15 August 2022
212-22

Approval report – Application A1238

Serine endopeptidase enzyme from GM *Trichoderma reesei*

Food Standards Australia New Zealand (FSANZ) has assessed an application made by AB Enzymes GmbH to amend the Australia New Zealand Food Standards Code to permit the use of the enzyme thermomycolin (EC 3.4.21.65), a serine endopeptidase (protease), sourced from a genetically modified (GM) strain of *Trichoderma reesei* containing the thermomycolin gene from *Malbranchea cinnamomea* as a processing aid. The enzyme will be used as a processing aid to catalyse the hydrolysis of peptide bonds in the manufacture and/or processing of meat, vegetable and seafood products.

On 27 April, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received two submissions.

FSANZ approved the draft variation on 3 August 2022. The Food Ministers' Meeting was notified of FSANZ's decision on 15 August 2022.

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

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Supporting document

The following document which informed the assessment of this application are available on the FSANZ website:

SD1 Risk and technical assessment

Executive summary

AB Enzymes GmbH applied to Food Standards Australia New Zealand (FSANZ) to amend Schedule 18 – Processing Aids of the Australia New Zealand Food Standards Code to permit thermomycolin (EC 3.4.21.65), a serine endopeptidase, as a processing aid to catalyse the hydrolysis of peptide bonds in the manufacture and/or processing of meat, vegetable and seafood products. The thermomycolin enzyme is produced from a genetically modified (GM) strain of *Trichoderma reesei* (*T. reesei*) containing the thermomycolin gene from *Malbranchea cinnamomea (M. Cinnamomea)*

FSANZ undertook an assessment to determine whether the enzyme achieves its technological purpose in the quantity and form proposed to be used and to evaluate public health and safety concerns that may arise from its use.

FSANZ concluded that the proposed use of thermomycolin is consistent with its typical function of hydrolysing peptide bonds in those foods. Analysis of the evidence provided adequate assurance that the use of the enzyme, in the quantity and form proposed and consistent with Good Manufacturing Practice (GMP), is technologically justified.

Thermomycolin performs its technological purpose during the manufacture and/or processing of the nominated foods and is not performing a technological purpose in the final food, 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.

A toxicological assessment combined with a dietary exposure assessment concluded the enzyme is safe under the proposed conditions of use. In the absence of any identifiable hazard, an acceptable daily intake ‘not specified’ is appropriate.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation.

FSANZ received two submissions – both of which were from government agencies supporting the draft variation.

Based on the information above and on other relevant considerations set out in this report, FSANZ has approved a draft variation to the table to subsection S18—9(3) of Code to permit the use of the enzyme, thermomycolin (EC 3.4.21.65), sourced from *T. reesei* containing the thermomycolin gene from *M. cinnamomea*, as a processing aid to catalyse the hydrolysis of peptide bonds during the manufacture and/or processing of meat, vegetable and seafood products. This permission will be subject to the condition that the maximum permitted level or amount of this enzyme that may be present in the food must be consistent with GMP. The effect of the approved draft variation is to permit the proposed use of this enzyme as a processing aid in accordance with the Code.

1 Introduction

1.1 The Applicant

The applicant is AB Enzymes GmbH (AB Enzymes), an industrial biotech company that develops enzyme products for food, animal feed and technical applications.

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 thermomycolin (EC 3.4.21.65), a serine endopeptidase, as a processing aid to catalyse the hydrolysis of peptide bonds in the manufacture and/or processing of meat, vegetable and seafood products. The enzyme is produced from a genetically modified (GM) strain of *Trichoderma reesei* (*T. reesei*) containing the thermomycolin gene from *Malbranchea cinnamomea* (*M. cinnamomea*). The specific name for the production organism is *T. reesei* RF8963.

AB Enzymes' thermomycolin is thermotolerant and suitable for catalysing the hydrolysis of peptide bonds under mildly alkaline conditions. It functions during the manufacture and/or processing of vegetable and animal protein hydrolysates including meat, poultry and game products, vegetable products and fish and seafood products. The enzyme will be marketed as a liquid enzyme preparation with the trade name COROLASE 8000.

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

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

Paragraph 1.1.1—10(6)(c) provides that food for sale cannot contain, as an ingredient or component, a substance 'used as a processing aid' unless that substance's use 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 processing that meets all the following conditions:

- it is used to perform a technological purpose during 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 Good Manufacturing Practice (GMP).

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) 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

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.

Paragraph 1.1.1—10(6)(g) requires that the presence as an ingredient or component in a food for sale of a food produced using gene technology must be expressly permitted by the Code. Paragraph 1.5.2—3(b) provides that permission in the Code for use as a processing aid also constitutes the permission required by paragraph 1.1.1—10(6)(g).

Thermomycolin is not currently listed in the Code and is one of a class of enzymes referred to by the International Union of Biochemistry and Molecular Biology (IUBMB) as serine proteinases EC 3.4.21.14. The IUBMB has further defined EC 3.4.21.14 to individual entries, which includes thermomycolin (EC 3.4.21.65) (IUBMB 2022). The Code lists several other sources of serine proteinase such as *Aspergillus oryzae, Bacillus amyloliquefaciens, Bacillus halodurans, Bacillus licheniformis* and *Bacillus subtilis* within S18—3(5) permitted enzymes of microbial origin.

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.

Subsection S3—2(1) of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications (FAO JECFA Monographs 23, 2019), and the United States Pharmacopeial Convention (USPC 2020) Food Chemicals Codex (12th edition). These include specifications for enzyme preparations used in food processing.

1.3.3 Labelling requirements

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

Subsection 1.2.3—4(1) requires certain foods or their derivatives (as listed in the table to section S9—3 of Schedule 9) to be declared when present in a food for sale. The food may be present as a substance used as a processing aid or as an ingredient or component of a substance used a processing aid (paragraph 1.2.3—4(5)(c)). Where the food to be declared is a substance used as a processing aid or an ingredient or component of such a substance, subsection 1.2.3—6(2) requires a declaration for the purposes of paragraph 1.2.1—8(1)(d) or subparagraph 1.2.4—5(6)(b)(i) to be made by (among other things) listing in the statement of ingredients the of the food for sale the required name[1] of the food to be declared and the words ‘processing aid’ in conjunction with that required name[2]. If the food is not required to

[1] ***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.

[2] On 25 February 2021 new requirements for the labelling of allergens were introduced in the Code and suppliers have until 25 February 2024 to change over to these new requirements. If a food was packaged and labelled

bear a label, the declaration must be displayed in connection with the display of the food or provided to the purchaser on request (subsections 1.2.1—9(6) and (7)).

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.

Section 1.5.2—4 requires processing aids that are, or have as ingredients, foods produced using gene technology to be labelled 'genetically modified' in conjunction with the name of that food, where novel DNA and/or novel protein from the processing aid remains present in the final food. The requirement applies to foods for sale that consist of or have as an ingredient, food that is a *genetically modified food*[3] (GM food). The requirements imposed by section 1.5.2—4 generally apply only to foods for retail sale and to foods sold to a caterer under subsection 1.2.1—8(1) and 1.2.1—9(3), and section 1.2.1—15, respectively.

1.3.4 International standards

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 Alimentarius 'general standard' for enzymes, however as noted above there are internationally recognised specifications for enzyme preparations established by JECFA and Food Chemicals Codex.

The applicant advised that the enzyme is approved for use as a processing aid in France, Denmark, Canada, Mexico, Brazil and the USA, the latter is where it has been determined as Generally Recognized as Safe (GRAS).

1.4 Reasons for accepting Application

The application was accepted for assessment because:

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

1.5 Procedure for assessment

The application was assessed under the General Procedure.

1.6 Decision

For reasons set out in this report, FSANZ decided to approve a draft variation amending the Code to permit the use of this enzyme as a processing aid to catalyse the hydrolysis of peptide bonds during the manufacture and/or processing of meat, vegetable and seafood products.

The draft variation as proposed following assessment was approved without change. The variation takes effect on gazettal. The approved draft variation is at Attachment A.

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before 25 February 2024 and it complied with the previous allergen labelling requirements, then that food can remain on sale for another two years as long as it complies with the rest of the Code.

[3] Section 1.5.2—4(5) defines ***genetically modified food*** to mean a *food produced using gene technology that
a) contains novel DNA or novel protein; or
b) is listed in Section S26—3 as subject to the condition that its labelling must comply with this section" (*that being section 1.5.2—4*).

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 sought public comments on the draft variation included in the call for submissions report between 27 April 2022 and 9 June 2022.

FSANZ received two submissions, both from government agencies (New Zealand Food Safety, The Victorian Department of Health), which supported the draft variation, and raised no issues that needed to be considered and addressed.

2.2 Risk assessment

FSANZ has assessed the public health and safety risks associated with thermomycolin produced from a GM *T. reesei,* strain RF8963, containing the thermomycolin gene from *M. cinnamomea* (see SD1). In its assessment, FSANZ's assessment was on the strain, however only the species will be listed in the Code.

The proposed use of thermomycolin is as a processing aid to catalyse the hydrolysis of peptide bonds during the manufacture and/or processing of meat, vegetable and seafood products. Analysis of the evidence provided concluded that the use of the enzyme in the quantity and form proposed is technologically justified.

No public health and safety concerns were identified in the assessment of thermomycolin sourced from a GM *T. reesei,* strain RF8963, containing the thermomycolin gene from *M. cinnamomea* under the proposed conditions of use. A microbiological assessment concluded that the GM host strain is neither pathogenic nor toxigenic, and a biotechnology assessment confirmed the genetic modification is as described and that the inserted gene has been stably introduced.

A toxicological assessment combined with a dietary exposure assessment concluded the enzyme is safe under the proposed conditions of use. The toxicological assessment noted a degree of similarity between the enzyme and several allergens. However, considering the use and exposure, the risk of food allergy is likely to be low.

In the absence of any identifiable hazard, an acceptable daily intake (ADI) 'not specified' is appropriate.

2.3 Risk management

After assessing an application, the risk management options available to FSANZ are to:

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

The Risk and Technical Assessment concluded that the use of the enzyme thermomycolin (EC 3.4.21.65) sourced from a GM *T. reesei*, strain RF8963, containing the thermomycolin gene from *M. cinnamomea*, is technologically justified and there are no concerns when used for its stated purpose, at levels consistent with GMP.

For the reasons listed below and in SD1, FSANZ decided to prepare a draft variation (see Attachment A) to permit the use of this enzyme as a processing aid to catalyse the hydrolysis of peptide bonds during the manufacture and/or processing of meat, vegetable and seafood products.

Other risk management considerations for this application are related to enzyme nomenclature and labelling, which are discussed below. The regulatory options analysed in Section 2.5.1.1 of this report take account of the safety of the enzyme.

2.3.1 Regulatory approval for enzymes

As stated above, FSANZ has prepared a draft variation to permit the use of the enzyme as a processing aid in the manufacture and/or processing of meat, vegetable and seafood products. The express permission for the enzyme to be used as a processing aid would also provide the permission for its potential presence in the food for sale as a food produced using gene technology. The enzyme is a food produced using gene technology for Code purposes as it is derived from 'an organism that has been modified using gene technology' (see subsection 1.1.2—2(3) of the Code)[4].

2.3.2 Enzyme and source microorganism nomenclature

FSANZ notes that for this serine endopeptidase classified as EC 3.4.21.65 by the IUBMB, the internationally recognised authority for enzyme nomenclature, uses the accepted name thermomycolin (IUBMB 2022). Thermomycolin (EC 3.4.21.65) will be listed in the table to subsection in S18—9(3).

The host organism species, *T. reesei,* is a commonly listed microorganism within Schedule 18. The nomenclature of the gene donor microorganism *M. cinnamomea* was confirmed as being appropriate as listed in the application (see section 3.2 of SD1).

2.3.3 Labelling requirements

The generic exemption from listing processing aids in the statement of ingredients will apply to foods produced using this processing aid (see section 1.3.3 above), unless other requirements apply (see Sections 2.3.3.1 and 2.3.3.2 below).

2.3.3.1 Declaration of certain substances

As noted in section 2.2.1 of SD1, wheat products are utilised in the production of this enzyme. Although the applicant states there is no allergenic risk associated with thermomycolin sourced from *T. reesei*, strain RF8963, if wheat or gluten is present in a food for sale, they must be declared in accordance with requirements in Division 3 of Standard 1.2.3 (see Section 1.3 of this report).

2.3.3.2 Labelling requirements for food produced using gene technology

Standard 1.5.2 in effect provides that a substance used as a processing aid that contains novel DNA or novel protein is a GM food. In contrast to the generic exemption for listing processing aids, subsection 1.5.2—4(2) states that the information relating to foods produced using gene technology must include the statement 'genetically modified' in conjunction with the name of the GM food. Subsection 1.5.2—4(3) states that if the GM food is used as a

[4] Food produced using gene technology' is defined in subsection 1.1.2—2(3) as meaning 'a food which has been derived or developed from an organism which has been modified by gene technology'.

processing aid, the information may be included in the statement of ingredients. A food for retail sale or sold to a caterer that contains thermomycolin sourced from *T. reesei,* strain RF8963 as an ingredient (for example, the enzyme is used in the manufacture of meat stock) will be required to be labelled ‘genetically modified’ in conjunction with the name of the enzyme.

2.3.4 Risk management conclusion

The risk management conclusion was to permit the use of the enzyme thermomycolin (EC 3.4.21.65) derived from *T. reesei* strain RF8963, containing the thermomycolin gene from *M. cinnamomea,* as a processing aid in the Code for the stated technological purpose. The maximum permitted level is an amount consistent with GMP. The enzyme, and its technological purpose and maximum permitted level, will be added into the table to subsection S18—9(3), which includes enzymes permitted for specific technological purposes.

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ’s standards development process. FSANZ developed and applied a basic communication strategy to this application. The call for submissions was notified via the Food Standards Notification Circular, media release and FSANZ’s social media tools.

The process by which FSANZ considers standard development matters is open, accountable, consultative and transparent. Public submissions were 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 was considered for approval by the FSANZ Board, having regard to all submissions made during the call for submissions period. As stated above, only two submissions were received.

2.5 FSANZ Act assessment requirements

When assessing this application and the subsequent development of a food regulatory measure, FSANZ 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

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for permitting new processing aids and genetically modified food (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting new enzyme processing aids and new genetically modified food is voluntary if the application concerned is approved. This standing exemption relates to the introduction of a food to the food supply that had been determined to be safe.

FSANZ, however, had considered the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the 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 is likely to benefit, on balance, from a move from the status quo (i.e. rejecting the application). This analysis considered permitting the proposed use of thermomycolin (EC 3.4.21.65) derived from *T. reesei* strain RF8963, containing the thermomycolin gene from *M. cinnamomea* as a processing aid. FSANZ concluded that no other realistic food regulatory measures exist. No information received during public consultation resulted in FSANZ arriving at a different outcome.

The consideration of the costs and benefits in this section was not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were 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 use of the enzyme.

Costs and benefits of permitting the use of enzyme thermomycolin from a GM strain of T. reesei

Industry

Thermomycolin may improve the hydrolysis of peptide bonds during the manufacture and/or processing of vegetable and animal protein hydrolysates including meat, poultry and game products, vegetable products, fish and seafood products. There are other enzymes available to industry that perform similar functions, including sources of serine proteinase. It would likely benefit industry to have additional choice available to them, especially where the enzyme is more effective or cheaper. The enzyme is permitted for use in France, Denmark, Canada, Mexico, Brazil and the USA. The international permissions for this enzyme may be a business opportunity for Australian and New Zealand industries, although there may also be competing imports from these countries into the domestic market.

Consumers

Consumers may also benefit from a greater number of higher quality hydrolysed protein products if there is significant use of this enzyme for that purpose. Industry may pass some of the possible cost savings from using the enzyme as proposed onto consumers."

Government

Permitting the proposed use of the enzyme as a processing aid may result in a small cost to government in terms of adding the new processing aid to the current range of processing aids that are monitored for compliance.

Conclusions from cost benefit considerations

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 as a processing aid most likely outweigh the associated costs. No further information was received during the consultation process to change that assessment.

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 because of the application.

2.5.1.3 Any relevant New Zealand standards

The relevant standards apply in both Australia and New Zealand. There are no other 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 had undertaken a safety assessment (SD1) and concluded there were no public health and safety concerns with permitting the use of the enzyme as a processing aid in food for the proposed technological purposes.

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

The labelling requirements related to this enzyme are discussed in section 2.3.3 above.

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 had used the best available scientific evidence to conduct the risk analysis, which is provided in SD1. The applicant submitted a dossier of scientific studies as part of the application. FSANZ had regard to this dossier, together with other technical information including scientific literature, 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 the Codex Alimentarius Commission (Codex). In contrast to food additives, there is no Codex Alimentarius 'general standard' for enzymes. However, there are relevant identity and purity specifications for enzymes in Schedule 3 of the Code with which this enzyme must comply. AB Enzymes provided evidence that their thermomycolin enzyme preparation complies the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications (FAO JECFA Monographs 23, 2019), and the United States Pharmacopeial Convention (USPC 2020) Food Chemicals Codex (12th edition). These include specifications for enzyme preparations used in food processing.

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

As the use of this enzyme is already permitted in France, Denmark, Canada, Mexico, Brazil and the USA, the approval for use would bring Australia and New Zealand into line with other jurisdictions where it is already authorised for use. In this way, Australia and New Zealand will remain competitive with other international markets."

Which enzyme preparation a food manufacturing company uses will depend on a number of economic and other factors. 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.

Permission to use this enzyme will help foster continued innovation and improvements in food manufacturing techniques and processes. It is appropriate that Australian and New Zealand food industries are given the opportunity to benefit from the use of this enzyme as an alternative to those currently permitted.

FSANZ understands that the use of enzymes in foods is not restricted or specifically regulated in several countries. Regulation (EC) No 1332/2008 (the Regulation) harmonises the rules for food enzymes in the European Union (EU) (EC 2008). Before the Regulation, food enzymes used as processing aids were not regulated at EU level. According to the Regulation, all food enzymes currently on the EU market, as well as new food enzymes, are subject to a safety evaluation by the European Food Safety Authority (EFSA) and subsequent approval by the European Commission by means of an EU list. Currently, there is no EU list of authorised food enzymes. Until the establishment of such a list, EU Member States' legislation applies.

- **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 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 regarding the substance.

FSANZ has determined that permitting the use of this enzyme as a processing aid is consistent with the specific order principles for 'Technological Function'. All other requirements of the policy guidelines were similarly met.

3 References

EC (2008) Regulation (EC) No 1332/2008 of 16 December 2008 on food enzymes. Accessed 8 June 2022

FCC (2018) Enzyme preparations. In: *Food Chemicals Codex*, 11th edition. Rockville (MD): United States Pharmacopeial Convention

International Union Of Biochemistry And Molecular Biology (IUBMB) 2020, https://www.qmul.ac.uk/sbcs/iubmb/enzyme/EC34/3421a.html#2162. Accessed 8 June 2022

IUBMB 2022 Enzyme Nomenclature EC 3.4.21.65 https://iubmb.qmul.ac.uk/enzyme/EC3/4/21/65.html Accessed 8 June 2022

JECFA (2006) General Specifications and Considerations for Enzyme Preparations. In: *Combined Compendium of Food Additive Specifications [Online Edition].* World Health Organization, Geneva, Switz. Available at: http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/. Accessed 8 June 2022

The United States Pharmacopeia (2020) Food Chemicals Codex 12th Edition, United States Pharmacopeial Convention, Rockville, MD

Attachments

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

[5] Available on the Food regulation website.

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

Food Standards (Application A1238 – Serine endopeptidase enzyme from GM *Trichoderma reesei*) 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]

[Delegate's name and position]
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 A1238 – Serine endopeptidase enzyme from GM* Trichoderma reesei*) 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:

Thermomycolin (EC 3.4.21.65) sourced from *Trichoderma reesei* containing the thermomycolin gene from *Malbranchea cinnamomea*	To catalyse the hydrolysis of peptide bonds during the manufacture and/or processing of the following types of food: (a) meat products; (b) vegetable products; and (c) seafood products.	GMP

Attachment B – 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 A1238 which sought to amend the Code to permit the use of the enzyme, thermomycolin (EC 3.4.21.65) sourced from a genetically modified (GM) strain of *Trichoderma reesei* containing the thermomycolin gene from *Malbranchea cinnamomea* as a processing aid to catalyse the hydrolysis of peptide bonds during the manufacture and/or processing of meat, vegetable and seafood products. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation.

Following consideration by the Food Ministers' Meeting (FMM)[6], section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunsetting under the *Legislation Act 2003*.

2. Variation will be 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

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

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 section S18—9(3) of the Code to permit the use of the enzyme, thermomycolin (EC 3.4.21.65) sourced from a GM strain of *Trichoderma reesei* containing the thermomycolin gene from *Malbranchea cinnamomea*, as a processing aid to catalyse the hydrolysis of peptide bonds during the manufacture and/or processing of meat, vegetable and seafood products. This permission is subject to the condition that the maximum permitted level or amount of this enzyme that may be used 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 will 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. Section S3—2 of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications (FAO JECFA Monographs 23 (2019)) and the United States Pharmacopeial Convention (2020) Food Chemicals Codex (12th edition). These include specifications for 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 A1238 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. Submissions were called for on 27 April 2022 for a six-week consultation period.

The Office of Best Practice Regulation (OBPR) granted the Authority a standing exemption from the requirement to develop a Regulatory Impact Statement for applications relating to permitting new processing aids and genetically modified food (OBPR correspondence dated 24 November 2010 - reference 12065). This standing exemption was provided as permitting new processing aids and genetically modified foods is deregulatory as their use will be voluntary if the application concerned is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

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

Item [1] of the Schedule to the draft variation inserts, in alphabetical order, a new entry into the table to subsection S18—9(3) in Schedule 18. The new entry consists of the following enzyme:

- 'Thermomycolin (EC 3.4.21.65) sourced from *Trichoderma reesei* containing the thermomycolin gene from *Malbranchea cinnamomea*' (column 1 of the table).

The permitted technological purpose for this enzyme is use as a processing aid to catalyse the hydrolysis of peptide bonds during the manufacture and/or processing of meat, vegetable and seafood products (column 2 of the table).

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

The variation permits the proposed use of the enzyme, thermomycolin (EC 3.4.21.65) sourced from *Trichoderma reesei* containing the thermomycolin gene from *Malbranchea cinnamomea* as a processing aid in accordance with the Code.