

10 March 2020
[117-20]

Approval report – Application A1182

Glucose Oxidase from GM *Trichoderma reesei* as a Processing Aid (Enzyme)

Food Standards Australia New Zealand (FSANZ) has assessed an application made by AB Enzymes GmbH to permit a glucose oxidase enzyme preparation from a particular genetically modified (GM) *Trichoderma reesei* for use as a processing aid in cereal-based products (baking) and egg processing.

On 21 November 2019, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received three submissions.

FSANZ approved the draft variation on 4 March 2020. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 6 March 2020.

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 documents](#) which informed the assessment of this application are available on the FSANZ website:

SD1 Risk and technical assessment report

Executive summary

AB Enzymes GmbH submitted an application to Food Standards Australia New Zealand (FSANZ) for a new microbial source of the already permitted enzyme processing aid, glucose oxidase (EC 1.1.3.4) for use as a processing aid in the manufacture of cereal-based products (baking) (such as bread, croissants, pasta and noodles), and in egg processing. The enzyme is derived from a genetically modified (GM) strain of *Trichoderma reesei* expressing the glucose oxidase gene from *Penicillium amagasakiense*.

Enzymes used to produce and manufacture food are considered processing aids and are regulated by Schedule 18 of the Australia New Zealand Food Standards Code (the Code). If approved for use, this enzyme would be listed in the table to subsection S18—9(3), which lists enzymes permitted for use for a specific technological purpose.

After undertaking a risk assessment, FSANZ concludes that there are no public health and safety concerns associated with using this new source of glucose oxidase. This GM strain of *T. reesei* is neither pathogenic nor toxigenic and in the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) of 'not specified' is appropriate. A dietary exposure assessment was therefore not required.

The enzyme preparation contains wheat protein and may contain traces of milk protein (casein) in the lactose from the culture medium used to grow the production organism, however, labelling requirements exist to inform wheat or milk-allergic individuals.

The evidence presented to support the proposed use of the enzyme provides adequate assurance that the enzyme, in the form and prescribed amounts, is technologically justified and has been demonstrated to be effective in achieving its stated purpose. The enzyme meets international purity specifications.

FSANZ proposes a draft variation to the Code to permit glucose oxidase derived from this particular GM strain of *T. reesei* to be used as a processing aid in the manufacture of bakery and other cereal-based products, and in egg processing. This is subject to the condition that the amount of enzyme used must be consistent with good manufacturing practice (GMP).

1 Introduction

1.1 The applicant

The applicant is AB Enzymes GmbH, an industrial biotech company that develops and produces food enzymes.

1.2 The application

FSANZ received an application seeking permission for an already permitted enzyme, glucose oxidase (EC 1.1.3.4) from a new source, as a processing aid. The enzyme is produced from a genetically modified (GM) strain of *Trichoderma reesei* containing the glucose oxidase gene from *Penicillium amagasakiense*.

If approved, this particular glucose oxidase will be used as a processing aid in the manufacture of bakery and other cereal-based products such as pasta and noodles, and in egg processing. Glucose oxidase will be used as a processing aid at low levels and is either not present in the final food or present in insignificant quantities, having no technological function in the final food.

1.3 The current Standards

Australian and New Zealand food laws require food for sale to comply with the following requirements of the Code.

Permitted use

Enzymes used to process and manufacture food are considered processing aids. Although they may be present in the final food, they do not provide a technological purpose in the final food.

Paragraph 1.1.1—10(6)(c) of the Code 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 that meets all of the following conditions: it is used during the course of processing 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 (Good Manufacturing Practice).

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. Enzymes of microbial origin listed in the table to subsection S18—4(5) are permitted for use as 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 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; and
- present in the food at a level not greater than the maximum permitted level specified

in the table.

There are currently permissions for glucose oxidase (EC 1.1.3.4) from both a GM and a non-GM *Aspergillus niger* within the table to subsection S18—4(5), to be used in the manufacture of all foods. However, glucose oxidase from this particular microbial source, is not currently permitted.

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) of Standard 1.5.2 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).

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/WHO 2017), and the United States Pharmacopeial Convention (USPC 2018) Food chemicals codex (11th edition). These include specifications for enzyme preparations used in food processing.

Labelling requirements

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

Subsection 1.2.3—4(1) requires certain foods and substances to be declared when present in a food for sale. Paragraph 1.2.3—4(2)(c) states the food or substance may be present as a substance or food used as a processing aid, or an ingredient or component of such a substance or 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 prevail.

Section 1.5.2—4 requires processing aids that are foods produced using gene technology to be labelled 'genetically modified', where novel DNA and/or novel protein from the processing aid remains present in the final food. The requirement applies to foods for sale that consist of or have as an ingredient, food that is a genetically modified food. The requirements imposed by section 1.5.2—4 generally apply to foods for retail sale and to foods sold to a caterer under subsection 1.2.1—8(1) and section 1.2.1—15 respectively.

1.3.1 International standards

AB Enzyme's glucose oxidase preparation is permitted for use in France, Denmark, Mexico and Canada, as well as the USA where the enzyme has been determined as Generally Recognized as Safe (GRAS).

The Codex Alimentarius does not establish standards for processing aids or enzymes. Individual countries regulate the use of enzymes differently to the Code. However, there are internationally recognised specifications for enzymes. These enzyme specifications are established by JECFA and the Food Chemicals Codex as noted above.

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 FSANZ Act
- 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.

1.6 Decision

The draft variation as proposed following assessment was approved without change. The variation takes effect on gazettal. The approved variation after consideration of submissions, 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 submissions

FSANZ called for submissions on a proposed draft variation on 21 November 2019. Three submissions were received from The Victorian Departments of Health and Human Services and Jobs, Precincts and Regions, the New Zealand Grocery Council, and New Zealand Food Safety. All three submissions were supportive of the proposed draft variation, with no issues being raised.

Table 1: Summary of submissions

Submitter	Comments
Victorian Department of Health and Human Services and the Victorian Department of Jobs, Precincts and Regions	Supportive
New Zealand Grocery Council	Supportive
New Zealand Food Safety	Supportive

2.2 Risk assessment

FSANZ concluded that there are no public health and safety concerns associated with the use of glucose oxidase from this particular GM *T. reesei*. The gene for glucose oxidase was chemically synthesised based on the gene sequence from *P. amagasakiense*, an anamorphic fungus commonly found in soil.

The production organism *T. reesei* is neither toxigenic nor pathogenic and is absent in the final enzyme preparation proposed to be used as a food processing aid. Further, *T. reesei* has a long history of safe use as the production organism for a number of enzyme processing aids that are already permitted in the Code. Molecular characterisation of the production strain confirmed the presence of the inserted DNA and showed that the introduced DNA is stably inherited.

Glucose oxidase from genetically modified *T. reesei* was not genotoxic *in vitro*, and did not cause adverse effects in short-term toxicity studies in rats. The no observed adverse effect level (NOAEL) in a 90-day repeated dose oral toxicity study in rats was the highest dose tested, 1000 mg/kg bw/day or 915 mg/kg bw/day on a total organic solids (TOS) basis. The applicant's estimated theoretical maximal daily intake (TMDI) based on the proposed uses is 0.088 mg/kg bw/day TOS. A comparison of these values indicates that the Margin of Exposure between the NOAEL and TMDI is more than 10,000.

Bioinformatic analysis indicated that the enzyme has no significant homology with any known toxins or food allergens, and is unlikely to pose an allergenicity or toxicity concern. Lactose is used in the fermentation medium which may contain traces of milk protein, however analysis of three batches of the dried enzyme concentrate indicated that lactose and casein levels were below the limit of detection (100 mg/kg and 0.25 mg/kg, respectively). Wheat flour is also an ingredient in the enzyme preparation. As wheat and milk are major food allergens, labelling risk management requirements already exist to inform wheat-allergic and milk-allergic individuals.

Based on the reviewed toxicological data it is concluded that, in the absence of any identifiable hazard, an acceptable daily intake (ADI) 'not specified' is appropriate. A dietary exposure assessment was therefore not required.

The food technology assessment concluded that glucose oxidase, in the form and prescribed amounts, is technologically justified and has been demonstrated to be effective in achieving its stated purpose. It performs its technological purpose during manufacture and processing of the specified foods, and is therefore appropriately categorised as a processing aid. Glucose oxidase needs to meet international purity specifications, or those set out in the Code, to be sold in Australia and New Zealand.

For further details on the risk assessment, refer to the Risk and Technical Assessment Report (SD1).

2.3 Risk management

The risk assessment concluded that there are no safety concerns relating to AB Enzyme's glucose oxidase as a food processing aid. As processing aids require permissions in the Code, the main risk management option available to FSANZ is to approve or reject the request to amend the Code and, if approved, to impose any conditions that may be appropriate. Other risk management issues for this application are related to enzyme nomenclature and labelling, which are discussed below. The regulatory options analysed in

section 2.5.1.1 take account of the safety of the enzyme.

If permitted, this enzyme preparation will provide the food industry with an alternative source of glucose oxidase.

2.3.1 Regulatory approval for enzymes

FSANZ has concluded that the glucose oxidase enzyme concerned meets its stated purpose as a processing aid in the manufacture of bakery and other cereal-based products, and in egg processing. The risk assessment has further concluded that in the absence of any identifiable hazard, an ADI of 'not specified' is appropriate for the enzyme. The enzyme preparation does contain wheat and may contain milk (casein present in the fermentation ingredient lactose), however labelling requirements are in place to inform consumers who are sensitive to these allergens.

Therefore, FSANZ prepared a draft variation to permit the use of the glucose oxidase enzyme concerned as a processing aid for its stated purpose.

The express permission for the enzyme to be used as a processing aid will also provide the permission for the enzyme's potential presence in the food for sale as a food produced using gene technology. The enzyme is a food produced using gene technology for Code purposes as it is derived from 'an organism that has been modified using gene technology' (see subsection 1.1.2—2(3) of the Code).

2.3.2 Enzyme and source microorganism nomenclature

FSANZ noted that the International Union of Biochemistry and Molecular Biology (IUBMB), the internationally recognised authority for enzyme nomenclature, uses the accepted name "glucose oxidase" for the enzyme with an EC number of EC 1.1.3.4 (IUBMB 2018). Glucose oxidase is already listed in the table to subsection S18—4(5) and will remain as such if approved and subsequently listed in the table to subsection in S18—9(3).

The nomenclature of the host and gene donor microorganism, *P. amagasakiense* was confirmed as being appropriate as listed in the application (see section 3.2 of SD1). The host organism, *T. reesei* is a commonly listed microorganism within Schedule 18.

2.3.3 Labelling requirements

The risk assessment concluded that the use of the glucose oxidase enzyme concerned poses no public health and safety concerns and that it performs its technological purpose as a processing aid. In approving a variation to permit the use of the enzyme as a processing aid, the generic exemption from listing processing aids in the statement of ingredients will apply to foods containing this processing aid. However, Standard 1.2.3 requirements will nevertheless apply to wheat as a component of the enzyme preparation, and any traces of milk (casein from the fermentation ingredient lactose), which may be carried over into the enzyme preparation (see section 2.2.3.2).

2.3.3.1 Labelling requirements for food produced using gene technology

The requirements to label food as 'genetically modified' differ depending on whether the GM food is an ingredient of the food for sale or not, as follows.

For example: if a food is for retail sale or sold to a caterer, and contains the enzyme glucose oxidase sourced from the GM strain of *T. reesei* (for example, the enzyme is used in the manufacture of pasta), that food would be required to be labelled 'genetically modified' in

conjunction with the name of the GM food, if novel DNA or novel protein from the GM strain of *T. reesei* remains in that food for sale (see paragraph 1.5.2—4(1)(b)).

However, FSANZ notes if the pasta made using the enzyme is not a food for sale itself (for example, an ingredient in a mixed food such as a pasta and sauce ready meal), the enzyme would not be an ingredient in the food for sale. Therefore, the requirement to label glucose oxidase as 'genetically modified' would not apply to the pasta and sauce ready meal because the labelling requirements only apply to food that consists of, or has as an ingredient, a GM food (section 1.5.2—4(1)).

2.3.3.2 Declaration of certain substances

The risk assessment (section 2.1) has identified the glucose oxidase enzyme preparation concerned contains wheat. Given the purity of the lactose fermentation ingredient and manufacturing process of glucose oxidase, it is highly unlikely that milk protein will be present in the final enzyme ingredient. However, when wheat or milk is present, including when present as a processing aid or an ingredient or component of a processing aid, it must be declared. If the food is not required to bear a label, the allergen information must be displayed in connection with the display of the food or provided to the purchaser on request (subsection 1.2.1—9(6) of Standard 1.2.1).

FSANZ notes the glucose oxidase enzyme concerned will be used to manufacture bakery and other cereal-based products, and in egg processing. Bakery and other cereal-based products that contain wheat as an ingredient will already require a mandatory wheat declaration. However, a wheat declaration will still be required if glucose oxidase enzyme is used in the manufacture of wheat-free bakery and other cereal-based products.

2.3.4 Risk management conclusion

The risk management conclusion is to permit the enzyme, glucose oxidase (EC 1.1.3.4) sourced from *T. reesei* containing the glucose oxidase gene from *P. amagasakiense*, for use as a food processing aid. The permission will be listed in the table to subsection S18—9(3) of the Code, which includes enzymes permitted for specific technological purpose. The technological purpose of this enzyme is use as a processing aid in the manufacture of bakery and other cereal-based products, and in egg processing. The maximum level at which the enzyme may be present in the food is an amount consistent with GMP. Labelling requirements exist to inform wheat-allergic and milk-allergic individuals about the presence of wheat and milk (respectively) in the final enzyme preparation. The express permission for the enzyme to be used as a processing aid in Schedule 18 will also provide the permission for the enzyme's potential presence in the food for sale as a food produced using gene technology.

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a basic communication strategy to this application. All calls for submissions are notified via the Food Standards Notification Circular, media release, FSANZ's social media tools and Food Standards News.

The process by which FSANZ considers standard development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views

of interested parties on issues raised by the application and the impacts of regulatory options.

The draft variation will be considered for approval by the FSANZ Board taking into account public comments received from this call for submissions.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application. Every submission on the application was considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

2.4.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are not any relevant international standards and amending the Code to permit a new microbial source of a currently permitted enzyme is unlikely to have a significant effect on international trade as Codex Alimentarius does not have regulations for enzymes used as processing aids. 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

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 permitting new processing aids (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as the use of the new enzyme process aid is voluntary once the application has been approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

FSANZ, however, has given 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 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 (i.e. rejecting the application). This analysis considers permitting the use of glucose oxidase derived from a GM strain of *T. reesei*, as a processing aid into the table to subsection S18—9(3), which includes enzymes permitted for a specific technological purpose. FSANZ is of the view that no other realistic food regulatory measures exist, however information received during public consultation may result in FSANZ arriving at a different outcome.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of

the effects that were 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 the enzyme.

Costs and benefits of permitting the use of enzyme glucose oxidase derived from a GM strain of T. reesei as a processing aid in the manufacture of bakery and other cereal-based-products, and in egg processing

Industry

The glucose oxidase enzyme concerned facilitates the manufacture of bakery and other cereal-based-products, and is used in egg processing. Due to the voluntary nature of the permission, industry will use the glucose oxidase enzyme concerned where they believe a net benefit exists. There are other enzymes available to industry that perform similar functions and it is of benefit to industry to have additional choice available to them, especially where the enzyme is more effective or cheaper.

AB Enzyme's enzyme preparation is permitted for use in France, Denmark, Mexico, Canada, and the USA. The international permissions for this enzyme may be a business opportunity for Australian and New Zealand industries, although there may also be competing imports from these countries into the domestic market.

Consumers

Industry may pass some of the possible cost savings from using the glucose oxidase enzyme concerned onto consumers. Consumers may also benefit from better and/or more consistent product quality.

Government

Permitting the glucose oxidase enzyme concerned 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 is that the direct and indirect benefits that would arise from permitting the use of the enzyme glucose oxidase derived from a GM strain of *T. reesei* as a processing aid for the proposed technological purpose most likely outweigh the associated costs.

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

Schedule 18 applies in both Australia and New Zealand. There are no other relevant New Zealand only standards.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2. Subsection 18(1)

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

during the assessment.

2.5.2.1 Protection of public health and safety

FSANZ has undertaken a safety assessment (SD1) and concluded there are no public health and safety concerns with permitting the use of glucose oxidase sourced from a GM *T. reesei*, as a processing aid in food for the proposed technological purpose.

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

The labelling considerations for glucose oxidase are discussed in Section 2.2.3 above.

2.5.2.3 The prevention of misleading or deceptive conduct

There are 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 has used the best available scientific evidence to conduct the risk analysis, which is provided in SD1. The applicant submitted a dossier of scientific studies as part of the application. This dossier, together with other technical information including scientific literature, was used in assessing the application.

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

The glucose oxidase enzyme concerned is permitted in the USA France, Denmark, Mexico and Canada. It also meets international specifications for enzyme preparations, being the JECFA Compendium of Food Additive Specifications and the Food Chemicals Codex specifications for enzymes.

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

As mentioned above, the use of the glucose oxidase enzyme concerned is already permitted in the United States France, Denmark, Mexico and Canada.

Approval for use of this enzyme would bring Australia and New Zealand into line with other jurisdictions where it is already authorised for use.

Consequently, Australia and New Zealand will remain competitive with other international markets as Australian and New Zealand food industries will have the opportunity to benefit from the use of this enzyme as an alternative to those currently permitted. Which enzyme preparation a food manufacturing company uses will depend on a number of economic and other factors.

This will also help foster continued innovation and improvements in food manufacturing techniques and processes.

- **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 Forum on Food Regulation**

The Ministerial Policy Guideline Addition to Food of Substances other than Vitamins and Minerals¹ 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 use of glucose oxidase sourced from *T. reesei* as a processing aid is consistent with the specific order principles for 'Technological Function'.

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.

4 References

FAO/WHO 2017 [General specifications and considerations for enzyme preparations used in food processing](#). Accessed 22 November 2019

IUBMB 2018. [EC 1.1.3.4](#) Accessed 22 November 2019

USPC 2018 [Food Chemicals Codex 11th Edition](#), United States Pharmacopeial Convention, Rockville, MD. Accessed 22 November 2019

Attachments

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

¹ [Food regulation website](#)

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



Food Standards (Application A1182 – Glucose Oxidase from a GM *Trichoderma reesei* as a Processing Aid (enzyme)) Variation

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

Dated [To be completed by Delegate]

[Insert Delegate's name and 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 A1182 – Glucose Oxidase from a GM Trichoderma reesei as a Processing Aid (Enzyme)) 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

[1] Schedule 18 is varied by inserting in the table to subsection S18—9(3), in alphabetical order

Glucose oxidase (EC 1.1.3.4)
sourced from *Trichoderma reesei*
containing the glucose oxidase
gene from *Penicillium*
amagasakiense

For use in:

- a. the manufacture of bakery and other cereal-based products; and
- b. egg processing.

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 A1182 which seeks to permit the use of glucose oxidase enzyme preparation from a particular GM *T. reesei* as a processing aid for use in the manufacture and processing of specified foods. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft Standard.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislation Act 2003*.

2. Purpose

The Authority has approved a draft variation to permit the use of glucose oxidase enzyme preparation from a particular GM *T. reesei* as a processing aid. The permission will be listed in the table to subsection S18—9(3), which includes enzymes permitted for a specific technological purpose. The technological purpose in this case is for use in the manufacture of bakery and other cereal-based products such as pasta and noodles, and for use in egg processing. The level of usage is an amount consistent with GMP. This permission requires varying the table to subsection S18—9(3) in Schedule 18.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

Existing provisions of the Code incorporate a document by reference that will 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. Section S3—2 of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives Compendium of Food Additive Specifications (FAO/WHO 2017) and the United States Pharmacopeial Convention (USPC 2018) Food Chemicals Codex (11th edition). These include specifications for enzyme preparations used in food processing.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of application A1182 included one round of public consultation following an assessment and the preparation of a draft Standard and associated assessment summary. Submissions were called for on 21 November 2019 for a six-week consultation period.

The Office of Best Practice Regulation (OBPR) granted the Authority a standing exemption from needing to develop a Regulatory Impact Statement for proposed variations of the Code to permit additional processing aids (OBPR correspondence dated 24 November 2010 - reference 12065). This standing exemption was provided as permitting additional processing aids is likely to have only a minor impact on business and individuals. It is a minor, deregulatory change that allows for the introduction of a food product to the food supply that has been determined to be safe. The use of the approved processing aid is also voluntary.

5. 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 94 of the FSANZ Act.

6. Variation

The variation inserts a new entry, in alphabetical order, into the table to subsection S18—9(3) in Schedule 18.

The new entry would permit the use of the enzyme, glucose oxidase (EC 1.1.3.4) sourced from a particular GM *T. reesei* (*T. reesei* containing the glucose oxidase gene from *P. amagasakiense*), as a processing aid in food for a specific technological purpose.

The technological purpose is for use as a processing aid in the manufacture of bakery and other cereal-based products, and in egg processing.

The permission is subject to the condition that the maximum permitted level or amount of this enzyme that may be present in the food must be consistent with good manufacturing practice.