18 May 2022
200-22

Call for submissions – 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 a new processing aid, phospholipase A1, derived from a genetically modified strain (GM) of *Aspergillus oryzae,* for use in the manufacture of bakery products and 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 through the FSANZ website via the link how to make a submission. You can also email 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) 29 June 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[1] which informed the assessment of this application is available on the FSANZ website:

SD1 Risk and Technical assessment

[1] https://www.foodstandards.gov.au/code/applications/Pages/A1246 - Phospholipase-A1-from-Aspergillus-oryzae.aspx

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),* containing the phospholipase A1 gene from *Valsaria rubricosa (V. rubricosa),* as a new processing aid for the manufacture of bakery products.

FSANZ has undertaken a risk and technical assessment of the enzyme phospholipase A1 sourced from a GM strain of *A. oryzae,* containing the phospholipase A1 gene from *V. rubricosa.* The assessment confirmed the enzyme's proposed use was appropriate and that the enzyme meets international purity specifications. The safety assessment considered the genetic modification, toxicity, allergenicity and an exposure assessment.

FSANZ concludes there are no public health and safety concerns with the use of phospholipase A1 produced from this GM strain of *A. oryzae,* under the proposed use conditions.

As phospholipase A1 performs its technological function during food processing, not in the food for sale, FSANZ also concludes that if the draft variation is approved (i.e. if phospholipase A1 is listed in Schedule 18), phospholipase A1 would be appropriately classified as a processing aid, as defined in the Code.

FSANZ has therefore prepared a draft variation to the Code which, if approved, would list the enzyme, phospholipase A1 sourced from *A. oryzae* containing the phospholipase A1 gene from *V. rubricosa*, in the table to subsection S18—9(3) of the Code as a permitted processing aid for use 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.

FSANZ invites submissions on the draft variation.

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 phospholipase A1 (EC 3.1.1.32), sourced from a genetically modified (GM) strain of *Aspergillus oryzae (A. oryzae)*, as a processing aid for use in the manufacture of bakery products. This organism contains the phospholipase A1 gene from *Valsaria rubricosa (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.

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 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).

Currently, one other source of phospholipase A1 is approved for use in the Code. Phospholipase A1 sourced from a GM strain of *A.oryzae* containing the phospholipase A1 gene from *Fusarium venenatum* is included in Schedule 18 of the Code.

Identity and purity requirements

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

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

Labelling requirements

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

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. The food may be present as a substance used as a processing aid or as an ingredient or component of a substance used a processing aid (paragraph 1.2.3—4(5)(c)). 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 declaration 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)).

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.

Section 1.5.2—4 requires processing aids that are, or have as ingredients, foods produced using gene technology to be labelled 'genetically modified', where novel DNA and/or novel

[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] On 25 February 2021 new requirements for the labelling of allergens were introduced in the Code and suppliers have until 25 February 2024 to change over to these new requirements. If a food was packaged and labelled before 25 February 2024 and it complied with the previous allergen labelling requirements, then that food can remain on sale for another two years as long as it complies with the rest of the Code.

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 generally apply only to foods for retail sale and to foods sold to a caterer, under subsections 1.2.1—8(1) and 1.2.1—9(3), and section 1.2.1—15 respectively.

1.3.1 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 above. The enzyme has been approved for use 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 of the FSANZ Act.

2 Summary of the assessment

2.1 Risk assessment

FSANZ has assessed the public health and safety risks associated with the use of Phospholipase A1 (EC 3.1.1.32), sourced from *A. oryzae* containing the phospholipase A1 gene from *V. rubricosa*, as a processing aid in 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 is technologically justified and achieves its stated purpose. The enzyme meets international purity specifications.

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

[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*).

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 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.

However wheat flour is used as a stabilising agent in the commercial enzyme preparation and the enzyme preparation 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 may 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*.

2.2 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 permitting the enzyme, phospholipase A1 (EC 3.1.1.32) sourced from *A. oryzae* containing the phospholipase A1 gene from *V. rubricosa*, to be used as a processing aid in the manufacture of bakery products, subject to the condition that the amount of enzyme used must be consistent with good manufacturing practice (GMP).

The Risk and Technical Assessment Report concluded that there are no safety concerns from using this enzyme for its stated purpose. In addition, the use of this enzyme, in the quantity and form (granulate) proposed to be used, which must be consistent with GMP controls and processes, is technologically justified. Therefore, FSANZ has prepared a draft variation of the Code as outlined above (see Attachment A).

Other risk management considerations for this application are related to enzyme nomenclature and labelling, which are discussed below. The regulatory options analysed in Section 2.4.1.1 of this report take account of the safety of the enzyme.

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 in the manufacture of bakery products. The express permission for the enzyme to be used as a processing aid would 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].

[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'.

2.2.2 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.

2.2.3 Labelling requirements

In general, processing aids are exempt from the requirement to be declared in the statement of ingredients, unless other labelling requirements apply (see Section 1.3 above). In the case of foods manufactured using this processing aid other requirements apply as detailed in sections 2.2.3.1 and 2.2.3.2 below.

2.2.3.1 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.

2.2.3.2 Labelling requirements for food produced using gene technology

Standard 1.5.2 in effect provides that a substance used as a processing aid that contains novel DNA or novel protein is a GM food. Subsection 1.5.2—4(2) states that the information relating to foods produced using gene technology must include the statement 'genetically modified' in conjunction with the name of the GM food. Subsection 1.5.2—4(3) states that if the GM food is used as a processing aid, the information may be included in the statement of ingredients.

The requirement for labelling as 'genetically modified' differs depending on whether the GM food is an ingredient of the food for sale or not. A food for retail sale or sold to a caterer that contains phospholipase A1 from GM *A. oryzae* as an ingredient (e.g. the enzyme is used in the manufacture of bread) would be required to be labelled 'genetically modified' in conjunction with the name of the enzyme. FSANZ notes however, that if the food made using the enzyme is not a food for sale itself (e.g. is present in bread used as a crumb coating on frozen fish fillets), the enzyme would not be an ingredient in the food for sale and the labelling requirement would not apply.

2.2.4 Risk management conclusion

The risk management conclusion is to permit the use of the enzyme, phospholipase A1 sourced from a GM strain of *A. oryzae*, containing the phospholipase A1 gene from *V. rubricosa,* as a processing aid. The table to subsection S18—9(3) of the Code, which includes enzymes permitted to be used as processing aids for specific technological purposes, would be amended to include this enzyme as a permitted processing aid. The technological purpose of this enzyme would be for use in the manufacture of bakery products. The maximum permitted level would be an amount consistent with GMP. 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.

There are no relevant international standards (i.e. Codex Alimentarius Standards) and amending the Code to approve the enzyme as a processing aid is unlikely to have a significant effect on international trade.

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 permitting 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 exception relates to the introduction of a food to the food supply that has been determined to be safe.

FSANZ, however, has given consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

The purpose of this consideration is to determine if the community, government and industry

as a whole is likely to benefit, on balance, from a move from the status quo (i.e. rejecting the application). This analysis considers permitting the use of the enzyme phospholipase A1 (EC 3.1.1.32), sourced from this GM strain of *A. oryzae* for the manufacture of bakery products. That enzyme would be listed in the table of subsection S18—9(3) of the Code, which includes enzymes permitted to be used as processing aids for specific technological purposes.

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.

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 seeks to highlight the likely positives and negatives of moving away from the status quo by permitting the proposed use of the enzyme from the new source GM strain of *A. oryzae*.

Costs and benefits of permitting the proposed 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.

2.4.1.2 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 and there are no 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 undertook a safety assessment (see SD1) and concluded there were no public health and safety concerns associated with the proposed use of this enzyme.

2.4.2.2 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, 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. The enzyme processing aid meets international specifications for enzyme preparations, being the JECFA Combined Compendium of Food Additive Specifications and the Food Chemicals Codex specifications for enzymes referred to in Section 1.3 of this report. 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 use of this enzyme 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. 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 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 the proposed use of this alternative 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 Forum on Food Regulation**

The Ministerial Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*[6] 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 is consistent with the specific order policy principles for 'Technological Function'. All other requirements of the policy guidelines are similarly met.

3 Draft variation

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

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

4 References

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

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

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

IUBMB EC 3.1.1.32. https://iubmb.qmul.ac.uk/enzyme/EC3/1/1/32.html. Accessed 11 April 2022.

The United States Pharmacopeia (2020) Food Chemicals Codex 12th 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

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

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

[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 – 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 A1246 which seeks to amend the Code to permit the use of the enzyme phospholipase A1 (EC 3.1.1.32) from a new genetically modified (GM) strain of *Aspergillus oryzae* as a 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 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 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 a draft variation amending the table to subsection S18—9(3) in Schedule 18 of the Code to permit the use of the enzyme phospholipase A1 (EC 3.1.1.32) from a specific GM strain of *Aspergillus oryzae* as a processing aid in the manufacture of bakery products. If approved, this permission would be subject to the condition that the amount of enzyme used must be consistent with good manufacturing practice (GMP).

The Authority noted that the International Union of Biochemistry and Molecular Biology uses the 'accepted' name 'phospholipase A_1' for the enzyme with an EC number of EC 3.1.1.32. This is consistent with how it is already permitted for use in the Code – i.e. with the number '1' shown in subscript. A variation of this name i.e. 'phospholipase **A1**' was used throughout the application and, as such, this document.

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 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 A1246 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*.

7. Variation

Item [1] of the draft variation would insert a new entry into the table to subsection S18—9(3) of the Code. The new entry would be inserted in alphabetical order and consist 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*'

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

The permission would 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 GMP.

If approved, the draft variation would permit the proposed use of the enzyme, phospholipase A1 (EC 3.1.1.32) sourced from *Aspergillus oryzae* containing the phospholipase A1 gene from *Valsaria rubricosa* as a processing aid in accordance with the Code.