

**20 March 2023**

**[235-23]**

Approval report – Application A1255

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

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by AB Enzymes GmbH to amend the Australia New Zealand Food Standards Code to permit alpha-amylase sourced from a genetically modified strain of *Bacillus subtilis* containing the alpha-amylase gene from *Thermoactinomyces vulgaris*, as a processing aid in the manufacture of bakery products.

On 14 October 2022, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received three submissions.

FSANZ approved the draft variation on 15 March 2023. The Food Ministers' Meeting<sup>1</sup> was notified of FSANZ's decision on 20 March 2023.

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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<sup>1</sup> 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:

SD1      Risk and technical assessment report

## Executive summary

AB Enzymes GmbH 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 alpha-amylase (EC 3.2.1.1) as a processing aid in the manufacture of bakery products. This alpha-amylase is produced from a genetically modified (GM) strain of *Bacillus subtilis*, containing the alpha-amylase gene from *Thermoactinomyces vulgaris*.

Alpha-amylase breaks down starch polysaccharides to produce large amounts of shorter oligosaccharides such as dextrans. Dextrans 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 completed a risk assessment and concluded 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.

Following assessment and the preparation of a draft variation to the Code, FSANZ called for submissions regarding the draft variation from 14 October 2022 to 25 November 2022. FSANZ received three submissions, all supportive of 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 alpha-amylase (EC 3.2.1.1) sourced from GM *B. subtilis* containing the alpha-amylase gene from *T. vulgaris* as a processing aid. The enzyme will be permitted for use in the manufacture of bakery products. This permission is subject to the condition that the maximum permitted level of the enzyme that may be present in the food is an amount 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

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), being the minimum amount 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 relevant requirements for 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 (12<sup>th</sup> 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.

Division 3 of Standard 1.2.3 requires declarations of certain foods (e.g. allergens) on the label of food for sale, unless an exemption applies. If the declaration relates to a processing aid, it must be made in the statement of ingredients and must include the required name<sup>2</sup> for the food which is to be declared in conjunction with the words 'processing aid'. If the requirement for a statement of ingredients does not apply, the required name must be declared on the label of the food for sale. If a food for retail sale is not required to bear a label, the required name must be displayed in connection with the display of the food or provided to the purchaser on request. If food sold to a caterer is not required to bear a label, the required name must be provided to the caterer with the food.

Section 1.5.2—4 of the Code requires a food for sale that consists of a *genetically modified food*<sup>3</sup> (GM food) or has a GM food as an ingredient to be labelled as 'genetically modified', unless an exemption applies. The label statement 'genetically modified' must be made in conjunction with the name of the GM food. If the GM food is used as a processing aid, this statement may be included in the statement of ingredients. The requirements imposed by section 1.5.2—4 apply only to foods for retail sale and to foods sold to a caterer in accordance with Standard 1.2.1.

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<sup>2</sup> **Required name**, of a particular food, means the name declared by section 1.2.3—5 as the required name for that food for the purposes of Division 3 of Standard 1.2.3 (see subsection 1.1.2—2(3)).

<sup>3</sup> 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*).

## 1.4 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 processing aids or enzymes. However, there are internationally recognised specifications for enzymes established by JECFA and Food Chemicals Codex as outlined in Section 1.3.2.

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.

## 1.5 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)
- it related to a matter that warranted the variation of a food regulatory measure.

## 1.6 Procedure for assessment

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

## 1.7 Decision

For reasons outlined 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 in the manufacture of bakery products.

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 called for submissions on a draft variation to the Code from 14 October 2022 to 25 November 2022. Three submissions were received. All submitters supported permitting the use of the new GM microbial source for the enzyme alpha-amylase as a processing aid in the manufacture of bakery products.

The submissions were received from:

- IMCD Australia Pty Ltd
- New Zealand Food Safety
- the Victorian Department of Health and the Victorian Department of Jobs, Precincts and Regions.

## 2.2 Risk assessment

FSANZ has assessed the public health and safety risks associated with alpha-amylase produced by GM *B. subtilis*, 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*, 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.

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.

## 2.3 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 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 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 manufacture of bakery products 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 (see Attachment A).

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

### 2.3.1 Regulatory approval for enzymes

FSANZ's assessment confirmed that alpha-amylase performs its technological purpose during the manufacture of bakery products and it does not perform a technological purpose in the food for sale. On that basis, the enzyme would function as a processing aid for the purposes of the Code. From the food technology assessment, FSANZ concluded that the proposed use of this enzyme is consistent with its typical function of catalysing the hydrolysis of polysaccharides during the manufacture of bakery products. Alpha-amylase increases the number of smaller oligosaccharides generated in this process, which improves the quality of the dough produced. As stated above (Section 1.7), FSANZ has approved a draft variation to permit the use of the enzyme as a processing aid in the manufacture of bakery products.

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 according to the Code as

it is derived from 'an organism which has been modified using gene technology' (see subsection 1.1.2—2(3) of the Code)<sup>4</sup>.

### **2.3.2 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 approved 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.

### **2.3.3 Labelling**

The labelling provisions in the Code will apply to foods for sale that are manufactured using this processing aid. See Section 1.3.3 above.

Section 3.3.5 of SD1 states that wheat flour is used in the enzyme preparation, and the final enzyme preparation contains wheat as part of its formulation. Declaration requirements for wheat and gluten will therefore apply in accordance with the Code if they are present in a food for sale that is manufactured using this processing aid.

### **2.3.4 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. The permission will 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 will be use 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 will 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 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**

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 considers standards' development matters is open, accountable, consultative and transparent. Public submissions were called for to assist consideration of the draft variation to the Code. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application.

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

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<sup>4</sup> 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'.



## 2.5 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 Impact Analysis (OIA)<sup>5</sup> granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for applications relating to processing aids and genetically modified foods (OIA 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, 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 the enzyme alpha-amylase from GM *B. subtilis* to be used as a processing aid in the manufacture of bakery products.

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 proposed use of the enzyme alpha-amylase produced from GM *B. subtilis*.

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

#### *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 and 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.

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<sup>5</sup> Formerly known as the Office of Best Practice Regulation (OBPR).

### *Conclusions from cost benefit considerations*

FSANZ's assessment at the call for submissions was 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) would 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 SD1) 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 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 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 risk assessment is provided in SD1.

- **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, with which this enzyme must comply.

- **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 as proposed by the applicant.

Ultimately, food businesses 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*<sup>6</sup> 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 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 (2021) Food Chemicals Codex 12th Edition, United States Pharmacopeial Convention, Rockville, MD. <http://publications.usp.org/>

### Attachments

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

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<sup>6</sup> [Food regulation website](#)

## Attachment A – Approved 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

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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 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:

$\alpha$ -Amylase (EC 3.2.1.1) sourced from <i>Bacillus subtilis</i> containing the $\alpha$ -amylase gene from <i>Thermoactinomyces vulgaris</i>	For use in the manufacture of bakery products	GMP
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## Attachment B

### EXPLANATORY STATEMENT

#### *Food Standards Australia New Zealand Act 1991*

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

##### **1. Authority**

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

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

The Authority accepted Application A1255 Alpha-amylase from GM *Bacillus subtilis* as a processing aid which sought permission to use alpha-amylase (EC 3.2.1.1) from a genetically modified 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 approved a draft variation – *Food Standards (Application A1255 – Alpha-amylase from GM *Bacillus subtilis* as a processing aid) Variation*.

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

##### **2. Variation is a legislative instrument**

The approved draft variation, *Food Standards (Application A1255 – Alpha-amylase from GM *Bacillus subtilis* as a processing aid) 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](http://www.legislation.gov.au)).

This instrument is not 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 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 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 is subject to the condition that the amount of enzyme used 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 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 Food Chemicals Codex (12th edition, 2020). These include specifications for 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 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 14 October 2022 for a six-week consultation period.

The Office of Impact Analysis (OIA)<sup>7</sup> granted the Authority a standing exemption from the requirement to develop a Regulatory Impact Statement for applications relating to permitting new processing aids and genetically modified foods (OBPR correspondence dated 24 November 2010 - reference 12065). This standing exemption was provided as permitting new genetically modified 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.

### **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 approved draft variation inserts a new entry, in alphabetical order, into the table to subsection S18—9(3). The new entry consists 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 is prescribed in column 2 of the table as use as a processing aid in the manufacture of bakery products.

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<sup>7</sup> Formerly known as the Office of Best Practice Regulation (OBPR).

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 approved draft variation is to 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.