**14 May 2025**
**340-25**

# Approval report – Application A1311

# Prolyl oligopeptidase from GM *Trichoderma reesei* 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 prolyl oligopeptidase (EC 3.4.21.26) from genetically modified *Trichoderma reesei* to be used as a processing aid in the production of brewed beverages and has prepared a draft food regulatory measure.

On 12 December 2024 FSANZ sought submissions on a draft variation and published an associated report. FSANZ received four submissions.

FSANZ approved the draft variation on 30 April 2025. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 14 May 2025.

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

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

# Table of contents



## Supporting document

The supporting document which informed the assessment of this application is available on the A1311 page on the FSANZ website:

SD Risk and technical assessment

# 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 prolyl oligopeptidase (EC 3.4.21.26) as a processing aid.

The enzyme is proposed for use as a processing aid in the production of brewed beverages. The prolyl oligopeptidase is sourced from genetically modified (GM) *Trichoderma reesei* containing the prolyl oligopeptidase gene from *Aspergillus niger.*

The proposed use of prolyl oligopeptidase is technologically justified in the form and quantity proposed during the production of brewed beverages. 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.

No public health and safety concerns were identified in the assessment of prolyl oligopeptidase produced by this GM *T. reesei* under the proposed use conditions. *T. reesei* has a long history of safe use as a production microorganism of enzyme processing aids, including several that are already permitted in the Code. The production organism is neither pathogenic nor toxigenic. Analysis of the GM production strain confirmed the presence and stability of the inserted DNA. Bioinformatics analysis indicated that the prolyl oligopeptidase does not have substantial homology with known toxins or food allergens.

Following assessment and the preparation of the draft variation, FSANZ called for submissions regarding the draft variation. Four submissions were received, one from a jurisdiction and three from individuals. The jurisdiction supported approval of the draft variation. The individuals did not support approval of the draft variation, based on general concerns regarding GM substances being added to food or technical matters, which have been addressed by FSANZ.

Based on the information above, and on other relevant considerations set out in this report, FSANZ has approved the draft variation proposed at the call for submissions, with minor formatting amendments. The approved draft variation amends the table to subsection S18—9(3) of the Code. The effect of the approved draft variation will be to permit the use of the enzyme prolyl oligopeptidase (EC 3.4.21.26) sourced from GM *T. reesei* containing the prolyl oligopeptidase gene from *A. niger* as a processing aid in brewing in accordance with the Code. The permission will 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.

# 1 Introduction

## 1.1 The applicant

The applicant is IFF Australia Pty Ltd, trading as Danisco Australia Pty Ltd.

## 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 prolyl oligopeptidase (EC 3.4.21.26) as a processing aid. It is proposed for use during the production of alcoholic and non-alcoholic brewed beverages.

The enzyme is produced from genetically modified (GM) *T. reesei* containing the prolyl oligopeptidase gene from *A. niger.*

The applicant has indicated that the enzyme is to be used at minimum levels necessary to achieve the desired effect, in accordance with Good Manufacturing Practice (GMP).

## 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) 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 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.

Standard 1.3.3 and Schedule 18 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 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.

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).

There is no permission in the Code for the use of prolyl oligopeptidase as a processing aid.

### 1.3.2 Identity and purity requirements

Paragraph 1.1.1—15(1)(b) 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) 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 26 (2021)), and the United States Pharmacopeial Convention (2022) Food chemicals codex (13th edition). 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[2] 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 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 does not have to bear a label, the required name must be provided to the caterer with the food.

Section 1.5.2—4 of the Code requires a food for sale that consists of a *genetically modified food*[3] (GM food) or has a GM food as an ingredient to be labelled as 'genetically modified', unless an exemption applies. The statement 'genetically modified' must be made in conjunction with the name of the GM food. If the GM food is used as a processing aid, this statement may be included in the statement of ingredients. The requirements imposed by section 1.5.2—4 apply to foods for retail sale and to foods sold to a caterer in accordance with Standard 1.2.1.

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[2] ***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)).

[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*).

## 1.4 International standards

In developing food regulatory measures, Food Standards Australia New Zealand (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 enzymes, however as noted in Section 1.3.2 above, there are internationally recognised specifications for enzyme preparations established by JECFA and Food Chemicals Codex.

In addition, 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.

## 1.5 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 the FSANZ Act.

## 1.7 Decision

For the reasons outlined in this report FSANZ decided to approve a draft variation amending the Code to permit prolyl oligopeptidase (EC 3.4.21.26) from GM *T. reesei* to be used as a processing aid in brewing.

The draft variation as proposed following assessment was approved with minor formatting amendments after FSANZ had regard to all submissions. The approved draft variation takes effect on gazettal and is at Attachment A. 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 the draft variation included in the call for submissions report between 12 December 2024 and 24 January 2025. Four submissions were received, one from New Zealand Food Safety and three from individuals. New Zealand Food Safety supported approval of the draft variation to amend the Code to permit prolyl oligopeptidase (EC 3.4.21.26) from genetically modified *T. reesei* to be used as a processing aid. The three individuals did not support approval of the draft variation. FSANZ's response in considering the submissions from individuals is provided in the table below.

**Table 1: Summary of issues raised in submissions and FSANZ's response**

| Issues raised | FSANZ response |
|---|---|
| Individual 1 | |
| Does not support any additive or product that is GM or that comes from a GM source.<br><br>Noted the following issues:<br>• the negative effects of GM products on health,<br>• concerns about the safety of the products they consume, and<br>• allowing harmful foods and additives into Australia. | All GM additives or products are subject to a thorough safety assessment by FSANZ before they are permitted for sale (see the SD – risk and technical assessment and Safety assessments of GM foods). |
| Individual 2 | |
| A 90-day test trial to gauge any effect on human consumption is not long enough to determine if there is any effect. Even if used as a processing aid, the use of GM ingredients is still in its infant stage, and not enough data has been collected to ensure safety. | 90-day rodent trials are recognised by national and international regulatory agencies as being of sufficient duration to detect toxic effects for enzyme processing aids.<br><br>The risk analysis framework for GM ingredients is well established. The use of GM organisms to produce processing aids has a substantial (30+ year) history of safe use in Australia and New Zealand, with many such processing aids already approved in the Code. |
| Individual 3 | |
| Queried whether the toxicology studies for prolyl oligopeptidase from the GM host were for this application or another source of prolyl oligopeptidase.<br><br>An issue was raised for novel products being available to the public before Randomised Control Trials (RCTs) have checked safety for consumption. Additionally, independent RCT's would facilitate acceptance. The application should be rejected until clarity is ascertained. | The toxicology studies were conducted using the prolyl oligopeptidase that is the subject of this application, produced by this specific *T. reesei* genetically modified to express the prolyl oligopeptidase gene from *A. niger*.<br><br>The data requirements for an enzyme processing aid of this type have been met. FSANZ's risk assessments are based on international best practice in line with the Codex risk analysis framework. RCTs are not required for the safety assessment of enzyme processing aids in Australia and New Zealand or internationally.<br><br>FSANZ's safety assessment includes:<br>• consideration of the safety of the source organism<br>• characterisation of the inserted DNA<br>• genetic stability of the inserted gene<br>• the history of safe use of the enzyme<br>• the lack of homology with known toxins and allergens<br>• the results of a 90-day toxicology study in rats<br>• the results of genotoxicity assays. |

| Issues raised | FSANZ response |
|---|---|
| | No safety concerns were identified. |
| A large variation in heavy metals for the two samples assayed was observed i.e. a 10% difference in lead. Has FSANZ considered more studies, as concentration maybe larger?<br><br>Have all possible contaminants been investigated. | Levels of lead, arsenic, cadmium and mercury were within the specifications set by JECFA, Food Chemicals Codex, and the Code according to results from two different batches of the enzyme preparation provided by the applicant.<br><br>The enzyme will be required to comply with the relevant identity and purity specifications in Schedule 3 of the Code concerning limits on contaminants of concern, when added to food in accordance with the Code, or sold for use in food. |
| The following issues relating to the genetic modification process of the production organism:<br><br>• potential unintended / off-target effects<br>• formation of toxic molecules<br>• monitoring of future novel mutations. | FSANZ's safety assessment did not identify any safety concerns regarding the genetically modified production organism. In response to the specific issues raised, FSANZ notes the following:<br><br>• The occurrence of unintended effects is not unique to genetic modification but also occurs for conventional approaches or naturally due to spontaneous mutation (Li et al. 2017; Taylor John et al. 2017; Habig et al. 2021). The accumulated regulatory experience over the last 25 years and the scientific literature does not support the hypothesis that foods derived from genetically modified sources have greater propensity for unintended / off-target effects or a major source of risk to the consumer, compared to food from other sources.<br><br>• The safety assessment of the prolyl oligopeptidase enzyme concluded there are no toxicity concerns. There is no credible scientific basis to support the notion that toxins can arise spontaneously as a result of the genetic modification process.<br><br>• FSANZ's safety assessment did not identify any new or altered hazards in the genetically modified production organism that would warrant long-term monitoring. |
| Heat generated during fermentation could create an environment for potential food spoilage, microbe or fungi mutation - and may affect the identity and purity of the genetically modified processing aid. | The enzyme fermentation processes are designed to prevent spoilage microorganisms from growing by creating an environment unfavourable to them. The target microbes dominate by rapidly consuming nutrients, lowering pH through acid production. Controlled conditions, such as temperature regulation and anaerobic environments, can further inhibit spoilage. |

| Issues raised | FSANZ response |
|---|---|
| | organisms, ensuring a successful fermentation process. No aspects of the production methodology and data presented raised microbiological concerns. |
| Vague conclusions about the processing aid dose - may not consider overuse from overindulging in beverages in a binge session or a chronic situation. | The method used for the dietary exposure assessment included several conservative assumptions which are outlined in the risk and technical assessment (see the SD). These include that all the total organic solids (TOS) remains in the final food, and that the final food containing the theoretical amount of TOS is consumed daily over a lifetime. The consumption amounts used in the dietary exposure assessment are also conservative and are based on physiological requirements, and not actual reported consumption amounts from national dietary surveys, representing a worst-case scenario for chronic dietary exposure.<br><br>In addition, the enzyme must be used in accordance with GMP i.e. used at the minimum level required to achieve the desired effect. The applicant stated that the enzyme is likely to either be reduced or removed during processing, or would be present in insignificant quantities. |
| Does the optimal temperature for prolyl oligopeptidase of 40-60°C get exceeded in fermentation prior to performing the desired effect?<br><br>If the enzyme is denatured at 75°C and not functional in the final product how does it prevent chill haze in the product i.e. in the glass ready for consumption. | During fermentation, a beverage manufacturer will optimise brewing conditions, including temperature, so the enzyme can work at its maximum efficiency. The applicant has advised FSANZ that the ideal temperature range is from 40 to 60°C (see Table 2 - SD). When the fermentation temperature reaches 75ºC the enzyme is denatured so no longer functions.<br><br>The enzyme hydrolyses certain proteins during the fermentation step of the brewing process. These proteins, if present in the final beverage, could otherwise cause chill haze. Therefore, by hydrolysing the proteins during fermentation, chill haze in the glass ready for consumption is prevented. |
| There seems to have been a focus on promoting sustainability which does not seem to consider the genetic modification and a 'clean' food processing aid. This is not natural and sustainable with multiple layers of lab involvement. | FSANZ's primary statutory objective in undertaking the assessment is the protection of public health and safety. Issues raised, such as sustainability, fall outside the scope of FSANZ's assessment. |

| Issues raised | FSANZ response |
|---|---|
| This GM brew will unlikely be accepted by consumers if GM labelling is obscured or is absent. Labelling is required to enable informed choice and protect the company from legal action.<br><br>In addition, gluten sources must be labelled. 'Possibly contains gluten' must be included in labelling just in case someone with a gluten allergy does have a reaction. | Existing labelling requirements for GM foods and allergen declarations will apply unless an exemption applies (see sections 1.3.3 and 2.3.3 of this report).<br><br>Precautionary allergen labelling (PAL) such as 'may contain' and 'may be present' is a voluntary statement that may be made by food suppliers to manage the risk of the possible unintended presence of allergens occurring during food manufacture. The Code does not regulate PAL statements. |

## 2.2 Risk assessment

FSANZ undertook 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 the SD). Summaries of both assessments are provided below.

### 2.2.1 Food technology assessment

The proposed use of the prolyl oligopeptidase as a processing aid in the production of brewed beverages is consistent with its typical function of catalysing the hydrolysis of proline ($Pro^+$) and alanine ($Ala^+$) in oligopeptides. The use of prolyl oligopeptidase prevents chill haze caused by proline/glutamate rich proteins and peptides. It is functioning as a processing aid for the purposes of the Code where it is does not perform a technological purpose in the food for sale. FSANZ also concluded 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 and has been demonstrated to be effective in achieving its stated purpose.

### 2.2.2 Risk assessment

The amino acid sequence of the enzyme shows no homology with any known toxins, venoms or allergens, and the enzyme concentrate showed no genotoxic potential in a bacterial reverse mutation assay or a micronucleus assay conducted using human lymphocytes.

A No Observed Adverse Effect Level (NOAEL) of 1000 mg TOS/kg bw/day was identified in a 90-day oral toxicity study in rats. The theoretical maximum daily intake (TMDI) was calculated to be 0.31 mg TOS/kg bw/day. A comparison of the NOAEL and the TMDI results in a Margin of Exposure (MOE) of approximately 3200.

No public health and safety concerns were identified concerning the use of the production organism, which is neither pathogenic nor toxigenic. Analysis of the GM production strain confirmed the presence and stability of the inserted DNA.

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.

## 2.3 Risk management

Following assessment, FSANZ prepared a draft variation and called for submissions on that

draft variation from 12 December 2024 to 24 January 2025.

The risk management options available to FSANZ following the call for submissions are to:

- approve the draft variation proposed following assessment, or
- approve that draft variation subject to such amendments as FSANZ considers necessary, or
- reject that draft variation.

Following the call for submissions and having regard to all submissions received, for the reasons set out in this report, FSANZ considers it appropriate to approve the draft variation proposed following assessment with minor formatting amendments (Attachment A).

The conclusions from the risk and technical assessment were that the proposed use of the enzyme is technologically justified and there were no safety concerns associated with its proposed use.

The permission to use this prolyl oligopeptidase is subject to the condition that the maximum permitted level or amount of enzyme that may be present in food must be consistent with GMP.

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

### 2.3.1 Regulatory approval

As stated above, FSANZ has approved a draft variation to permit the use of the enzyme prolyl oligopeptidase (EC 3.4.21.26) from GM *T. reesei* as a processing aid for use in brewing. The proposed draft variation is consistent with the wording used in other similar processing aid permissions for a specific technological purpose i.e. for 'use in brewing'.

The express permission for the enzyme to be used as a processing aid also provides the permission for its potential presence in food for sale as a food produced using gene technology (see section 1.3.1 above). 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.[4]

### 2.3.2 Enzyme nomenclature, source microorganism nomenclature and specifications

Nomenclature for the production and gene donor organisms – *T. reesei and A. niger* respectively – is in accordance with accepted international norms for fungal taxonomy. The International Union of Biochemistry and Molecular Biology (IUBMB) lists the accepted name prolyl oligopeptidase for the enzyme EC 3.4.21.26 (see section 2.1 of the SD).

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 above).

[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'.

### 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 the SD states that wheat is used in the fermentation process to produce prolyl oligopeptidase but is not present in the final enzyme preparation. Declaration requirements for wheat and gluten will apply if they are present in a food for sale that is manufactured using this processing aid. Certain products including beer are, however, exempt from the requirement to declare wheat and gluten in accordance with subsection 1.2.3—4(4) and the table to subsection S9—3(3).

As explained in section 1.3.3, the Code requires certain foods for sale to be labelled as 'genetically modified', unless an exemption listed in subsection 1.5.2—4(1) applies. It is likely that these exemptions will apply to food for sale manufactured using this prolyl oligopeptidase enzyme. This is because novel DNA or novel protein from the production strain *T. reesei* is unlikely to be present in such foods. However, if the labelling exemptions in subsection 1.5.2—4(1) do not apply, the requirement to label as 'genetically modified' will apply.

### 2.3.4 Risk management conclusion

The risk management conclusion is to permit the enzyme prolyl oligopeptidase (EC 3.4.21.26) produced from GM *T. reesei* containing the prolyl oligopeptidase gene from *A. niger* as a processing aid in the production of brewed beverages (see section 1.2 above).

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 will have to 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 will also provide the permission for the enzyme's potential presence in the food for sale as a food produced using gene technology.

## 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. The call for submissions was notified via the FSANZ 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 to make submissions on this application.

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

## 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*

Changes have been made to the impact analysis requirements by the Office of Impact Analysis (OIA)[5]. Impact analysis is no longer required to be finalised with the OIA. Prior to these changes, the OIA advised FSANZ that a Regulatory Impact Statement (RIS) was not needed for applications relating to processing aids and GM foods. This is because applications relating to permitting the use of processing aids and GM foods that have been determined to be safe are minor and deregulatory in nature, as their use will be voluntary if the draft variation concerned is approved. Under the new approach, FSANZ's assessment is that a RIS is not required for this application.

FSANZ, however, has 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 is to determine if the community, government and industry is likely to benefit, on balance, from a move from the status quo (where the status quo is rejecting the application). This analysis considers the costs and benefits of approving this application.

The consideration of the costs and benefits in this section was not intended to be an exhaustive, quantitative economic analysis of the proposed measure. In fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment sought to highlight the positives and negatives of moving away from the status quo by approving the draft variation to the Code proposed by the application.

FSANZ's conclusions regarding the costs and benefits of the proposed measure are set out below.

*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 production of brewed beverages. 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.

[5] Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis (pmc.gov.au)

*Conclusions from cost benefit assessment*

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting prolyl oligopeptidase (EC 3.4.21.26) from GM *T. reesei* to be used as a processing aid for brewing is likely to outweigh the associated costs. No further information was received during the consultation process that changed 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 as a result of the application.

#### *2.5.1.3 Any relevant New Zealand standards*

The relevant standards in the Code 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 undertook a safety assessment (see section 2.2 above and the SD) and concluded there were no public health and safety concerns associated with the proposed use of this enzyme.

#### *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 sections 1.3.3 and 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 its application. This dossier, together with other technical and scientific information, was considered by FSANZ in assessing the application. The risk assessment is provided in the SD.

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

As noted in sections 1.3.2 and 1.4 above, the relevant international standard setting body is Codex. In contrast to food additives, there is no Codex 'general standard' for enzymes, however there are internationally recognised specifications for enzyme preparations established by JECFA and Food Chemicals Codex, with which this enzyme would have to comply.

In addition, 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.

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

Details on approvals on permissions for use of this enzyme that is the subject of this application were provided as confidential commercial information and considered as part of this assessment.

Australia and New Zealand will remain competitive with other international markets, where approval for the use of the enzyme in other markets is granted in the future. 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 food industry will make their own economic decisions, considering 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*[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

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

specific order policy principles for ‘Technological Function’. All other relevant requirements of the policy guideline are similarly met.

# 3 References

Habig M, Lorrain C, Feurtey A, Komluski J, Stukenbrock EH (2021) Epigenetic modifications affect the rate of spontaneous mutations in a pathogenic fungus. Nature Communications. 12(1):5869.

Li W-C, Huang C-H, Chen C-L, et al. (2017) Trichoderma reesei complete genome sequence, repeat-induced point mutation, and partitioning of CAZyme gene clusters. Biotechnology for Biofuels. 10(1):170.

Taylor John W, Branco S, Gao C, et al. (2017) Sources of Fungal Genetic Variation and Associating It with Phenotypic Diversity. Microbiology Spectrum. 5(5):10.1128/microbiolspec.funk-0057-2016.

## Attachments

A. Approved draft variation to the Australia New Zealand Food Standards Code
B. Explanatory Statement
C. Draft variation to the Australia New Zealand Food Standards Code (call for submissions)

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

**Food Standards (Application A1311 – Prolyl oligopeptidase from GM *Trichoderma reesei* as a processing aid) Variation**

---

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by Delegate]

[Insert Delegate's name and position title]
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 A1311 – Prolyl oligopeptidase from GM* Trichoderma reesei *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:

| | | |
|---|---|---|
| Prolyl oligopeptidase (EC 3.4.21.26) sourced from *Trichoderma reesei* containing the prolyl oligopeptidase gene from *Aspergillus niger* | For use in brewing | GMP |

# Attachment B – Explanatory Statement

## EXPLANATORY STATEMENT

*Food Standards Australia New Zealand Act 1991*

***Food Standards (Application A1311 – Prolyl oligopeptidase from GM* Trichoderma reesei *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 purpose of the application was to permit the use of the enzyme prolyl oligopeptidase (EC 3.4.21.26) from a genetically modified *Trichoderma reesei* containing the prolyl oligopeptidase gene from *Aspergillus niger* as a processing aid.

The enzyme was proposed for use during the production of brewed beverages.The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation – the *Food Standards (Application A1311 – Prolyl oligopeptidase from GM* Trichoderma reesei *as a processing aid) 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 approved 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.

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 prolyl oligopeptidase enzyme (EC 3.4.21.26) sourced from genetically modified *Trichoderma reesei* containing the prolyl oligopeptidase gene from *Aspergillus niger* as a processing aid in brewing.

The 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. 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 A1311 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for over a consultation period from 12 December 2024 until 24 January 2025. Further details of the consultation process, the issues raised during consultation and by whom, and the Authority's response to these issues are available in an approval report published on the Authority's website at www.foodstandards.gov.au.

Changes have been made to the impact analysis requirements by the Office of Impact Analysis (OIA)[7]. Impact analysis is no longer required to be finalised with the OIA. Prior to these changes, the OIA advised FSANZ that a Regulatory Impact Statement (RIS) was not needed for applications relating to processing aids and genetically modified food. This is because applications relating to permitting the use of processing aids and genetically modified food that have been determined to be safe are minor and deregulatory in nature, as their use will be voluntary if the draft variation concerned is approved.

[7] Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis (pmc.gov.au).

Under this approach, FSANZ's assessment is that a RIS is not needed for this application.

## 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 A1311 – Prolyl oligopeptidase from GM* Trichoderma reesei *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:

- 'Prolyl oligopeptidase (EC 3.4.21.26) sourced from *Trichoderma reesei* containing the prolyl oligopeptidase gene from *Aspergillus niger.*

The permitted technological purpose for this enzyme is prescribed in column 2 of the table i.e. for use in brewing.

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 effect of item [1] of the Schedule to the variation is to permit the use of the enzyme Prolyl oligopeptidase (EC 3.4.21.26) sourced from *Trichoderma reesei* containing the prolyl oligopeptidase gene from *Aspergillus niger* as a processing aid in accordance with the Code.

# Attachment C – Draft variation to the Australia New Zealand Food Standards Code

**Food Standards (Application A1311 – Prolyl oligopeptidase from GM *Trichoderma reesei* as a processing aid) Variation**

---

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by Delegate]

[Insert Delegate's name and position title]
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 A1311* – Prolyl oligopeptidase *from GM Trichoderma reesei 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:

| | | |
|---|---|---|
| Prolyl oligopeptidase (EC 3.4.21.26) sourced from *Trichoderma reesei* containing the prolyl oligopeptidase gene from *Aspergillus niger* | For use in brewing | GMP |