12 December 2024
321-24

Call for submissions – 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 propyl oligopeptidase from genetically modified *Trichoderma reesei* for use as a processing aid in the production of brewed beverages and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

Submissions on this application need to be made through the Consultation Hub (https://consultations.foodstandards.gov.au/).

All submissions on applications and proposals 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) 24 January 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

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Supporting document

The following document which informed the assessment of this application is available on the 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 sourced from genetically modified GM *Trichoderma reesei* containing the prolyl oligopeptidase gene from *Aspergillus niger*.

The use of prolyl oligopeptidase is technologically justified in the quantity and form 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 preparation in the Code.

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 Total Organic Solids (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. In the absence of any identifiable hazard an Acceptable Daily Intake (ADI) 'not specified' is appropriate for this prolyl oligopeptidase.

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 as processing aids for specific technological purposes. The draft variation, if approved, would permit the use of the enzyme prolyl oligopeptidase (EC 3.4.21.26) sourced from *T. reesei* containing the prolyl oligopeptidase gene from *A. niger* as a processing aid in the production of brewed beverages, 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 (GMP).

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.

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 in in the production of brewed beverages. The stated purpose is to prevent chill haze caused by proline/glutamate rich proteins and peptides.

The enzyme is produced from a genetically modified (GM) strain of *Trichoderma reesei* containing the prolyl oligopeptidase gene from *Aspergillus niger*. Thus, *T. reesei* is the host (source) species and *A. niger* is the donor for the gene.

The applicant has indicated that the enzyme is to be used in accordance with Good Manufacturing Practice (GMP). GMP is defined in the section 1.1.2—2 of the Code.[1]

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 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

[1] GMP is defined in section 1.1.2—2 of the Code as follows: *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.

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.

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). 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*[2] (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

[2] 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*).

with Standard 1.2.1.

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.

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 the Supporting Document (SD)). Summaries of both assessments are provided below.

2.1 Food technology assessment

The enzyme is intended for use as a processing aid in the production of brewed beverages. The proposed use is technologically justified for use at levels consistent with GMP.

There are relevant identity and purity specifications for the enzyme in the Code and the applicant provided evidence that their enzyme meets these specifications.

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.

T. reesei QM6a has a history of safe use as a production microorganism of enzyme processing aids. The production organism is neither pathogenic or toxigenic. Analysis of the production strain confirmed the presence and stability of the inserted DNA.

A No Observed Adverse Effect Level (NOAEL) of 1000 mg Total Organic Solids (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.

Based on the reviewed data no public health and safety concerns were identified for the enzyme under the proposed conditions of use. An Acceptable Daily Intake (ADI) 'not specified' is appropriate for this prolyl oligopeptidase.

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 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. 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 use of the enzyme as a processing aid in the production of brewed beverages.

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[3].

2.3.2 Enzyme nomenclature, source microorganism nomenclature and specifications

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). This is the name used in the proposed draft variation.

Nomenclature for the host and gene donor organisms – *Trichoderma reesei* and *Aspergillus niger* - is consistent with accepted international norms for fungal taxonomy.

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).

[3] 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 SD1 states that wheat is used in the fermentation process to produce prolyl oligopeptidase (EC 3.4.21.26) but that it is not present in the final enzyme preparation. However, declaration requirements for wheat will apply if it is 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 prolyl oligopeptidase produced from GM *T. reesei* containing the oligopeptidase gene from *A. niger* as a processing aid in the production of brewed beverages. 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 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. Calls for submissions are notified via the FSANZ Notification Circular, media release, FSANZ's social media 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 considering 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 Alimentarius Standards) 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

Changes have been made to the impact analysis requirements by the Office of Impact Analysis (OIA)[4]. Impact analysis no longer must 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 (OIA23-06225). This is because applications relating to permitting the use of processing aids that have been determined to be safe are considered to be 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 permitting the use of the enzyme prolyl oligopeptidase from GM *T. reesei* as a processing aid in the production of brewed beverages.

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 that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the positives and negatives of moving away from the status quo by approving the variation to the Code proposed by the application.

FSANZ's conclusions regarding the costs and benefits of the proposed measure are set out below. However, information received from the call for submissions may result in FSANZ arriving at a different outcome.

Costs and benefits of permitting the proposed use of prolyl oligopeptidase from GM T. reesei as a processing aid

Industry may benefit from the use of this additional processing aid either in terms of increased efficiency and/or improved products. Due to the voluntary nature of the permission, industry will only use the processing aid as proposed where they believe a net benefit exists for them.

If industry were to experience cost savings because of using this processing aid, industry may pass on some of the cost savings to consumers. Additionally, consumers may have access to improved products.

Permitting the proposed use of this processing aid 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 considerations

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting the use of prolyl oligopeptidase from GM *T. reesei* as a processing aid is likely to outweigh the associated costs.

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

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 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 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 section 2.2.3 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**

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, there are internationally recognised specifications for enzyme preparations established by JECFA and Food Chemicals Codex, with which this enzyme would have to comply.

There is also 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).

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

United States GRAS confirmation has been given for prolyl oligopeptidase from a different production strain and in relevant European legislation for enzyme processing aids. Approvals for the 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 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 use proposed by the applicant. Ultimately, the domestic 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*[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.

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

[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 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 A1311 – Prolyl oligopeptidase from GM *Trichoderma reesei* 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 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 – Draft Explanatory Statement

DRAFT 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 Authority accepted Application A1311 which seeks to permit the use of the enzyme prolyl oligopeptidase from genetically modified *Trichoderma reesei* containing the prolyl oligopeptidase gene from *Aspergillus niger* as a processing aid. The enzyme is proposed for use in the production of brewed beverages. The Authority considered the application in accordance with Division 1 of Part 3 and has prepared a draft variation - the *Food Standards (Application A1311 – Prolyl oligopeptidase from GM* Trichoderma reesei *as a processing aid) 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 prolyl oligopeptidase enzyme sourced from genetically modified *Trichoderma reesei* containing the prolyl oligopeptidase gene from *Aspergillus niger* as a processing aid for use in 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.

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 specification 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. 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 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.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)[6]. Impact analysis is no longer must be finalised with the OIA. Prior to these changes, the OIA advised FSANZ that a Regulatory Impact Statement (RIS) was not required for the applications relating to processing aids (OIA23-06225). This is because applications relating to permitting the use of processing aids 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 needed for this application.

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 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 draft variation.

Clause 1 of the variation provides that the name of the variation is the *Food Standards*

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

(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 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:

- '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 would be prescribed in column 2 of the table i.e. for use in brewing.

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 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.