolysin is functioning as a processing aid for the purposes of the Code and it does not perform a technological purpose in the food for sale
- the evidence presented to support its proposed use provides adequate assurance that the use of the enzyme, in the quantity and form proposed to be used (which must be consistent with GMP), is technologically justified.

There are relevant identity and purity specifications in the Code with which the enzyme will have to comply whenever it is added to food in accordance with the Code or sold for use in food.

2.3 Risk assessment

FSANZ has assessed the public health and safety risks associated with thermolysin and its use as a processing aid (see SD1). A summary of this risk assessment is provided below.

Thermolysin from *A. caldiproteolyticus* Rokko has been used in some countries for more than 10 years.

The microbiological assessment undertaken by FSANZ did not identify any public health and safety concerns associated with the use of *A. caldiproteolyticus* Rokko as a source of thermolysin.

Bioinformatics analysis found no significant homology of the enzyme with known toxins or food allergens. Glucose and sorbitol (sourced from wheat), and soy meal could be used as fermentation nutrients in the manufacture of thermolysin.

Thermolysin was not genotoxic *in vitro* and did not cause adverse effects in a 13-week oral toxicity study in rats. The no observed adverse effect level (NOAEL) in this study was 337.5 mg total organic solids (TOS)/kg bw/day, the highest dose tested.

The theoretical maximum daily intake (TMDI) of the TOS from the enzyme preparation was calculated to be 2.45 mg TOS/kg bw/day. A comparison of the NOAEL and the TMDI results in a Margin of Exposure (MOE) of approximately 100.

Based on the reviewed data it is concluded that in the absence of any identifiable hazard, an acceptable daily intake (ADI) ‘not specified’ is appropriate.

2.4 Risk management

Following assessment, FSANZ prepared a draft variation and called for submissions on that draft variation during a period of six weeks.

The risk management options available to FSANZ after the call for submissions were to:

- approve the draft variation proposed at the call for submissions, or
- approve that draft variation subject to such amendments as FSANZ considers necessary, or
- reject that draft variation.

The conclusions from the risk and technical assessment were that the proposed use of thermolysin as a processing aid is technologically justified and there were no safety concerns associated with the use of the enzyme. See sections 1.3.3 and 2.4.3 of this report for labelling considerations associated with soy and wheat in the enzyme preparation.

Having regard to the submissions received and, for the reasons set out in this report, FSANZ considers it appropriate to approve the draft variation proposed following assessment (Attachment A).

Risk management considerations for this application relating to the regulatory approval, nomenclature, specifications and labelling are discussed below.

2.4.1 Regulatory approval for processing aids

As stated above, FSANZ has approved a draft variation to permit the proposed use of the enzyme as a processing aid in the manufacture and/or processing of dairy foods, eggs, meat and fish, protein concentrates and isolates, yeast and in beer brewing. The express permission also provides the permission for the enzyme's potential presence in the food for sale (Attachment A).

2.4.2 Enzyme nomenclature, source microorganism nomenclature and specifications

The International Union of Biochemistry and Molecular Biology (IUBMB) lists the accepted name 'thermolysin' for the enzyme EC 3.4.24.27 (see section 2.1 of SD1). This is the name used in the approved draft variation.

Nomenclature for the production organism – *Anoxybacillus caldiproteolyticus* – is in accordance with accepted international norms for taxonomy. The organism's nomenclature has recently been updated to *Thermaerobacillus caldiproteolyticus*, however the basionym *A. caldiproteolyticus* is a valid homotypic synonym.

There are relevant identity and purity specifications in primary sources of specifications listed in Schedule 3 for enzyme preparations used in food processing (refer to section 1.3.2 of this report).

2.4.3 Labelling

The labelling provisions in the Code apply to foods for sale that are manufactured using this processing aid (see section 1.3.3 of this report).

Section 2.4 of SD1 states that wheat and soy are used in the manufacturing process to produce thermolysin from *A. caldiproteolyticus* Rokko and therefore may be present in the final enzyme preparation. Declaration requirements in the Code for wheat and soy may apply if they are present in a food for sale that is manufactured using this processing aid.

2.4.4 Risk management conclusion

The risk management conclusion is to permit the enzyme thermolysin (EC 3.4.24.27) produced by *A. caldiproteolyticus* Rokko as a processing aid for protein hydrolysis in the manufacture and/or processing of dairy foods, eggs, meat and fish, protein concentrates and isolates, yeast and in beer brewing.

The enzyme and its associated technological purpose will be listed in the table to subsection

S18—9(3) of the Code, which includes enzymes permitted for a specific technological purpose. The maximum permitted level or amount of the enzyme that may be present in the food must be an amount consistent with GMP. The express permission for the enzyme to be used as a processing aid in Schedule 18 of the Code also provides the permission for the enzyme's potential presence in the food for sale.

2.5 Risk communication

2.5.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a standard communication strategy to this application. All calls for submissions are notified via a Food Standards Notification Circular, media release, FSANZ's digital channels and Food Standards News.

The process by which FSANZ considers standards development matters is open, accountable, consultative and transparent. Public submissions were called to assist consideration of the draft variation to the Code. FSANZ acknowledges the time taken by individuals and organisations who made submissions on this application.

The draft variation was considered for approval by the FSANZ Board having regard to all submissions made during the call for submissions period.

2.6 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:

2.6.1 Section 29

2.6.1.1 Consideration of costs and benefits

FSANZ assessed the costs and benefits of the proposed amendment to the Code to permit the proposed use of the enzyme thermolysin from *A. caldiproteolyticus* Rokko as a processing aid, and concluded the benefits are likely to outweigh the costs. The reasons for this conclusion are outlined below.

Background to the cost and benefit analysis

Section 29 of the FSANZ Act requires FSANZ to have regard to whether costs that would arise from a proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

The purpose of this consideration was to determine if the community, government and industry as a whole is likely to benefit, on balance, from a move from the status quo (where the *status quo* is rejecting the application).

The consideration of the costs and benefits in this section was not intended to be an exhaustive, quantitative economic analysis of the proposed measures. In fact, most of the effects considered could not easily be assigned a dollar value. Rather, the assessment sought to highlight the likely positives and negatives of moving away from the status quo by permitting the proposed use of this enzyme as a processing aid.

A regulation impact statement (RIS) was not prepared. FSANZ's assessment was that a RIS was not required for this application. This was on the basis that the application is minor and

deregulatory in nature. It sought to permit the use of a processing aid found to be safe and that use will be voluntary. This position is consistent with previous advice from the Office of Impact Analysis (OIA) (OIA23-06225) when the OIA undertook assessments of whether a RIS was required for these types of applications.

Costs and benefits of permitting the proposed use of this enzyme

Industry may benefit from several improvements and efficiencies from the use of this enzyme in the manufacture and/or processing of dairy foods, eggs, meat and fish, protein concentrates and isolates, yeast and in beer brewing. Due to the voluntary nature of the permission, industry will only use the enzyme as proposed where they believe a net benefit exists for them.

If industry were to experience cost savings because of using this enzyme, industry may pass on some of the cost savings to consumers.

Permitting the proposed use of this enzyme may result in a small, inconsequential cost to government in terms of an addition to the current range of processing aids that are already monitored for compliance.

Conclusions from cost benefit assessment

FSANZ's assessment at the call for submissions was that the direct and indirect benefits that would arise from permitting the proposed use of the enzyme thermolysin from *A. caldiproteolyticus* Rokko as a processing aid would most likely outweigh any costs. No further information was received during the consultation process that changed that assessment.

2.6.1.2 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.

2.6.1.3 Any relevant New Zealand standards

The standards in the Code that are relevant to the permitted use of processing aids apply in both Australia and New Zealand. There are no relevant New Zealand only standards.

2.6.1.4 Any other relevant matters

Other relevant matters are considered below.

2.6.2 Subsection 18(1)

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

2.6.2.1 Protection of public health and safety

FSANZ undertook a safety assessment and concluded there were no public health and safety concerns associated with the proposed use of this enzyme (see section 2.3 of this report and SD1). Labelling provisions are appropriate to manage the potential presence of wheat and soy in the enzyme preparation (see sections 1.3.3 and 2.4.3 of this report).

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

Existing labelling requirements will apply to this enzyme processing aid in accordance with the Code to enable consumers to make informed choices (see sections 1.3.3 and 2.4.3 of this report).

2.6.2.3 The prevention of misleading or deceptive conduct

There were no issues identified with this application relevant to this objective.

2.6.3 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 used the best available scientific evidence to conduct the risk analysis, which is provided in SD1. The applicant submitted a dossier of information and scientific literature as part of their application. This dossier, together with other technical and scientific information, was considered by FSANZ in assessing the application.

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

In terms of food safety, the relevant international standard setting body is Codex. There is no Codex 'general standard' for enzymes, however as noted in section 1.3.2 of this report, there are internationally recognised specifications for enzyme preparations established by JECFA and Food Chemicals Codex, with which this enzyme would have to comply when added to food in accordance with the Code or sold for use in food.

There is also a Codex guideline, *Guidelines on Substances used as Processing Aids* (CAC/GL 75-2010), which sets out general principles for the safe use of substances used as processing aids, including that substances used as processing aids shall be used under conditions of GMP (see section 1.4.1 of this report).

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

As stated in section 1.4.2 of this report, thermolysin from *A. caldiproteolyticus* Rokko has been self-affirmed as GRAS in the USA and has been authorised/approved for use in a number of other countries. Australia and New Zealand will remain competitive with international markets where approval for the use of the enzyme is granted. This will also help foster continued innovation and improvements in food manufacturing techniques and processes.

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

No issues were identified for this application relevant to this consideration.

- **any written policy guidelines formulated by the Food Ministers' Meeting**

The Ministerial Policy Guideline *Addition to Food of Substances other than Vitamins and*

Minerals[6] includes specific order policy principles for substances added to achieve a solely technological function, such as processing aids. These specific order policy principles state that permission should be granted where:

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the 'stated purpose')
- the addition of the substance to food is safe for human consumption
- the amounts added are consistent with achieving the technological function
- the substance is added in a quantity and a form which is consistent with delivering the stated purpose
- no nutrition, health or related claims are to be made in regard to the substance.

FSANZ determined that permitting the proposed use of this enzyme is consistent with these specific order policy principles for 'technological function'. All other relevant requirements of the policy guideline are similarly met.

Attachments

A. Approved draft variation to the Australia New Zealand Food Standards Code
B. Explanatory Statement

[6] https://www.foodregulation.gov.au/resources/publications/policy-guideline-addition-substances-other-vitamins-and-minerals

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

Food Standards (Application A1288 – Thermolysin from *Anoxybacillus caldiproteolyticus* Rokko as a processing aid) Variation

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The 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 A1288 – Thermolysin from* Anoxybacillus caldiproteolyticus *Rokko as a processing aid) 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

Schedule 18 – Processing aids

[1] Subsection S18—9(3) (table)

Insert:

Thermolysin (EC 3.4.24.27) sourced from *Anoxybacillus caldiproteolyticus* Rokko	For protein hydrolysis during: (a) beer brewing; and (b) the manufacture and/or processing of the following types of food: (i) dairy; (ii) eggs; (iii) meat; (iv) fish; (v) protein concentrates and isolates; and (vi) yeast.	GMP

Attachment B – Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1288 – Thermolysin from* Anoxybacillus caldiproteolyticus *Rokko as a processing aid) Variation

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 A1288 which sought to permit the use of the enzyme thermolysin (EC 3.4.24.27) from *Anoxybacillus caldiproteolyticus* Rokko as a processing aid. The application proposed the enzyme be used for protein hydrolysis in the manufacture and/or processing of dairy foods, eggs, meat and fish, protein concentrates and isolates, yeast and in beer brewing. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation – the *Food Standards (Application A1288 – Thermolysin from* Anoxybacillus caldiproteolyticus *Rokko as a processing aid) Variation* (the approved draft variation).

Following consideration by the Food Ministers' Meeting (FMM), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the draft variation.

2. Variation is a legislative instrument

The approved draft variation is a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and is publicly available on the Federal Register of Legislation (www.legislation.gov.au).

This instrument is not subject to the disallowance or sunsetting provisions of the *Legislation Act 2003.* Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunsetting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by

the FMM. The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has approved a draft variation amending the table to subsection S18—9(3) in Schedule 18 of the Code to permit the use of the enzyme thermolysin (EC 3.4.24.27) from *Anoxybacillus caldiproteolyticus* Rokko as a processing aid for protein hydrolysis in the manufacture and/or processing of dairy foods, eggs, meat and fish, protein concentrates and isolates, yeast and in beer brewing. This permission is subject to the condition that the maximum permitted level or amount of the enzyme that may be present in the food must be consistent with good manufacturing practice (GMP).

4. Documents incorporated by reference

The approved draft variation does not incorporate any documents by reference.

However, existing provisions of the Code incorporate documents by reference that would prescribe identity and purity specifications for the processing aid to be permitted by the approved draft variation. Section 1.1.1—15 of the Code requires substances used as processing aids to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code when added to food in accordance with the Code or sold for use in food. Section S3—2 of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Compendium of Food Additive Specifications (FAO/WHO 2021) and the United States Pharmacopeial Convention (2022) Food Chemicals Codex (13th edition). These include general specifications for the identity and purity parameters of enzyme preparations used in food processing.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1288 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. FSANZ called for submissions on the draft variation from 22 May to 3 July 2025.

A regulation impact statement (RIS) was not prepared because FSANZ's assessment was that a RIS was not required for this application. This was on the basis that the application was minor and deregulatory in nature. It sought to permit the use of a processing aid found to be safe and that use is voluntary. This position is consistent with previous advice from the Office of Impact Analysis (OIA) (OIA23-06225) when the OIA undertook assessments of whether a RIS was required for these types of applications.

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 44 of the *Legislation Act 2003*.

7. Variation

References to 'variation' in this section are references to the approved draft variation.

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1288 – Thermolysin from* Anoxybacillus caldiproteolyticus *Rokko as a processing aid) Variation*.

Clause 2 of the variation provides that the Code is amended by the Schedule to the variation.

Clause 3 of the variation provides that the variation will commence on the date of gazettal of the instrument.

Schedule to the variation

Item [1] of the Schedule to the variation inserts a new entry, in alphabetical order, into the table to subsection S18—9(3) of the Code.

The new entry consists of the following enzyme in column 1 of the table:

- 'Thermolysin (EC 3.4.24.27) sourced from *Anoxybacillus caldiproteolyticus* Rokko'

The permitted technological purpose for this enzyme is prescribed in column 2 of the table i.e. For protein hydrolysis during (a) beer brewing; and (b) the manufacture and/or processing of the following types of food:

- dairy;
- eggs;
- meat;
- fish;
- protein concentrates and isolates; and
- yeast.

The permission is subject to the condition, as prescribed in column 3 of the table, that the maximum permitted level or amount of this enzyme that may be present in the food must be consistent with GMP.

The approved draft variation permits the proposed use of the enzyme thermolysin (EC 3.4.24.27) sourced from *Anoxybacillus caldiproteolyticus* Rokko as a processing aid in accordance with the Code.