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

22 May 2025
342-25

Call for submissions – 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 made 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) as a processing aid and has prepared a draft food regulatory measure. The enzyme is proposed to 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. 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.

Submissions on this application need to be made through the Consultation Hub (https://consultations.foodstandards.gov.au/). All submissions on this application will be published on the Consultation Hub. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published following consultation and before the next stage in the statutory assessment process.

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 Making a submission. For information on how FSANZ manages personal information when you make a submission, see FSANZ's Privacy Policy.

FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices. There is no need to send an email or hard copy of your submission if you have submitted it through the FSANZ Consultation Hub.

DEADLINE FOR SUBMISSIONS: 11:59pm (Canberra time) 3 July 2025

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.

For information about making a submission, visit the FSANZ website at current calls for public comment and how to make a submission. Questions about making a submission or application and proposal processes can be sent to standards.management@foodstandards.gov.au.

Submissions in hard copy may be sent to the following addresses:

Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604
AUSTRALIA
Tel +61 2 6228 8226

Food Standards Australia New Zealand
PO Box 10559
WELLINGTON 6140
NEW ZEALAND
Tel +64 4 978 5630

Table of contents

Supporting document

The following document which informed the assessment of this application is available on the FSANZ website[1]:

SD1 Risk and technical assessment report

[1] 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) has 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) as a processing aid.

The enzyme is proposed for use as a processing aid for the hydrolysis of protein in the manufacture and/or processing of dairy foods, eggs, meat and fish, protein concentrates and isolates, yeast processing and in beer brewing. The thermolysin is sourced from a non-genetically modified Rokko strain of *Anoxybacillus caldiproteolyticus.*

The proposed use of thermolysin is technologically justified in the quantity and form stated by the applicant for hydrolysing protein in the above-mentioned foods. The enzyme 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 relevant identity and purity specifications for the enzyme in the Code with which the enzyme would have to comply when added to food in accordance with the Code or sold for use in food.

No public health and safety concerns were identified in the assessment of thermolysin (EC 3.4.24.27) produced by *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.

Following assessment, for reasons set out in this report, FSANZ has prepared a draft variation to amend subsection S18—9(3) of the Code by listing this enzyme and its associated technological purpose in the table to subsection S18—9(3). This table lists substances (including enzymes) permitted to be used as processing aids for specific technological purposes. The draft variation, if approved, would permit the use of the enzyme thermolysin (EC 3.4.24.27) sourced from *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, in accordance with the Code. The permission would be subject to the condition that the maximum permitted level or amount of the enzyme that may be present in the food must be an amount consistent with Good Manufacturing Practice.

FSANZ now seeks submissions on the draft variation of 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 is to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of the enzyme thermolysin (EC 3.4.24.27) as a processing aid. The enzyme is proposed to 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 enzyme is produced by *Anoxybacillus caldiproteolyticus* Rokko (formerly classified as *Geobacillus caldoproteolyticus*) that has not been genetically modified.

Thermolysin converts the substrate proteins and peptides in various proteinaceous foods, 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).[2]

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.

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[2] 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.

Enzymes of microbial origin permitted to be used as processing aids are listed in the table to 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 former 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 latter 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 S18—9 and so 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[3] 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.

1.4 International standards

1.4.1 International

In developing food regulatory measures, FSANZ must have regard to the promotion of

[3] ***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)).

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[4].

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 is being assessed under the General Procedure in accordance with the FSANZ Act.

2 Summary of the assessment

FSANZ has undertaken an assessment to determine whether the enzyme achieves its technological purpose in the quantity and form proposed, and to evaluate public health and safety risks that may arise from the use of this enzyme (see Supporting Document 1 (SD1)). Summaries of both assessments are provided below.

2.1 Food technology assessment

The proposed use of thermolysin as a processing aid is in the hydrolysis of protein in the manufacture and/or processing of dairy foods, eggs, meat and fish, protein concentrates and isolates, yeast and in beer brewing. This is consistent with its function and that of proteases generally, with reaction products being protein fragments of various lengths, peptides and free amino acids. The applicant states the benefits of using the enzyme in these applications include flavour improvement, improved physical properties, increased yields (e.g. extracts) and processing efficiencies. It is functioning as a processing aid for the purposes of the Code and does not perform a technological purpose in the food for sale.

FSANZ concludes that 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

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

identity and purity specifications for the enzyme 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.

2.2 Risk assessment

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.

Sufficient information has been provided to assess the safety of the thermolysin that is the subject of this application. Thermolysin from *A. caldiproteolyticus* Rokko has been used in some countries overseas for more than 10 years. 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.

Based on the safety assessment and considering the theoretical maximum daily intake (2.45 mg TOS/kg bw/day), no public health and safety concerns were identified in the assessment of thermolysin produced by *A. caldiproteolyticus* Rokko under the proposed use conditions.

2.3 Risk management

The risk management options available to FSANZ after assessment were to either:

- reject the application, or
- prepare a draft variation of the Code.

For the reasons listed in this report, FSANZ decided to prepare a draft variation to the Code permitting the proposed use of 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. If approved, this permission would be subject to the condition that the maximum permitted level or amount of enzyme used in the food must be consistent with GMP.

Other risk management considerations for this application are related to the enzyme and source microorganism nomenclature, specifications and labelling. These are discussed below.

2.3.1 Regulatory approval

As stated above, FSANZ has prepared 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.

2.3.2 Enzyme nomenclature, source microorganism nomenclature and specifications

FSANZ notes 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 proposed 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).

2.3.3 Labelling

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

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 would apply if they are present in a food for sale that is manufactured using this processing aid.

2.3.4 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. If approved, the enzyme and its associated technological purpose would 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.

2.4 Risk communication

2.4.1 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 the FSANZ Notification Circular, media release, FSANZ's digital channels and Food Standards News.

The process by which FSANZ approaches standards development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on the draft variation.

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

2.4.2 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 not substantially the same as existing international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards (i.e. Codex) and amending the Code to permit the proposed use of this enzyme as a processing aid is unlikely to have a significant effect on international trade. 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.

2.5 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:

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

FSANZ has assessed the costs and benefits of the proposed amendment to the Code to permit the use of the enzyme thermolysin as a processing aid, and concludes 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 is 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 is not intended to be an exhaustive, quantitative economic analysis of the proposed measures. In fact, most of the effects considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo by permitting the proposed use of the enzyme thermolysin as a processing aid.

A regulation impact statement (RIS) has not been prepared. FSANZ's assessment is that a RIS is not required for this application. This is on the basis that the application is minor and deregulatory in nature. It seeks to permit the use of a processing aid found to be safe and, if the draft variation concerned is approved, that use will be voluntary. This position is consistent with advice from the Office of Impact Analysis (OIA23-06225).

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 is that the direct and indirect benefits that would arise from permitting

the proposed use of the enzyme thermolysin as a processing aid are likely to outweigh the associated costs.

Information received through this call for submissions process may result in FSANZ arriving at a different outcome.

2.5.1.2 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.

2.5.1.3 Any relevant New Zealand standards

The relevant standards in the Code apply in Australia and New Zealand. There are no relevant New Zealand only standards.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2 Subsection 18(1)

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

2.5.2.1 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 2.2 of this report and SD1).

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

The labelling requirements for this enzyme are discussed in section 2.3.3 of this report.

2.5.2.3 The prevention of misleading or deceptive conduct

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

2.5.3 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. 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 risk assessment is provided in SD1.

- **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 conclusion of the risk assessment is that there are no public health and safety concerns associated with the proposed use of this enzyme as a processing aid. It is therefore appropriate that Australian and New Zealand food industries are given the opportunity to benefit from the use of this enzyme for the applications proposed by the applicant. Ultimately, the domestic food industry will make their own economic decisions, taking into account the costs and benefits of using the new enzyme, to determine if it is of benefit to their particular business.

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

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

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

The Ministerial Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*[5] 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.

3 Draft variation

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

[5] https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Substances-other-than-Vitamins-and-Minerals

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

Attachment A – 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 – Draft Explanatory Statement

DRAFT 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 seeks to permit the use of the enzyme thermolysin (EC 3.4.24.27) from *Anoxybacillus caldiproteolyticus* Rokko as a processing aid. The enzyme is proposed to 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 prepared a draft variation – the *Food Standards (Application A1288 – Thermolysin from* Anoxybacillus caldiproteolyticus *Rokko as a processing aid) Variation* (the draft variation).

2. Variation will be a legislative instrument

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

If approved, this instrument would not be 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 Food Ministers Meeting (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 prepared 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. If approved, this permission would be 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 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 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 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) will be open for a six-week consultation period.

A regulation impact statement (RIS) has not been prepared. FSANZ's assessment is that a RIS is not required for this application. This is on the basis that the application is minor and deregulatory in nature. It seeks to permit the use of a processing aid found to be safe and, if the draft variation concerned is approved, that use will be voluntary. This position is consistent with earlier advice from the Office of Impact Analysis (OIA23-06225).

6. Statement of compatibility with human rights

If approved, this instrument would be exempt from the requirements for a statement of compatibility with human rights as it would be a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

References to 'variation' in this section are references to the 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 would insert a new entry, in alphabetical order, into the table to subsection S18**—**9(3) of the Code.

The new entry would consist 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 would be 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 would be 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.

If approved, the draft variation would permit 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.