**19 December 2022**
**[223-22]**

# Approval report – Application A1224

# Glucose oxidase from *Penicillium rubens* as a processing aid

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by Shin Nihon Chemical Co. Ltd to amend the Australia New Zealand Food Standards Code to permit the use of glucose oxidase from *Penicillium rubens* as a processing aid in the manufacture of certain foods.

On 2 August 2022, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received three submissions.

FSANZ approved the draft variation on 14 December 2022. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 19 December 2022.

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

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

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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

Shin Nihon Chemical Co. Ltd 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 glucose oxidase (EC 1.1.3.4), sourced from a non-genetically modified *Penicillium rubens* (*P. rubens*), as a processing aid in a range of foods. After assessing the application, FSANZ has prepared a draft food regulatory measure to permit that use in the manufacture of cooked products made from a dough (such as bread); pasta; noodles; and dried egg powder.

FSANZ undertook an assessment to determine whether the enzyme achieves the requested technological purpose in the quantity and form proposed to be used, and to evaluate public health and safety concerns associated with its use.

FSANZ concluded that the proposed use of the glucose oxidase enzyme is consistent with its typical function as an oxidising agent catalysing the breakdown of glucose to reduce glucose content. Analysis of the evidence provides adequate assurance that the use of the enzyme, in the form and requested amount (i.e. at a level not higher than necessary to achieve the desired enzyme reaction according to Good Manufacturing Practice (GMP)), is technologically justified and has been demonstrated to be effective in achieving the stated purpose.

Glucose oxidase performs its technological purpose during the production of the nominated foods and is not performing a technological purpose in the final food, therefore functioning as a processing aid for the purposes of the Code. Relevant identity and purity specifications for the enzyme are included in the Code.

No public health and safety concerns were identified in the assessment of glucose oxidase from *P. rubens* under the proposed conditions of use. A microbiological assessment concluded that *P. rubens* has a long history of safe use in food, is not pathogenic, and does not produce toxicologically significant amounts of mycotoxins. A toxicological assessment combined with a dietary exposure assessment concluded the enzyme is safe under the proposed conditions of use. In the absence of any identifiable hazard, an acceptable daily intake (ADI) ‘not specified’ is appropriate.

Following assessment and the preparation of a draft variation to the Code, FSANZ called for submissions regarding the draft variation from 2 August to 13 September 2022. FSANZ received three submissions which all supported the draft variation.

Based on the information above and on other relevant considerations set out in this report, FSANZ has approved a draft variation to the table to subsection S18—9(3) of the Code, to permit the use of the enzyme, glucose oxidase (EC 1.1.3.4) sourced from *P. rubens,* as a processing aid, during the manufacture of cooked products made from a dough (such as bread); pasta; noodles; and dried egg powder. This permission is subject to the condition that the maximum permitted level or amount of this enzyme that may be present in food must be consistent with GMP. The effect of the approved draft variation will be to permit the proposed use of this enzyme as a processing aid in accordance with the Code.

# 1 Introduction

## 1.1 The Applicant

Shin Nihon Chemical Co. Ltd, based in Japan, is a manufacturer of enzymes used in the food industry.

## 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 glucose oxidase (EC 1.1.3.4), sourced from a non-genetically modified (non-GM) *Penicillium rubens* (*P. rubens*) as a processing aid in the manufacture of a range of certain foods. However, following subsequent consultation with Food Standards Australia New Zealand (FSANZ), the applicant clarified that the outcome sought was the use of the enzyme as a processing aid in the manufacture of cooked products made from a dough (such as bread); pasta; noodles; and dried egg powder.

The applicant markets two powdered preparations containing this enzyme as the active component (at two different levels of enzyme activity), under the name 'Sumizyme PGO' in other countries where its use is permitted (see Section 2.5.3 of this report).

The applicant has indicated the enzyme is to be used in accordance with Good Manufacturing Practice (GMP) i.e. the minimum amount is used to achieve the technological purpose.

## 1.3 The current Standard

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

### 1.3.1 Permitted use

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

Paragraph 1.1.1—10(6)(c) provides that food for sale cannot contain, as an ingredient or component, a substance 'used as a processing aid' unless that substance's use as a processing aid is expressly permitted by the Code. Section 1.1.2—13 provides that a substance 'used as a processing aid' in relation to a food is a substance used during the course of processing that meets all of the following conditions:

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

Standard 1.3.3 and Schedule 18 of the Code list the permitted processing aids. Enzymes of microbial origin permitted to be used as processing aids are listed in the table to subsection S18—4(5) or in the table to subsection S18—9(3) of Schedule 18, depending on whether a technological purpose has been specified. Enzymes of microbial origin listed in the table to subsection S18—4(5) are permitted for use as a processing aid to perform any technological purpose if the enzyme is derived from the corresponding source specified in the table. The

table to subsection S18—9(3) lists those substances, including enzymes derived from 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.

The Code does not currently permit glucose oxidase derived from *P. rubens* to be used as a processing aid in the manner requested by the applicant. However, the Code does permit glucose oxidase obtained from other specific microbial origins to be used as a processing aid (*Aspergillus niger,* GM *Aspergillus oryzae* and *Trichoderma reesei* - see subsections S18—4(5) and S18—9(3)).

### 1.3.2 Identity and purity requirements

Paragraph 1.1.1—15(1)(b) 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.

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

### 1.3.4 International standards

In developing food regulatory measures, FSANZ must have regard to the promotion of consistency between domestic and international food standards. In terms of food safety, the relevant international standard setting body is the Codex Alimentarius Commission (Codex). In contrast to food additives, there is no Codex Alimentarius ‘general standard’ for enzymes, however as noted above, there are internationally recognised specifications for enzyme preparations established by JECFA and Food chemicals codex.

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.

## 1.4 Reasons for accepting Application

The application was accepted for assessment because:

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

## 1.5 Procedure for assessment

The Application was assessed under the General Procedure in the FSANZ Act.

## 1.6 Decision

For the reasons set out in this report, FSANZ decided to approve a draft variation amending the Code to permit the use of this enzyme as a processing aid in the manufacture of cooked products made from a dough (such as bread); pasta; noodles; and dried egg powder.

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

The related explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

# 2 Summary of the findings

## 2.1 Summary of issues raised in submissions

FSANZ sought public comments on the draft variation included in the call for submissions report between 2 August and 13 September 2022.

FSANZ received three submissions and had regard to all three submissions. Two were from government agencies (New Zealand Food Safety and The Victorian Departments of Health and Jobs, Precincts and Regions), and one was from the New Zealand Food and Grocery Council. All submitters supported the draft variation and raised no issues that needed to be considered and addressed.

## 2.2 Risk assessment

FSANZ assessed the public health and safety risks associated with glucose oxidase produced from *P. rubens* and its proposed use as a processing aid.

The proposed use of this glucose oxidase as a processing aid for use in the manufacture of cooked products made from a dough (such as bread); pasta; noodles; and dried egg powder, is technologically justified.

No public health and safety concerns were identified in the assessment of glucose oxidase from *P. rubens* under the proposed conditions of use. A microbiological assessment concluded that *P. rubens* has a long history of safe use in food, is not pathogenic, and does not produce toxicologically significant amounts of mycotoxins. A toxicological assessment combined with a dietary exposure assessment concluded the enzyme is safe under the proposed conditions of use.

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

For further details on the risk assessment, refer to the Supporting Document (SD) – Risk and Technical Assessment.

## 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.

The conclusions of the risk and technical assessment were that the use of this enzyme is technologically justified in the foods requested and there are no concerns when used for its stated purpose, at levels consistent with GMP.

FSANZ therefore considered it appropriate to prepare a draft variation amending the Code to permit the proposed use of this enzyme in the foods requested; and called for submissions on the draft variation.

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

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

### 2.3.1 Regulatory approval for enzymes

Glucose oxidase performs its technological purpose in the manufacture of cooked products made from a dough (such as bread); pasta; noodles; and dried egg powder and does not perform a technological purpose after the foods are produced. On that basis, the enzyme would function as a processing aid for the purposes of the Code, for the foods specified. Based on the food technology assessment, FSANZ concluded that the proposed use of this glucose oxidase enzyme is consistent with its typical function of catalysing the breakdown of β-D-glucose to D-glucono-1, 5-lactone in the presence of molecular oxygen, which, at the same time, converts oxygen to hydrogen peroxide. As stated above (Section 1.6), FSANZ has approved a draft variation to permit the use of the enzyme as a processing aid in the manufacture of the specified foods.

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

FSANZ notes that the International Union of Biochemistry and Molecular Biology (IUBMB) uses the accepted name ‘glucose oxidase’ (see section 2.1.1 of the SD). This is the name used in the approved draft variation and the name used in existing permissions for glucose oxidase in Schedule 18.

Nomenclature for the production organism (*P. rubens*), is in accordance with accepted international norms. As noted in section 3.1.1 of the SD, it is one of several strains of *Penicillium chrysogenum* which were recently re-categorised as belonging to the species *P. rubens.*

There are relevant identity and purity general specifications for enzyme preparations in two of the primary sources of specifications listed in Schedule 3 of the Code – namely the JECFA Combined Compendium of Food Additive Specifications, and the United States Pharmacopeial Convention Food chemicals codex (refer to Section 1.3.2 above). As noted in

section 2.2.2 of the SD, the enzyme will have to comply with those identity and purity specifications.

### 2.3.3 Labelling requirements

The generic exemption from listing processing aids in the statement of ingredients will apply to foods produced using this processing aid (see Section 1.3.3 above).

### 2.3.4 Risk management conclusion

The risk management conclusion is to permit the enzyme, glucose oxidase (EC 1.1.3.4) sourced from *P. rubens*, for use as a food processing aid, by amending the table to subsection S18—9(3) of the Code, which includes enzymes permitted for a specific technological purpose. The technological purpose of this enzyme will be use as a processing aid in the manufacture of cooked products made from a dough (such as bread); pasta; noodles; and dried egg powder. The maximum level at which the enzyme may be present in the food will be an amount consistent with GMP.

## 2.4 Risk communication

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

FSANZ developed and applied a standard communication strategy to this application. The call for submissions was notified via the Food Standards Notification Circular, media release, FSANZ's social media tools and Food Standards News.

The process by which FSANZ approaches standards development matters is open, accountable, consultative and transparent. Public submissions were called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application.

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

## 2.5 FSANZ Act assessment requirements

When assessing this application and the subsequent development of a food regulatory measure, FSANZ had regard to the following matters in section 29 of the FSANZ Act.

### 2.5.1 Section 29

#### *2.5.1.1 Consideration of costs and benefits*

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

FSANZ, however, gave consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed

measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

The purpose of this consideration was to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo. This analysis considered permitting the proposed use of glucose oxidase sourced from a non-GM *P. rubens* (the enzyme) as a processing aid.

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

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

*Costs and benefits of permitting the use of enzyme*

Due to the voluntary nature of the proposed permission, industry will use the enzyme, where businesses in the industry believe a net benefit exists for them.

The applicant advised that use of the enzyme has approval for various purposes in Japan, and glucose oxidase from various microbial sources (including *P. rubens*) has GRAS status for use in a variety of food categories in the US. Therefore, the approval of this enzyme in the Code may help some of Australia's and New Zealand's sales in international markets. There may, however, be more competing imports in the domestic market from countries that use this enzyme into the future.

There may also be some benefits to consumers in terms of better quality or cheaper products as a result of the use of this enzyme.

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

*Conclusions from cost benefit considerations*

FSANZ's assessment at the call for submissions stage was that the direct and indirect benefits that would arise from permitting the proposed use of the enzyme from this source most likely outweigh the associated costs. No further information was received during the consultation process that changed that assessment.

#### *2.5.1.2 Other measures*

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

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

The relevant standards 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 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 2.3.3 of this report.

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

There were no issues identified with this application relevant to this objective.

### 2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ used the best available scientific evidence to conduct the risk analysis. The applicant submitted a dossier of information and scientific literature as part of its application. This dossier, together with other technical and scientific information, was considered by FSANZ in assessing the application. The risk assessment is provided in the SD.

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

There are relevant international specifications for enzyme preparations, being the JECFA Compendium of Food Additive Specifications and the Food chemicals codex specifications for enzymes referred to in Section 1.3 of this report.

The applicant advised that glucose oxidase from *P. rubens* is approved for use as a processing aid in Japan and has GRAS status (with a no questions response) in the USA.[2]

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

As mentioned above, the applicant advised that use of glucose oxidase from *P. rubens* is currently approved for use as a processing aid in Japan, and has GRAS status in the USA.

[2] No questions response means the FDA does not question the basis for the notifier's GRAS conclusion (About the GRAS Notification Program).

Therefore, approval for use would bring Australia and New Zealand into line with other jurisdictions where it is already authorised for use. In this way, Australia and New Zealand would remain competitive with other international markets. This would also help foster continued innovation and improvements in food manufacturing techniques and processes.

The conclusion of the risk assessment is 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 have access to this alternative enzyme for the various applications proposed by the applicant.

Ultimately, the domestic food industry will make their own economic decisions, taking into account the costs and benefits of using the new enzyme, to determine if it is of benefit to their particular business.

- **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*[3] 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 has 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.

## Attachments

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

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

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

**Food Standards (Application A1224 – Glucose oxidase from *Penicillium rubens* 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 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 A1224 – Glucose oxidase from* Penicillium rubens *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:

| | | |
|---|---|---|
| Glucose oxidase (EC 1.1.3.4) sourced from *Penicillium rubens* | For use in the manufacture of:<br>(a) cooked products made from a dough including bread;<br>(b) pasta;<br>(c) noodles; and<br>(d) dried egg powder. | GMP |

# Attachment B – Explanatory Statement

## 1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

The Authority accepted Application A1224 which sought to amend the Code to permit the enzyme, glucose oxidase (EC 1.1.3.4) from a non-genetically modified *Penicillium rubens*, to be used as a processing aid in the manufacture of a range of specified foods. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation to permit the enzyme's use as a processing aid in the manufacture of: cooked products made from a dough (such as bread); pasta; noodles; and dried egg powder.

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

## 2. Variation will be a legislative instrument

The approved draft variation is a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and is publicly available on the Federal Register of Legislation (www.legislation.gov.au).

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) in Schedule 18 of the Code to permit the use of the enzyme, glucose oxidase (EC 1.1.3.4) sourced from *P. rubens*, as a processing aid for use in the manufacture of: cooked products made from a dough (such as bread); pasta; noodles; and dried egg powder. 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 will prescribe identity and purity specifications for the processing aid to be permitted by the approved draft variation. Section 1.1.1—15 of the Code requires substances used as processing aids to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code. Section S3—2 of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications (FAO JECFA Monographs 23 (2019)) and the United States Pharmacopeial Convention (2020) Food chemicals codex (12th edition). These include general specifications for the identity and purity 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 A1224 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. Submissions were called for on 2 August 2022 for a six-week consultation period.

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

## 6. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

## 7. Variation

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

- glucose oxidase (EC 1.1.3.4) sourced from *Penicillium rubens*

The technological purpose for this enzyme prescribed in column 2 of the table is use as a processing aid in the manufacture of: cooked products made from a dough (such as bread); pasta; noodles; and dried egg powder. Specifically, the enzyme reduces residual glucose and/or facilitates cross linking of proteins during the production of those foods.

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 variation is to permit the proposed use of the enzyme, glucose oxidase (EC 1.1.3.4) sourced from *Penicillium rubens,* as a processing aid in accordance with the Code.