18 December 2025
373-25

Approval report – 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 aminopeptidase Y from *Trichoderma reesei,* containing the aminopeptidase gene from *Aspergillus clavatus*, as a processing aid in protein and yeast processing and flavour production.

On 8 July 2025, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received two submissions.

FSANZ approved the draft variation on 10 December 2025. The Food Ministers' Meeting was notified of FSANZ's decision on 18 December 2025.

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

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Supporting document

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

SD Risk and technical assessment

The published submissions from the call for submissions can be found on the A1328 Consultation Hub page.

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 the enzyme aminopeptidase Y (EC 3.4.11.15), from a strain of *Trichoderma reesei* containing the gene for aminopeptidase from *Aspergillus clavatus,* as a processing aid in protein and yeast processing and flavour production.

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

FSANZ concludes that aminopeptidase from *T. reesei* does not raise any public health and safety concerns under the proposed use conditions. Similar enzymes from other sources have a long history of safe use in food. The production organism is neither pathogenic nor toxigenic. Relevant identity and purity specifications for the enzyme are provided in the Code with which the enzyme must comply when added to food or sold for use in food.

Following the assessment and the preparation of the draft variation, FSANZ called for submissions on that draft variation. Two submissions were received, one from a jurisdiction and one from the Food Intolerance Network. The jurisdiction supported approval of the draft variation. The Food Intolerance Network did not support approval of the draft variation, for reasons outlined in this report.

Based on the evaluation of all information and on other relevant considerations outlined in this report, including submissions, FSANZ has approved the draft variation as proposed at the call for submissions, without amendment.

The approved draft variation will amend Schedule 18 of the Code to list aminopeptidase Y (EC 3.4.11.15) from *T. reesei*, containing the gene for aminopeptidase Y from *A. clavatus*, as a permitted processing aid for use in protein processing, yeast processing and flavour production in accordance with the Code.

This enzyme and its associated technological purposes will be added to the table to subsection S18—9(3), which lists substances (including enzymes) permitted for use as processing aids for specific technological purposes. The permission will be subject to the condition that the enzyme's maximum permitted level or amount in food must be consistent with Good Manufacturing Practice.

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 *Trichoderma reesei*[1] containing the gene for aminopeptidase Y from *Aspergillus clavatus,* as a processing aid in protein and yeast processing as well as flavour production.

The applicant has indicated that the enzyme is to be used at the minimum levels necessary to achieve the desired effect, in accordance with Good Manufacturing Practice (GMP).[2]

1.3 The current standard

Australian and New Zealand food laws require that food for sale must comply with relevant requirements in the Code. The requirements in the Code 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 must not have, as an ingredient or a component, a substance that is used as a processing aid unless expressly permitted by the Code.

Section 1.1.2—13 provides that a substance 'used as a processing aid' in relation to a food is a substance used during processing that meets all the following conditions:

- It is used to perform a technological purpose during processing.
- It does not perform a technological purpose in the food for sale.
- It is a substance listed in Schedule 18 or identified in section S16—2 as an additive permitted at GMP.

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[1] Under recent Code changes following Proposal P1055 – Definitions for gene technology and new breeding techniques, a new definition for 'genetically modified food' was adopted that excludes substances used as a processing aid. As a result of this change, enzyme processing aids produced from organisms that have been genetically modified to contain novel DNA are no longer subject to Code requirements for genetically modified food.

[2] GMP is defined in section 1.1.2—2 of the Code as follows: ***GMP*** *or* ***Good Manufacturing Practice****, with respect to the addition of substances used as food additives and substances used as processing aids to food, means the practice of:*
(a) limiting the amount of substance that is added to food to the lowest possible level necessary to accomplish its desired effect; and
(b) to the extent reasonably possible, reducing the amount of the substance or its derivatives that:
*(i) remains as a *component of the food as a result of its use in the manufacture, processing or packaging; and*
(ii) is not intended to accomplish any physical or other technical effect in the food itself;
(c) preparing and handling the substance in the same way as a food ingredient.

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 the table to section S18—9.

Aminopeptidase Y is not listed in Schedule 18. Therefore, use of aminopeptidase Y (EC 3.4.11.15) from *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 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)[3], 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 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[4] for the food which is to be declared in conjunction with the words ‘processing aid’.

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

[4] ***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)).

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

1.4 International standards

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 processing aids. However, as noted in Section 1.3.2 above, there are internationally recognised specifications for enzyme preparations established by JECFA and Food Chemicals Codex.

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 these substances 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 in accordance with the FSANZ Act.

1.7 Decision

Following assessment, FSANZ prepared a draft variation amending the Code to permit the use of aminopeptidase Y (EC 3.4.11.15) from *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 in accordance with the Code – including that this permission will be subject to the condition that the enzyme's maximum permitted level or amount in food must be an amount consistent with GMP.

For the reasons outlined in this report and after consideration of submissions received during the consultation period, FSANZ decided to approve the draft variation proposed at the call for submissions without amendments.

The approved draft variation takes effect on gazettal and is in Attachment A.

The related explanatory statement is in 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 received a total of 2 submissions to the call for submissions between 8 July 2025 and 19 August 2025. The submissions are publicly available on the FSANZ website A1328 Consultation hub page.

The first submission was made by New Zealand Food Safety, which supported the draft variation. The submission noted that the supporting document did not provide information on the gene donor organism, *A. clavatus*. FSANZ has clarified that the gene for aminopeptidase Y is synthetically constructed (see SD at Approval, section 3.2).

The second submission was made on behalf of the Food Intolerance Network, which did not support the draft variation for several reasons listed and addressed in Table 1.

Table 1: Summary of issues

Issue	Raised By	FSANZ response
The supporting document did not provide information on the gene donor organism.	New Zealand Food Safety	The gene for aminopeptidase Y is synthetically constructed based on the published amino acid sequence from *A. clavatus*. As this process did not involve the direct use of genetic material from *A. clavatus*, there is no possibility of any extraneous DNA from the donor organism being present in the production strain. This is now clarified in the SD.
Processing aids are not labelled. The use of this enzyme as a processing aid hides it from consumers and denies them the chance to make an informed choice.	Food Intolerance Network	FSANZ understands that food labels are an important source of information to assist consumers in making food choices. Processing aids are expressly prohibited unless permitted by the Code – their use is permitted only after their safety to consumers, including sensitive consumers, has been assessed as safe. As noted in Section 1.3.3 above, paragraphs 1.2.4—3(2)(d) and (e) of the Code exempt processing aids from the requirement to be declared in the statement of ingredients unless other requirements apply, for example, that exemption does not apply if a processing aid contains an allergen.
The Risk and Technical Assessment report prefers to focus on lysine, leucine and phenylalanine production and carefully		The enzyme preferentially releases N-terminal lysine residues and other hydrophobic amino acids (SD, 3.2) because its active site is structured to recognise and bind bulky, nonpolar side chains. Glutamate

avoids mentioning the word 'glutamate', although the 'umami' taste is mentioned.		is not hydrophobic — it is hydrophilic, which is why it is not described in this section of the SD.
Aminopeptidase Y releases acidic amino acids. Therefore, the result will be a hidden increase in flavour-enhancing glutamates, which many people seek to avoid; this will not be visible to consumers.		FSANZ notes glutamates are present in the diet as protein bound or free glutamates. When protein bound glutamate is consumed, it is metabolised in the body to free glutamate as a part of normal dietary protein metabolism. Should relatively small amounts of free glutamate be released in food through the use of aminopeptidase Y, dietary intake of total glutamates (protein bound and free) and therefore exposure of tissues will not change significantly. Current evidence indicates that process-related increases in free glutamate remain within normal dietary variability. FSANZ remains attentive to consumer reports of food sensitivities and intolerances. Additional information on intolerances and allergies can be found on the FSANZ website[5].
The application states that approval of this enzyme would provide manufacturers and/or consumers with 'countless benefits', without mentioning those who are affected by excess glutamates and seek to avoid them.		The quoted statement on the benefits of the enzyme represents the Applicant's view. FSANZ did not rely on the applicant's views to assess the costs and benefits of the application. When assessing this application, FSANZ had regard to the costs and benefits under section 29 of the FSANZ Act. FSANZ concludes that the direct and indirect benefits of permitting aminopeptidase Y likely outweigh the associated costs.

[5] Food allergies and intolerances | Food Standards Australia New Zealand

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

2.3 Safety assessment

FSANZ has assessed the public health and safety risks associated with the proposed use of aminopeptidase Y from *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.

No significant homology between the enzyme and known toxins or allergens was identified. Aminopeptidase Y is not genotoxic and did not cause adverse effects in a subchronic toxicity study in rats. 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 aminopeptidase Y poses no concerns for public health and safety.

2.4 Risk management

Following assessment, FSANZ prepared a draft variation and called for submissions on that draft variation for a period of six weeks.

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 both submissions received, for the reasons set out in this report, FSANZ considers it appropriate to approve the draft variation proposed following assessment without change (Attachment A).

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

The permission to use this aminopeptidase Y as a processing aid is subject to the condition that the maximum permitted level or amount of this enzyme present in the food must be consistent with GMP.

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

2.4.1 Regulatory approval for processing aids

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

2.4.2 Enzyme nomenclature, source microorganism nomenclature and specifications

The International Union of Biochemistry and Molecular Biology (IUBMB)[6] uses the accepted name aminopeptidase Y for EC 3.4.11.15. Therefore, 'aminopeptidase Y (EC 3.4.11.15)' is used in the approved 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 will have to comply with those specifications when added to food in accordance with the Code or sold for use in food.

2.4.3 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 this strain of *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.

2.4.4 Risk management conclusion

The risk management conclusion is to permit the use of aminopeptidase Y (EC 3.4.11.15) from *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.

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.

2.5 Risk communication

2.5.1 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 Food Standards Notification Circular, media release 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 all

[6] https://iubmb.org/

submissions made during the call for submissions period.

2.6 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.

2.6.1 Section 29

2.6.1.1 Consideration of costs and benefits

Background

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

The purpose of this consideration was 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). This analysis considers permitting the use aminopeptidase Y (EC 3.4.11.15) from this 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.

The consideration of the costs and benefits in this section were not intended to be an exhaustive, quantitative economic analysis of the proposed measures. In fact, most of the effects considered could not easily be assigned a dollar value. Rather, the assessment sought to highlight the likely positives and negatives of moving away from the status quo by permitting the proposed use of the enzyme as a processing aid.

A regulation impact statement (RIS) was not prepared. FSANZ's assessment was that a RIS was not required for this application. This was 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 that use is voluntary. This position is consistent with previous advice from the Office of Impact Analysis (OIA23-06225).

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 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 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 monitored for compliance.

Conclusions from cost-benefit considerations

FSANZ has assessed that the direct and indirect benefits of permitting this aminopeptidase Y from *T. reesei* to be used as a processing aid in protein and yeast processing as well as flavour production are likely to outweigh the associated costs. No further information was

received during the consultation process that changed that assessment.

2.6.1.2 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.

2.6.1.3 Any relevant New Zealand standards

The standards in the Code that 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.

2.6.1.4 Any other relevant matters

Other relevant matters are considered below.

2.6.2 Subsection 18(1)

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

2.6.2.1 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 this aminopeptidase Y derived from *T. reesei* as a processing aid.

2.6.2.2 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 2.4.3 of this report.

2.6.2.3 The prevention of misleading or deceptive conduct

There were no issues identified relevant to this objective.

2.6.3 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. The risk assessment is provided in the SD. The applicant submitted a dossier of information and 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 processing aids, however, as noted in section 1.3.2 above, there are internationally recognised specifications for enzyme preparations established by JECFA and Food Chemicals Codex, with which this enzyme will 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 these substances 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 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*[7] includes specific order policy principles for substances added to achieve a solely technological function, such as processing aids. These specific order policy principles state that permission should be granted where:

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the 'stated purpose')
- the addition of the substance to food is safe for human consumption
- the amounts added are consistent with achieving the technological function
- the substance is added in a quantity and a form which is consistent with delivering the stated purpose
- no nutrition, health or related claims are to be made regarding the substance.

FSANZ 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.

Attachments

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

[7] Available on the Food regulation website

Attachment A – Approved 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 – Explanatory Statement

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 the enzyme aminopeptidase Y (EC 3.4.11.15) from *Trichoderma reesei*, containing the gene for 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 approved a draft variation – the *Food Standards* (*Application A1328 – Aminopeptidase from* Trichoderma reesei *as a processing aid*) *Variation* (the approved draft 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 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.

The 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) 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.

This 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 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), 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 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary.

FSANZ called for submissions on the draft variation between 8 July and 19 August 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.

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

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 A1328 – Aminopeptidase from* 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 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:

- '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 is prescribed in column 2 of the table. The prescribed purpose is 'For use in protein processing, yeast processing and flavour production'.

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 the proposed amendment in **item [1]** is to 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.