

14 October 2022

217-22

Call for submissions – Application A1255

Alpha-amylase from GM *Bacillus subtilis* as a processing aid

FSANZ has assessed an application made by AB Enzymes GmbH to permit the use of the enzyme alpha-amylase (EC 3.2.1.1) as a processing aid in the manufacture of bakery products such as bread, steamed bread, bread buns, tortillas, cakes, pancakes, and waffles. FSANZ has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [current calls for public comment and how to make a submission](#).

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published as soon as possible after the end of the submission period.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

For information on how FSANZ manages personal information when you make a submission, see FSANZ's [Privacy Policy](#).

Submissions should be made in writing; be marked clearly with the word 'Submission'. You also need to include the correct application or proposal number and name. Electronic submissions can be made by emailing your submission to submissions@foodstandards.gov.au. FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 25 November 2022

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making a submission or application and proposal processes can be sent to standards.management@foodstandards.gov.au.

Submissions in hard copy may be sent to the following addresses:

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Supporting document

The [following document](#) which informed the assessment of this Application is available on the FSANZ website:

SD1 Risk and technical assessment report

Executive summary

The application seeks to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of the enzyme alpha-amylase (EC 3.2.1.1) as a processing aid in the manufacture of bakery products such as bread, steamed bread, bread buns, tortillas, cakes, pancakes, and waffles. This alpha-amylase is produced from a genetically-modified (GM) strain of *Bacillus subtilis*, containing the alpha-amylase gene from *Thermoactinomyces vulgaris*. Alpha-amylases from other sources are permitted in the Code.

Alpha-amylase breaks down starch polysaccharides to produce large amounts of shorter oligosaccharides such as dextrins. Dextrins are fermented by yeast, and increased dextrin fermentation improves the volume and texture of the bakery products. The addition of alpha-amylase during manufacture can also reduce the rate of staling of bakery products.

B. subtilis is neither toxigenic nor pathogenic and has a long history of safe use as a source of enzyme processing aids, including several already permitted in the Code. Analysis of the production strain confirmed the presence and stability of the inserted DNA.

FSANZ has completed a risk assessment and concludes there are no public health and safety concerns associated with the proposed use of this alpha-amylase enzyme. In the absence of any identifiable hazard, an acceptable daily intake (ADI) of 'not specified' is appropriate.

The application clearly states the technological purpose of the enzyme. It contains adequate evidence that the proposed use of the enzyme in the recommended form and quantity is technologically justified and has been demonstrated to be effective in achieving its stated purpose. The enzyme meets international purity specifications.

FSANZ has therefore prepared a draft variation to the Code, which if approved, would list the enzyme alpha-amylase derived from a GM strain of *B. subtilis*, containing the alpha-amylase gene from *T. vulgaris*, in the table to subsection S18—9(3) as a permitted processing aid for use in the manufacture of bakery products. This permission would be subject to the condition that the maximum permitted level or amount of the enzyme that may be present in the food must be consistent with Good Manufacturing Practice.

FSANZ now seeks submissions to assist consideration of the draft variation to the Code.

1 Introduction

1.1 The applicant

The applicant is AB Enzymes GmbH (AB Enzymes), an industrial biotech company that develops enzyme products for food, animal feed and technical applications.

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 alpha-amylase (EC 3.2.1.1) as a processing aid in the manufacture of bakery products such as bread, steamed bread, bread buns, tortillas, cakes, pancakes, and waffles. This alpha-amylase is produced from a genetically modified (GM) strain of *Bacillus subtilis*, containing the alpha-amylase gene from *Thermoactinomyces vulgaris*.

The applicant markets a powdered preparation containing this enzyme as the active component, under the name VERON® 1000, in other countries where its use is permitted (see Section 2.4.3 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 processing that meets all the following conditions:

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

Paragraph 1.1.1—10(6)(g) requires that the presence as an ingredient or component in a food for sale of a food produced using gene technology must be expressly permitted by the Code. Paragraph 1.5.2—3(b) provides that permission in the Code for use as a processing aid also constitutes the permission required by paragraph 1.1.1—10(6)(g).

Alpha-amylase is already permitted to be used as a processing aid by the Code including from plant sources (malted cereals (subsection S18—4(4)), and from various microbial origins including *B. subtilis* (subsections S18—4(5) and S18—9(3)), however not from *B. subtilis* carrying the alpha-amylase gene from *T. vulgaris* as requested by the applicant.

1.3.2 Identity and purity requirements

Paragraph 1.1.1—15(1)(b) of the Code requires substances used as processing aids in food to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code.

Subsection S3—2(1) 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 (USPC 2020) Food Chemicals Codex (12th edition). These include specifications for enzyme preparations used 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.

Subsection 1.2.3—4(1) requires certain foods or their derivatives (as listed in the table to section S9—3 of Schedule 9) to be declared when present in a food for sale (unless they are exempt under subsection 1.2.3—4(4)). Paragraph 1.2.3—4(5)(c) states the food may be present as a substance used as a processing aid, or an ingredient or component of such a substance. Where the food to be declared is a substance used as a processing aid or an ingredient or component of such a substance, subsection 1.2.3—6(2) requires a declaration for the purposes of paragraph 1.2.1—8(1)(d) or subparagraph 1.2.4—5(6)(b)(i) to be made by (among other things) listing in the statement of ingredients of the food for sale the required name¹ of the food to be declared and the words ‘processing aid’ in conjunction with that required name¹. 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 (subsections 1.2.1—9(6) and (7)).

Section 1.5.2—4 requires processing aids that are, or have as ingredients, foods produced using gene technology to be labelled ‘genetically modified’ in conjunction with the name of that food, 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*¹ (GM food). The requirements imposed by section 1.5.2—4 apply only to foods for sale prescribed by Divisions 2 to 4 of Standard 1.2.1.

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.

The applicant advised that the enzyme is approved for use as a processing aid in Denmark and France.

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 might be developed as a food regulatory measure.

1.5 Procedure for assessment

The Application is being assessed under the General Procedure in the FSANZ Act.

2 Summary of the assessment

2.1 Risk assessment

FSANZ has assessed the public health and safety risks associated with alpha-amylase produced by GM *B. subtilis* AR-651, containing the alpha amylase gene from *T. vulgaris* (see SD1). The proposed use of the enzyme is as a processing aid in the manufacture of bakery products such as bread, steamed bread, bread buns, tortillas, cakes, pancakes, and waffles.

No public health and safety concerns were identified in the assessment of alpha-amylase produced by GM *B. subtilis* AR-651, under the proposed conditions of use. A microbiological assessment concluded that the GM host strain is neither pathogenic nor toxigenic, and a biotechnology assessment confirmed the genetic modification is as described and that the inserted gene has been stably introduced.

¹ Section 1.5.2—4(5) defines **genetically modified food** to mean a “food produced using gene technology that

- a) contains novel DNA or novel protein; or
- b) is listed in Section S26—3 as subject to the condition that its labelling must comply with this section’ (*that being section 1.5.2—4*).

A toxicological assessment combined with a dietary exposure assessment concluded the enzyme is safe under the proposed conditions of use. Bioinformatics analysis confirmed that the produced enzyme has no significant similarity with known toxins or food allergens.

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

2.2 Risk management

The risk management options available to FSANZ after assessment, were to either:

- reject the application, or
- prepare a draft variation of the Code.

For the reasons listed in this report, FSANZ decided to prepare a draft variation to the Code permitting the use of alpha-amylase produced using a GM strain of *B. subtilis*, containing the alpha-amylase gene from *T. vulgaris*, as a processing aid in the manufacture of bakery products. If approved, this permission would be subject to the condition that the maximum permitted level or amount of enzyme used in the food must be consistent with GMP.

The conclusions from the risk and technical assessment were that the proposed use of the enzyme is technologically justified and there were no safety concerns associated with its proposed use.

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

2.2.1 Regulatory approval for enzymes

As stated above, FSANZ has prepared a draft variation to permit the use of the enzyme 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 its 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.

2.2.2 Enzyme and source microorganism nomenclature

The International Union of Biochemistry and Molecular Biology (IUBMB) uses the accepted name 'α-amylase'. This is the name used in the proposed draft variation and the name used in existing permissions for alpha-amylase in Schedule 18. The word 'alpha' has been used in this report and was used by the applicant in the application, instead of its symbol.

The nomenclature of the gene donor and production microorganisms were assessed and confirmed as being appropriate as listed in the application. The host organism *B. subtilis* is a commonly listed microorganism within Schedule 18 of the Code.

² Food produced using gene technology' is defined in subsection 1.1.2—2(3) as meaning 'a food which has been derived or developed from an organism which has been modified by gene technology'.

2.2.3 Labelling

Subject to subsections 2.2.3.1 and 2.3.3.2 below, the generic exemption from listing processing aids in the statement of ingredients would apply to foods manufactured using this enzyme processing aid (see Section 1.3.3 above).

2.2.3.1 Declaration of certain foods

Sections 2.2.1 and 3.3.5 of SD1 state that wheat flour is used in the enzyme preparation. If wheat is present in a food for sale, including when present as a processing aid or an ingredient or component of a processing aid, it must be declared unless an exemption applies (Division 3 of Standard 1.2.3).

As noted in Section 1.2 of this report, alpha-amylase produced from a GM strain of *Bacillus subtilis* will be used to manufacture bakery products. Bakery products made with wheat-derived ingredients (e.g. wheat flour, wheat bran) are already required to declare 'wheat' and 'gluten' declarations in accordance with requirements in Division 3 of Standard 1.2.3. Wheat-free bakery products that are manufactured using alpha-amylase produced from a GM strain of *Bacillus subtilis* will also be subject to 'wheat' and 'gluten' declarations if wheat and gluten from the enzyme remain in the food for sale.

2.2.3.2 Labelling requirements for food produced using gene technology

Section 1.5.2—4 of the Code generally requires a food for sale that consists of a GM food or has a GM food as an ingredient to be labelled as 'genetically modified', unless one of the exemptions listed in that subsection apply. If the GM food is present in the food for sale as an ingredient due to its use as a processing aid, the 'genetically modified' statement must be used in conjunction with the name of the GM food (subsection 1.5.2—4(2)) and it may be included in the statement of ingredients for the food for sale (subsection 1.5.2—4(3)).

2.2.4 Risk management conclusion

The risk management conclusion is to permit the enzyme alpha-amylase (EC 3.2.1.1) sourced from *B. subtilis*, containing the alpha-amylase gene from *T. vulgaris*, for use as a food processing aid. If approved, the permission would be listed in 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 would be as a processing aid in the manufacture of bakery products. The maximum permitted level or amount of the enzyme that may be present in the food would have to be consistent with GMP. The express permission for the enzyme to be used as a processing aid in Schedule 18 of the Code would also provide the permission for the enzyme's potential presence in the food for sale as a food produced using gene technology.

Mandatory declarations for wheat and gluten would apply when present in a food for sale.

2.3 Risk communication

2.3.1 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, 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 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 all public comments received from this call for submissions.

2.3.2 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.

As noted Section 1.3.4 above, the relevant international standard setting body is the Codex Alimentarius Commission (Codex). As noted, there is no Codex Alimentarius 'general standard' for processing aids, however there are JECFA and Food Chemicals Codex general specifications, and a Codex guideline on processing aids. In addition, under JECFA, enzyme preparations must meet the specifications criteria contained in the individual specification monographs. In the case of this particular alpha-amylase, there is no specific monograph.

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.

2.4 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:

2.4.1 Section 29

2.4.1.1 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 processing aids and GM food (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting new GM foods and 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.

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 proposed use of alpha-amylase (EC 3.2.1.1) derived from a GM strain of *B. subtilis* as a processing aid in the manufacture of bakery products such as bread, steamed bread, bread buns, tortillas, cakes, pancakes, and waffles.

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 proposed use of the enzyme.

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

Costs and benefits of permitting the use of enzyme alpha-amylase (EC 3.2.1.1) sourced from a GM strain of B. subtilis as a processing aid (the new enzyme source)

Using the enzyme alpha-amylase sourced from a GM strain of *B. subtilis* may benefit industry by having additional choice of inputs to their manufacturing process especially if it proves cheaper, is more effective than what is presently available, resulting in higher profits or better-quality products. Due to the voluntary nature of the permission, manufacturers would only use it where they believe a net benefit exists for them. Part of savings to the manufacturing industry may be passed on to consumers. As a result of its use consumers may conceivably also have access to higher quality or cheaper products.

Permitting the enzyme to be used as a processing aid may result in a small cost to government in terms of adding this new substance 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 proposed use of the enzyme alpha-amylase sourced from a GM strain of *B. subtilis* (as a processing aid in the manufacture of bakery products) most likely outweigh the associated costs.

2.4.1.2 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.

2.4.1.3 Any relevant New Zealand standards

The relevant standards apply in both Australia and New Zealand. There are no other relevant New Zealand only standards.

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2. Subsection 18(1)

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

2.4.2.1 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 the enzyme as a processing aid in food for the proposed technological purpose.

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

The labelling requirements for this enzyme are discussed in Section 2.2.3 of this report.

2.4.2.3 The prevention of misleading or deceptive conduct

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

2.4.3 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 relevant technical and scientific information, was considered by FSANZ in assessing the application.

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

The enzyme meets 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 enzyme is permitted for use in food production in Denmark and France.

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

As the use of this enzyme is already permitted in Denmark and France, 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 will remain competitive with other international markets. This will 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 the enzyme as a food processing aid. It is therefore appropriate that Australian and New Zealand food industries are given the opportunity to benefit from 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 Forum on Food Regulation**

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 determined that permitting the proposed use of this enzyme is consistent with these specific order policy principles for 'Technological Function'. All other relevant requirements of the policy guideline are similarly met.

3 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

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

4 References

IUBMB (2018). EC 3.2.1.1 <https://iubmb.qmul.ac.uk/enzyme/EC3/2/1/1.html> Accessed 12 July 2022

JECFA (2017) Combined compendium of food additive specifications (FAO JECFA Monograph 1) <http://www.fao.org/docrep/009/a0691e/A0691E03.htm>

USPC (2018) Food Chemicals Codex 11th Edition, United States Pharmacopeial Convention, Rockville, MD. <http://publications.usp.org/>

Attachments

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

³ [Food regulation website](#)

Attachment A – Draft variation to the Australia New Zealand Food Standards Code



Food Standards (Application A1255 – Alpha-amylase from GM *Bacillus subtilis* as a processing aid) 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 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 A1255 – Alpha-amylase from GM Bacillus subtilis 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:

α -Amylase (EC 3.2.1.1) sourced from <i>Bacillus subtilis</i> containing the α -amylase gene from <i>Thermoactinomyces vulgaris</i>	For use in the manufacture of bakery products	GMP
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Attachment B – Draft 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 A1255 which sought permission to use alpha-amylase (EC 3.2.1.1) from a genetically modified (GM) strain of *Bacillus subtilis* as a new processing aid for use in the manufacture of bakery products. The Authority considered the application in accordance with Division 1 of Part 3 and has prepared a draft variation.

2. Variation will be a legislative instrument

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

If approved, this instrument would not be subject to the disallowance or sunset 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 sunset 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 sunset legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the Food Ministers Meeting (FMM). The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has prepared a draft variation amending the table to subsection S18—9(3) in Schedule 18 of the Code to permit the use of the enzyme alpha-amylase (EC 3.2.1.1) from a specific GM strain of *B. subtilis* as a processing aid in the manufacture of bakery products. This permission would be subject to the condition that the amount of enzyme used must be consistent with Good Manufacturing Practice (GMP).

4. Documents incorporated by reference

The draft variation does not incorporate any documents by reference.

However, existing provisions of the Code incorporate documents by reference that 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 (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 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 A1255 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) will be open for a six-week period.

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 and GM foods (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting new processing aids and GM foods is deregulatory as their use will be voluntary if the application 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

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

7. Variation

Item [1] of the draft variation would insert a new entry, in alphabetical order, into the table to subsection S18—9(3). The new entry would consist of the following enzyme in column 1 of the table:

- 'α-Amylase (EC 3.2.1.1) sourced from *Bacillus subtilis* containing the α-amylase gene from *Thermoactinomyces vulgaris*'

The permitted technological purpose for this enzyme would be prescribed in column 2 of the table as use as a processing aid in the manufacture of bakery products.

The permission would be subject to the condition, as prescribed in column 3 of the table, that the maximum permitted level or amount of this enzyme that may be present in the food must be consistent with GMP.

If approved, the draft variation would permit the proposed use of alpha-amylase (EC 3.2.1.1) sourced from *Bacillus subtilis* containing the alpha-amylase gene from *Thermoactinomyces vulgaris* as a processing aid in accordance with the Code.