28 September 2022
215-22

Approval report – Application A1246

Phospholipase A1 from GM *Aspergillus oryzae*

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Novozymes Australia Pty Ltd to amend the Australia New Zealand Food Standards Code to permit the use of the enzyme phospholipase A1 (EC 3.1.1.32), sourced from a genetically modified (GM) strain of *Aspergillus oryzae*, as a processing aid in the manufacture of bakery products.

On 18 May 2022, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received three submissions.

FSANZ approved the draft variation on 14 September 2022. The Food Minister's Meeting[1] was notified of FSANZ's decision on 28 September 2022.

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

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

Table of contents

Supporting document

The following document[1] which informed the assessment of this application is available on the FSANZ website:

SD1 Risk and Technical Assessment Report

[1] A1246 – Phospholipase A1 from GM Aspergillus oryzae (foodstandards.gov.au)

Executive summary

Novozymes Australia Pty Ltd submitted an application 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 phospholipase A1 (EC 3.1.1.32), sourced from a genetically modified (GM) strain of *Aspergillus oryzae (A. oryzae),* as a new processing aid in the manufacture of bakery products. This phospholipase A1 is sourced from *A. oryzae*, containing the phospholipase A1 gene from *Valsaria rubricosa* (*V. rubricosa*).

The safety assessment included consideration of bioinformatics, toxicity and dietary exposure and identified no public health and safety concerns. There are relevant identity and purity specifications in Schedule 3 of the Code with which the enzyme must comply.

After undertaking its risk and technical assessment, FSANZ concluded that there are no public health and safety concerns with the use of this phospholipase A1 enzyme.

As phospholipase A1 performs its technological function during food processing, not in the food for sale, it would function as a processing aid for the purposes of the Code.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation from 18 May 2022 to 29 June May 2022. FSANZ received three submissions from government agencies and industry stakeholders which all supported the draft variation.

Based on the information above and on other relevant considerations set out in this report, FSANZ has approved a draft variation to the table to subsection S18—9(3) of the Code to permit the use of the enzyme phospholipase A1 (EC 3.1.1.32), sourced from *A. oryzae* containing the phospholipase A1 gene from *V. rubricosa,* as a processing aid in the manufacture of bakery products. This permission will be 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. 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

Novozymes Australia Pty Ltd is a manufacturer of enzymes, microorganisms and precision proteins based in Sydney, Australia.

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 phospholipase A1 (EC 3.1.1.32), sourced from a genetically modified (GM) strain of *A. oryzae*, as a processing aid for use in the manufacture of bakery products. This organism contains the phospholipase A1 gene from *V. rubricosa*. Novozymes is requesting the approval of this phospholipase A1 to perform the technological function of hydrolysing phospholipids into lysophospholipids and free fatty acids in the manufacture of bakery products.

Novozymes claims that the benefits of using this enzyme include improved dough strength and stability, resulting in increased fermentation tolerance and better stability during baking. It will also improve dough structure and ensure a uniform crumb and structure which might otherwise be impaired by industrial processing of the dough.

1.3 The current standard

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

1.3.1 Permitted use

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

Paragraph 1.1.1—10(6)(c) provides that food for sale cannot contain, as an ingredient or component, a substance ‘used as a processing aid’ unless that substance’s use as a processing aid is expressly permitted by the Code. Section 1.1.2—13 provides that a substance ‘used as a processing aid’ in relation to a food is a substance used during the course of processing that meets all of the following conditions: it is used to perform a technological purpose during the course of processing; it does not perform a technological purpose in the food for sale; and it is a substance listed in Schedule 18 or identified in section S16—2 as an additive permitted at Good Manufacturing Practice (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 of a food produced using gene technology as an ingredient or component in a food for sale 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).

There is currently a permission for phospholipase A1 (EC 3.1.1.32) derived from different sources in the table to subsection S18—4(5), to be used in the manufacture of any foods. However, phospholipase A1 from the particular microbial source requested in this application is not currently permitted.

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 Food Chemicals Codex (12th edition, 2020). These include general specifications for enzyme preparations used in food processing for identity and purity parameters.

1.3.3 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.

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 (foods listed in the table to section S9—3 or their derivatives e.g., cereals containing gluten, and sulphites added at a certain concentration level) to be declared when present in a food for sale. 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 name[2] of the food to be declared and the words ‘processing aid’ in conjunction with that required name[3]. 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)).

[2] ***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)).
[3] If a food was packaged and labelled before 25 February 2024, that food may continue to be sold until 24 February 2026 if the food complies with either the previous Code requirements as in force before 25 February 2021, or the amended Code requirements that came into force on 25 February 2021.

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*[4] (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.

1.4 International standards

The Codex Alimentarius does not establish standards for processing aids or for enzymes. Individual countries regulate the use of enzymes differently to the Code. However, there are internationally recognised specifications for enzymes established by JECFA and Food Chemicals Codex, as outlined in Section 1.3.2 above. These include general specifications for enzyme preparations used in food processing for identity and purity parameters.

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 set out in this report, FSANZ decided to approve a draft variation amending the Code to permit the use of this enzyme as a processing aid in the manufacture of bakery products.

The draft variation as proposed following assessment was approved without change. The variation takes effect on the date of gazettal. The approved draft variation 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 18 May 2022 to 29 June 2022. Three submissions were received from government agencies and industry stakeholders, and all supported the application and draft variation (see Table 1).

Table 1: Summary of submitters comments

[4] 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*).

Submitter	Comments
New Zealand Food Safety	Supports amending the Code to permit use of the enzyme.
Victorian Department of Health and the Victorian Department of Jobs, Precincts and Regions	Supports progression of the application.
New Zealand Food & Grocery Council	Agree that the processing aid should be included in the Code and agree with the draft variation.

2.2 Risk assessment

FSANZ assessed the public health and safety risks associated with the use of phospholipase A1 (EC 3.1.1.32), sourced from a GM strain of *A. oryzae* containing the phospholipase A1 gene from *V. rubricosa*, as a processing aid in the manufacture of bakery products (see SD1). A summary of this risk assessment is provided below.

The evidence evaluated by FSANZ provides adequate assurance that the enzyme, in the quantity and form proposed to be used, is technologically justified and achieves its stated purpose. There are relevant identity and purity specifications for the enzyme in Schedule 3 of the Code with which the enzyme must comply.

No public health and safety concerns were identified in the assessment of phospholipase A1 from this GM *A. oryzae* under the proposed use conditions. *A. oryzae* has a long history of safe use as a source of enzyme processing aids, including several that are already permitted in the Code. The *A. oryzae* host is neither pathogenic or toxigenic. The assessment confirmed both presence and genetic stability of the inserted DNA.

Toxicology studies conducted with the phospholipase A1 that is the subject of this application included a 13-week repeat-dose oral gavage study in rats, and two genotoxicity studies - a bacterial reverse mutation assay (Ames test) and an in vitro micronucleus assay. A no observed adverse effect level (NOAEL) of 957 mg total organic solids (TOS)/kg bw/day was established in rats. The theoretical maximum daily intake (TMDI) based on FSANZ's calculations for solid food is 0.12 mg TOS/kg body weight/day. Comparison of the NOAEL and the TMDI results in a Margin of Exposure (MOE) of around 8000. No evidence of genotoxicity was found in either genotoxicity assay.

Recent bioinformatics searches were conducted by comparing the amino acid sequence of the phospholipase A1 enzyme to the amino acid sequences of known allergens. No significant matches with food allergens were found. A match with an occupational respiratory allergen was identified, with 36.4% identity. However, there is good evidence that respiratory allergens do not pose an allergic hazard when consumed (Bindslev-Jensen et al 2006).

Wheat flour is used as a stabilising agent in the commercial enzyme preparation which therefore contains wheat and gluten. The enzyme is intended for use in manufacture of baked products, and the quantity of wheat and gluten in the enzyme would be expected to be negligible relative to the wheat and gluten in other ingredients of baked goods.

Based on the reviewed data it is concluded that in the absence of any identifiable hazard an Acceptable Daily Intake (ADI) 'not specified' is appropriate for this phospholipase A1 from GM *A. oryzae*.

2.3 Risk management

2.3.1 Regulatory approval for processing aids

After assessing an application, FSANZ must either prepare a draft food regulatory measure or reject the application.

As outlined above, FSANZ concluded that there are no public health and safety concerns relating to the proposed use of this phospholipase A1 (EC 3.1.1.32) sourced from a GM strain of *A. oryzae* as a processing aid.

FSANZ's food technology assessment concluded that use of this enzyme in the manufacture of bakery products is consistent with its typical function of hydrolysing phospholipids into lysophospholipids and free fatty acids. Analysis of the evidence provided adequate assurance that the enzyme's use in the quantity and form proposed, which must be consistent with GMP controls and processes, is technologically justified. There are relevant identity and purity specifications for the enzyme in Schedule 3 of the Code with which the enzyme must comply.

Phospholipase A1 performs its primary technological purpose during food processing and does not perform a technological purpose in the final food, therefore functioning as a processing aid as defined in the Code.

FSANZ therefore considered it appropriate to prepare a draft variation amending the Code to permit the proposed use of this enzyme, and called for submissions on the draft variation. Following the call for submissions and having regard to all submissions received, FSANZ considers it appropriate to approve the draft variation proposed following assessment without change (Attachment A).

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).[5]

2.3.2 Enzyme nomenclature

FSANZ noted that the International Union of Biochemistry and Molecular Biology (IUBMB), the internationally recognised authority for enzyme nomenclature, uses the 'accepted' name 'phospholipase A_1' for the enzyme with an EC number of EC 3.1.1.32 (IUBMB 1999). This is consistent with how it is already permitted for use in the Code i.e. with the number '1' shown in subscript (using an alternate gene host). A variation of this name i.e. 'phospholipase **A1**' was used throughout the application and, as such, is used in this document and SD1.

2.3.3 Labelling requirements

Subject to subsections 2.3.3.1 and 2.3.3.2 below, the generic exemption from listing processing aids in the statement of ingredients will apply to foods manufactured using this enzyme processing aid (see Section 1.3.3 above).

[5] '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'.

2.3.3.1 Declaration of certain foods

Wheat flour is used in the enzyme preparation as discussed in Section 3.3.4 of SD1. As noted in Section 1.2 of this report, this phospholipase A1 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' in accordance with requirements in Division 3 of Standard 1.2.3. Wheat-free bakery products that are manufactured using phospholipase A1 will also be subject to 'wheat' and 'gluten' declarations if wheat and gluten from the enzyme remain in the food for sale.

2.3.4.1 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 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)).

2.4 Risk communication

2.4.1 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 considers standards development matters is open, accountable, consultative and transparent. Public submissions were called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options.

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

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

2.5 FSANZ Act assessment requirements

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

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for applications relating to permitting processing aids and genetically modified food (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.

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 (i.e. rejecting the application). This analysis considered permitting the use of phospholipase A1 derived from a new source, i.e., from GM *A. oryzae* containing the phospholipase A1 gene from *V. rubricosa* (the enzyme), as a processing aid in the manufacture of bakery products.

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

Costs and benefits of permitting the use of enzyme phospholipase A1 (EC 3.1.1.32) sourced from this GM strain of A. oryzae as a processing aid

Industry

Phospholipase A1 can provide benefits during baking, including improving dough strength and stability, resulting in increased fermentation tolerance. It can also improve dough structure and ensure a uniform crumb and structure, which might otherwise be impaired by industrial processing of the dough.

Phospholipase A1 is already available to industry from another production source. Due to the voluntary nature of the proposed permission, industry will use phospholipase A1 from this additional source, GM *A. oryzae,* where businesses in the industry believe a net benefit exists for them. An additional source of this enzyme may help industry save on production costs of certain bakery products.

The use of this enzyme from this source is already permitted in Denmark and France. Therefore, the approval for use of this enzyme would bring Australia and New Zealand into line with the other countries where it is already authorised for use. That may help some of Australia's and New Zealand's sales in international markets. There may, however, be more competing imports in the domestic market from countries that already use the source GM *A. oryzae* for the enzyme.

Consumers

Industry may pass some of any cost savings to consumers, where it is cheaper to source the phospholipase A1 enzyme from this GM *A. oryzae*. Consumers may also benefit from a greater number of higher quality bakery products if this additional source of phospholipase A1 leads to greater use of the enzyme.

Government

Permitting this additional source of phospholipase A1 may result in a small cost to government in terms of adding the permitted source 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 in question 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

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 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 (SD1) and concluded that there were no public health and safety concerns relating to the use of the enzyme.

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

Existing labelling requirements in the Code related to the enzyme are discussed in Section 2.3.3 of the report above.

2.5.2.3 The prevention of misleading or deceptive conduct

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

2.5.3 Subsection 18(2) considerations

FSANZ 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, which is provided in SD1. The applicant submitted a dossier of information and scientific literature as part of its application. This dossier, together with other technical and scientific information, was considered by FSANZ in assessing the application.

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

There are no Codex Alimentarius Standards for processing aids or enzymes. However, there are relevant identity and purity specifications for the enzyme in Schedule 3 of the Code with

which the enzyme must comply. The enzyme from this source is already permitted in Denmark and France.

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

As mentioned above, the applicant has advised that the enzyme is permitted for use in Denmark and France. Therefore, the approval for use of this enzyme would bring Australia and New Zealand into line with the other countries 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 was that there are no public health and safety concerns associated with the production microorganism or with using 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 enzyme.

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

- **the promotion of fair trading in food**

No issues were identified for this application relevant to this objective.

- **any written policy guidelines formulated by the Food Ministers' Meeting[6]**

The Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*[7] formulated by the Food Ministers' Meeting, 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 this enzyme as a processing aid is consistent with the specific order policy principles for 'Technological Function'. All other relevant requirements of the policy guideline are similarly met.

3 References

Bindslev-Jensen C, Skov PS, Roggen EL, Hvass P, Brinch DS (2006) 'Investigation on possible allergenicity of 19 different commercial enzymes used in the food industry' *Food and Chemical Toxicology* 44:1909-1915.

FAO/WHO (2006) Combined compendium of food additive specifications, Food and Agriculture

[6] Formerly known as the Forum on Food Regulation.
[7] Available on the Food regulation website (accessed 18 January 2022).

Organization of the United Nations, Rome. http://www.fao.org/docrep/009/a0691e/A0691E03.htm

IUBMB (2021) EC 3.1.1.32. https://iubmb.qmul.ac.uk/enzyme/EC3/1/1/23.html

The United States Pharmacopeia (2020) 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

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

Food Standards (Application A1246 – Phospholipase A1 from GM *Aspergillus oryzae)* 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]

[Delegate's name and position]
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 A1246 – Phospholipase A1 from GM* Aspergillus oryzae*) 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:

Phospholipase A_1 (EC 3.1.1.32) sourced from *Aspergillus oryzae* containing the phospholipase A_1 gene from *Valsaria rubricosa*	For use in the manufacture of bakery products	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 A1246 which sought to amend the Code to permit the use of the enzyme phospholipase A1 (EC 3.1.1.32) sourced from a genetically modified (GM) strain of *Aspergillus oryzae* (*A. oryzae*), expressing a phospholipase A1 gene from *Valsaria rubricosa*, as a processing aid 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.

Following consideration by the Food Ministers' Meeting (FMM)[8], 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 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).

This instrument is not subject to the disallowance or sunsetting provisions of the *Legislation Act 2003.* Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunsetting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

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

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

3. Purpose

The Authority has approved a draft variation amending the table to section S18—9(3) of the Code to permit the use of the enzyme, phospholipase A1 (EC 3.1.1.32) sourced from a GM strain of *A. oryzae* expressing a phospholipase A1 gene from *V. rubricosa*, as a processing aid in the manufacture of bakery products. This 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 (GMP).

4. Documents incorporated by reference

The approved draft variation does not incorporate any documents by reference.

However, existing provisions of the Code incorporate documents by reference that will prescribe identity and purity specifications for the processing aid to be permitted by the approved draft variation. Section 1.1.1—15 of the Code requires substances used as processing aids to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code. Section S3—2 of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications (FAO/WHO 2019) and the United States Pharmacopeial Convention (2020) Food Chemicals Codex (12th edition). These include general specifications for enzyme preparations used in food processing for identity and purity parameters.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1246 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 18 May 2022 for a six-week consultation period.

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

6. Statement of compatibility with human rights

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

7. Variation

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

"Phospholipase A_1 (EC 3.1.1.32) sourced from *Aspergillus oryzae* containing the phospholipase A_1 gene from *Valsaria rubricosa*" (column 1 of the table).
The International Union of Biochemistry and Molecular Biology, the internationally recognised

authority for enzyme nomenclature, uses the 'accepted' name 'phospholipase A_1' (with the number '1' shown in subscript) for the enzyme with an EC number of EC 3.1.1.32 (IUBMB 1999). The accepted name is used in the variation, which is consistent with how this enzyme is already referred to in the Code. 'Phospholipase A1' is simply a variation of the accepted name used throughout the application and this Explanatory Statement.

The permitted technological purpose for this enzyme is use as a processing aid in the manufacture of bakery products (column 2 of the table).

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 GMP (column 3 of the table).

The effect of the variation is to permit the proposed use of the enzyme, phospholipase A1 (EC number 3.1.1.32), sourced from *A, oryzae* containing the phospholipase A1 gene from *V. rubricosa*, as a processing aid in accordance with the Code.