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

**8 July 2025**

**348-25**

# Call for submissions – Application A1328 Aminopeptidase from *Trichoderma reesei* as a processing aid

Food Standards Australia New Zealand (FSANZ) has assessed an application made by IFF Australia Pty Ltd (Trading as Danisco Australia Pty Ltd) to amend the Australia New Zealand Food Standards Code to permit the use of an aminopeptidase Y from a genetically modified strain of *Trichoderma reesei,* containing the aminopeptidase gene from *Aspergillus clavatus*, as a processing aid and has prepared a draft food regulatory measure. This aminopeptidase would be used as a processing aid in protein and yeast processing, as well as flavour production. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist in considering the draft food regulatory measure.

Submissions on this application need to be made through the Consultation Hub.

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) 19 August 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:

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PO Box 5423
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WELLINGTON 6140
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### Supporting document

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

SD Risk and technical assessment

# Executive summary

Food Standards Australia New Zealand (FSANZ) received an application from IFF Australia Pty Ltd (Trading as Danisco Australia Pty Ltd) to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of aminopeptidase Y (EC 3.4.11.15) from a genetically modified (GM) strain of *Trichoderma reesei,* containing the gene for aminopeptidase from *Aspergillus clavatus,* as a processing aid in protein and yeast processing, as well as flavour production.

The proposed use of this aminopeptidase as an enzyme processing aid in the quantity and form proposed is consistent with its typical function. Aminopeptidase performs its technological purpose during food processing but not in food for sale, therefore functioning as a processing aid for Code purposes.

FSANZ concludes that aminopeptidase from GM *T. reesei* does not raise safety concerns. Similar enzymes from other sources have a long history of safe use in food. The production organism is neither pathogenic nor toxigenic.

Following assessment, for reasons set out in this report, FSANZ has prepared a draft variation to 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.

If approved, the draft variation would permit the use of the enzyme aminopeptidase Y (EC 3.4.11.15) from a GM *T. reesei* containing the gene for aminopeptidase Y from *A. clavatus* as a processing aid in protein processing, yeast processing, and flavour production.

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 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). Danisco develops and manufactures a variety of ingredients used in the food and beverage, nutrition, and health industries.

## 1.2 The application

This application seeks to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of the enzyme aminopeptidase Y (EC 3.4.11.15) from a genetically modified (GM) strain of *Trichoderma reesei,* containing the gene for aminopeptidase Y from *Aspergillus clavatus,* as a processing aid in protein and yeast processing, as well as flavour production.

If approved, this enzyme would be used at minimum levels necessary to achieve the desired effect, according to Good Manufacturing Practice (GMP).

## 1.3 The current standard

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

### 1.3.1 Permitted use

Paragraph 1.1.1—10(6)(c) provides that a food for sale cannot contain, as an ingredient or a 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 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 a food 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), depending on whether a technological purpose has been specified.

An enzyme of microbial origin listed in the table to subsection S18—4(5) is 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 a row 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).

Aminopeptidase Y is not listed in Schedule 18. Therefore, use of aminopeptidase Y (EC 3.4.11.15) from a GM *T. reesei* containing the gene for aminopeptidase Y from *A. clavatus* as a processing aid is not currently permitted by the Code.

### 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 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)[1], and the United States Pharmacopeial Convention (2022) Food Chemicals Codex (13th edition). These include general specifications for enzyme preparation for identity and purity parameters in food processing.

### 1.3.3 Labelling requirements

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

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 retail sale is not required to bear a label, the required name must be displayed in connection with the display of the food or provided to the purchaser on request. If food sold to a caterer is not required to bear a label, the required name must be provided to the caterer with the food.

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.

## 1.4 International standards

In developing food regulatory measures, FSANZ must have regard to the promotion of consistency between domestic and international food standards. Regarding 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

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[1] https://www.fao.org/documents/card/fr/c/cb4737en/

[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*).

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 they shall be used under GMP conditions.

## 1.5 Reasons for accepting the 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)
- 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 of the FSANZ Act.

# 2 Summary of the assessment

## 2.1 Food technology assessment

FSANZ conducted a food technology assessment to determine whether the enzyme achieves its technological purpose in the proposed quantity and form (see the Supporting Document (SD)).

The proposed use of this aminopeptidase Y as an enzyme processing aid in the quantity and form proposed is consistent with its typical function. Aminopeptidase Y performs its technological purpose during food processing but does not perform it in food for sale. Therefore, it functions as a processing aid for the purposes of the Code. This aminopeptidase Y is not protein-engineered.

## 2.2 Safety assessment

FSANZ has assessed the public health and safety risks associated with the proposed use of aminopeptidase Y from a GM strain of *B. T. reesei* containing the aminopeptidase Y gene from *A. clavatus* as a processing aid (see SD).

The proposed use of this enzyme raises no safety concerns. Similar enzymes from other sources have a long history of safe use in food. The production organism is neither pathogenic nor toxigenic.

Based on the reviewed data, including consideration of dietary exposure, an Acceptable Daily Intake (ADI) 'not specified' is appropriate in the absence of any identifiable hazard.

FSANZ concludes that the proposed use of this aminopeptidase Y poses no concerns for public health and safety.

## 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 to permit the proposed use of aminopeptidase Y (EC 3.4.11.15) from GM *T. reesei* containing the aminopeptidase Y gene from *A. clavatus* as a processing aid in protein processing, yeast processing, and flavour production. 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.

The risk and technical assessment concluded the proposed use of the enzyme is technologically justified and there are no public health and safety concerns associated with it.

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 for processing aids

As stated above, FSANZ has prepared a draft variation to permit the use of this enzyme as a processing aid in protein processing, yeast processing, and flavour production.

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

The International Union of Biochemistry and Molecular Biology (IUBMB)[4] uses the accepted name aminopeptidase Y for EC 3.4.11.15. Therefore, 'aminopeptidase Y (EC 3.4.11.15)' is used in the draft variation.

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). This enzyme would have to comply with those specifications when added to food in accordance with the Code or sold for use in food.

### 2.3.3 Labelling

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

Section 3.3.4 of SD1 states wheat is used in the fermentation process to produce aminopeptidase Y from GM *T. reesei* and therefore may be 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.

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 these exemptions will apply to food for sale manufactured using this aminopeptidase Y from GM *T. reesei* 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 use of aminopeptidase Y (EC 3.4.11.15) from a GM strain of *T. reesei*, containing the gene for aminopeptidase Y from *A. clavatus* as a processing aid in protein and yeast processing, as well as flavour production.

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 would have to be 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.

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[4] https://iubmb.org/

## 2.4 Risk communication

### 2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process.

FSANZ developed and applied a standard communication strategy to this application. All calls for submissions are notified via the FSANZ notification circular, media release, FSANZ's digital channels and Food Standards News. Subscribers and interested parties are also notified about the availability of reports for public comment.

The process by which FSANZ considers standards development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on the draft variation. FSANZ will consider all submissions received through this call for submissions process before deciding on whether to approve the application.

### 2.4.2 World Trade Organization

As members of the World Trade Organization (WTO)[5], 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 and amending the Code to permit the use of aminopeptidase Y 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). 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.

**Background to the cost and benefit analysis**

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

[5] World Trade Organization - Home page - Global trade (wto.org)

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

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures. In fact, most of the effects considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo by permitting the use of aminopeptidase Y derived from *T. reese*i as a processing aid.

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

**Costs and benefits of permitting the proposed use of this enzyme**

Industry may benefit from efficiency improvements from the proposed use of this enzyme. Due to the voluntary nature of the permission, industry will only use the enzyme as proposed where they believe a net benefit exists.

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

There are not expected to be any costs for consumers, as the enzyme has been assessed as safe.

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 monitored for compliance.

**Conclusions from cost-benefit considerations**

FSANZ considers the direct and indirect benefits of permitting this enzyme to be used in protein and yeast processing, as well as flavour production, will likely outweigh the associated costs.

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

#### *2.5.1.2 Other measures*

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied because of the application.

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

The standards in the Code which are relevant to the permitted use of the enzyme processing aid in question apply in both Australia and New Zealand. There are no relevant New Zealand only standards.

#### *2.5.1.4 Any other relevant matters*

Other relevant matters are considered below.

### 2.5.2 Subsection 18(1)

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

#### *2.5.2.1 Protection of public health and safety*

FSANZ undertook a safety assessment (see section 2.2 above and the SD), which

concluded there were no public health and safety concerns with permitting the proposed use of aminopeptidase Y derived from *T. reese*i as a processing aid.

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

Existing labelling requirements will apply to this enzyme and its proposed use in accordance with the Code to enable consumers to make informed choices (see sections 1.3.3 and 2.3.3).

#### *2.5.2.3 The prevention of misleading or deceptive conduct*

There were no issues 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 has used the best available scientific evidence to conduct the risk analysis and assessment, provided in the SD. The applicant submitted a dossier of scientific studies as part of the application. This dossier, together with other technical information including scientific literature, was considered by FSANZ in assessing the application.

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

In terms of food safety, the relevant international standard setting body is Codex. 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, with which this enzyme would have to comply when added to food in accordance with the Code or sold for use in food.

Also, as noted in section 1.4 above, 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**

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 food 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 as proposed by the applicant.

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 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:

[6] Available on the Food regulation website

- 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 determined that permitting the proposed use of this enzyme as a processing aid is consistent with the 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

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 A1328 – Aminopeptidase from *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 the Delegate]

[Insert name and position of Delegate]
Delegate of the Board of Food Standards Australia New Zealand

**Note:**

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

## 1 Name

This instrument is the *Food Standards (Application A1328 – Aminopeptidase from* 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:

| | | |
|---|---|---|
| Aminopeptidase Y (EC 3.4.11.15) sourced from *Trichoderma reesei* containing the aminopeptidase Y gene from *Aspergillus clavatus* | For use in protein processing, yeast processing, and flavour production. | GMP |

# Attachment B – Draft Explanatory Statement

**DRAFT EXPLANATORY STATEMENT**

*Food Standards Australia New Zealand Act 1991*

***Food Standards (Application A1328—Aminopeptidase from* 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 A1328, which sought to amend the Code to permit the use of aminopeptidase Y (EC 3.4.11.15) from a genetically modified (GM) *Trichoderma reesei*, containing the gene to aminopeptidase from *Aspergillus clavatus* as a processing aid in protein processing, yeast processing, and flavour production.

The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation – *Food Standards* (*Application A1328—Aminopeptidase from* 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) of the Code to permit the use of aminopeptidase Y (EC 3.4.11.15) sourced from *Trichoderma reesei* containing the aminopeptidase gene from *Aspergillus clavatus*, as a processing aid for use in protein processing, yeast processing, and flavour production.

If approved, this permission would be subject to the condition that the maximum permitted level or amount of the enzyme that may be present in the food must be consistent with good manufacturing practice (GMP).

## 4. Documents incorporated by reference

The draft variation does not incorporate any documents by reference.

However, existing provisions of the Code incorporate documents by reference that would prescribe identity and purity specifications for the processing aid to be permitted by the draft variation. Section 1.1.1—15 of the Code requires substances used as processing aids to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code when added to food in accordance with the Code or sold for use in food.

Section S3—2 of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Compendium of Food Additive Specifications (FAO/WHO 2021) and the United States Pharmacopeial Convention (2022) Food Chemicals Codex (13th edition). These include general specifications for the identity and purity parameters of enzyme preparations used in food processing.

## 5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1328 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 period.

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 Regulation Impact Statement (RIS) was not needed for applications relating to processing aids. 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 this approach, FSANZ's assessment is that a RIS is not required for this application for those reasons.

## 6. Statement of compatibility with human rights

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

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

## 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 A1328—Aminopeptidase 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 commences 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 consists of the following enzyme in column 1 of the table:

- 'Aminopeptidase Y (EC 3.4.11.15) sourced from *Trichoderma reesei* containing the aminopeptidase gene from *Aspergillus clavatus*'

The permitted technological purpose for this enzyme would be prescribed in column 2 of the table. The prescribed purpose would be 'For use in protein processing, yeast processing, and flavour production'.

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, aminopeptidase Y (EC 3.4.11.15) sourced from *Trichoderma reesei* containing the aminopeptidase gene from *Aspergillus clavatus*, as a processing aid in accordance with the Code.