FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

15 July 2025
349-25

Call for submissions – Application A1292

Phospholipase C from GM *Bacillus licheniformis* as a processing aid

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Novozymes Japan Ltd to permit the use of a protein engineered variant of the enzyme phospholipase C from a genetically modified (GM) strain of *Bacillus licheniformis* containing the phospholipase C gene from *Bacillus thuringiensis* as a processing aid and has prepared a draft food regulatory measure. This phospholipase C would be used as a processing aid in degumming vegetable fats and oils. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist in considering the draft food regulatory measure.

Submissions on this application need to be made through the Consultation Hub.

All submissions on applications and proposals will be published on the Consultation Hub. 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 following consultation and before the next stage in the statutory assessment process.

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 Making a submission.

For information on how FSANZ manages personal information when you make a submission, see FSANZ's Privacy Policy.

FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices. There is no need to send an email or hard copy of your submission if you have submitted it through the FSANZ Consultation Hub.

DEADLINE FOR SUBMISSIONS: 11:59pm (Canberra time) 26 August 2025

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.

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

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:

Food Standards Australia New Zealand
PO Box 5423
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PO Box 10559
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Supporting document

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

SD Risk and technical assessment – Application A1292 Phospholipase C from GM *Bacillus licheniformis* as a processing aid

Executive summary

Food Standards Australia New Zealand (FSANZ) received an application from Novozymes Japan Ltd to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of a protein engineered variant of the enzyme phospholipase C (EC 3.1.4.3) from a genetically modified (GM) *Bacillus licheniformis* containing the phospholipase C gene from *Bacillus thuringiensis* as a processing aid in degumming vegetable fats and oils.

The proposed use of this phospholipase C as an enzyme processing aid in the quantity and form proposed is consistent with its typical function. Phospholipase C performs its technological purpose during food processing and not in food for sale, therefore functioning as a processing aid for the purposes of the Code.

FSANZ concludes that there are no safety concerns about the protein engineered variant of the enzyme phospholipase C from *B. licheniformis*. The production organism is neither pathogenic nor toxigenic. There are relevant identity and purity specifications for the enzyme in the Code with which the enzyme would have to comply when added to food in accordance with the Code or sold for use in food.

Following assessment, for reasons set out in this report, FSANZ has prepared a draft variation to the Code, which, if approved, would amend Schedule 18 by listing this enzyme and its associated technological purpose in the table to subsection S18—9(3). This table lists substances (including enzymes) permitted to be used as processing aids for specific technological purposes.

If approved, the effect of the draft variation would be to permit the use of the protein engineered variant of the enzyme phospholipase C (EC 3.1.4.3) from *B. licheniformis* containing the phospholipase C gene from *B. thuringiensis as* a processing aid in degumming vegetable fats and oils in accordance with the Code.

The permission would be subject to the condition that the maximum permitted level or amount of the enzyme in the food must be consistent with Good Manufacturing Practice.

FSANZ now seeks submissions on the draft variation of the Code.

1 Introduction

1.1 The applicant

The applicant is Novozymes Japan Ltd. Novozymes specialises in the development and production of enzymes and microorganisms used in various industries, including food and beverages.

1.2 The application

This application seeks to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of a protein engineered variant of the enzyme phospholipase C (EC 3.1.4.3) from a GM strain of *Bacillus licheniformis* containing the phospholipase C gene from *Bacillus thuringiensis* as a processing aid in the degumming of vegetable fats and oils.

If approved, this enzyme would be used at minimum levels necessary to achieve the desired effect, according to Good Manufacturing Practice (GMP).[1]

1.3 The current standard

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

1.3.1 Permitted use.

Paragraph 1.1.1—10(6)(c) provides that a food for sale must not have, as an ingredient or a component, a substance that is used as a processing aid unless 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.
- 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 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), depending on whether a technological purpose has been specified.

An enzyme of microbial origin listed in the table to subsection S18—4(5) is 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 a row 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

[1] GMP is defined in subsection 1.1.2—2(3) of the Code.

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).

Phospholipase C is not listed in Schedule 18. Therefore, the proposed use of this protein engineered variant of phospholipase C from a GM strain of *B. licheniformis* containing the phospholipase gene C from *B. thuringiensis* as a processing aid is not currently permitted by the Code.

1.3.2 Identity and purity requirements

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

Subsection S3—2(1) 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 26 (2021)[2], the United States Pharmacopeial Convention (2022) Food Chemicals Codex (13th edition). These include general specifications for enzyme preparation for identity and purity parameters 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 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.

Section 1.5.2—4 of the Code requires a food for sale that consists of a *genetically modified food*[3] (GM food) or has a GM food as an ingredient to be labelled as 'genetically modified', unless an exemption applies. The 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 to foods for retail sale and to foods sold to a caterer in accordance with Standard 1.2.1.

1.3.4 Proposal P1055

In Proposal P1055 – Definitions for gene technology and new breeding techniques, FSANZ approved a draft variation to the Code that introduces a new definition for GM food. Under that new definition substances used as a processing aid will no longer be GM food for Code purposes. This amendment, if endorsed by Food Ministers, will mean the above labelling requirements will no longer apply to enzyme processing aids derived from GM sources.

1.4 International standards

In developing food regulatory measures, FSANZ must have regard to the promotion of consistency between domestic and international food standards. Regarding food safety, the relevant international standard-setting body is the Codex Alimentarius Commission (Codex). In contrast to food additives, there is no Codex 'general standard' for enzymes. However, as noted in Section 1.3.2 above, there are internationally recognised specifications for enzyme preparations established by JECFA and Food Chemicals Codex.

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[2] https://www.fao.org/documents/card/fr/c/cb4737en/

[3] Section 1.5.2—4(5) defines ***genetically modified food*** to mean a '*food produced using gene technology that contains novel DNA or novel protein; or
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*).

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 they shall be used under GMP conditions.

1.5 Reasons for accepting the 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 of the FSANZ Act.

2 Summary of the assessment

2.1 Food technology assessment

FSANZ conducted a food technology assessment to determine whether the enzyme achieves its technological purpose in the proposed quantity and form (see the Supporting Document (SD)).

Phospholipase C from a GM strain of *B. licheniformis* containing a protein engineered variant of the phospholipase C gene from *B. thuringiensis* performs its typical function technological function in degumming vegetable fats and oils and does not perform a technological function in food for sale. Therefore, it functions as a processing aid for the purposes of the Code.

2.2 Safety assessment

FSANZ has assessed the public health and safety risks associated with the proposed use of a protein engineered variant of phospholipase C from a GM stain of *B. licheniformis* containing the phospholipase C gene from *B. thuringiensis* as a processing aid (see SD).

The proposed use of this phospholipase C raises no safety concerns. The production organism is neither pathogenic nor toxigenic.

A no observed adverse effect level (NOAEL) of 714 mg total organic solids (TOS)/kg bw/day was identified in a 13-week oral toxicity study in rats. The theoretical maximum daily intake (TMDI) was calculated to be 0.1 mg TOS/kg bw/day. A comparison of the NOAEL and the TMDI results in a Margin of Exposure (MOE) of approximately 7100.

Based on the reviewed data, no public health and safety concerns were identified for this enzyme under the proposed conditions of use. An Acceptable Daily Intake (ADI) ‘not specified’ is appropriate for this phospholipase C.

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.

For the reasons listed in this report, FSANZ decided to prepare a draft variation to the Code to permit the proposed use of a protein engineered variant of the enzyme phospholipase C (EC 3.1.4.3) from a GM strain of *B. licheniformis* containing the phospholipase C gene from *B. thuringiensis* as a processing aid. If approved, this permission would be subject to the condition that the maximum permitted level or amount of this enzyme present in the food

must be consistent with GMP.[4]

The risk and technical assessment concluded the proposed use of this enzyme is technologically justified and there are no public health and safety concerns associated with it.

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

2.3.1 Regulatory approval for processing aids

As stated above, FSANZ has prepared a draft variation to permit the proposed use of this enzyme as a processing aid.

The express permission for the enzyme to be used as a processing aid would also provide the permission for its potential presence in food for sale as a food produced using gene technology (see Section 1.3.1 above). 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, source microorganism nomenclature and specifications

The International Union of Biochemistry and Molecular Biology (IUBMB)[6] uses the accepted name phospholipase C for EC 3.1.4.3. Therefore, item 1 of the draft variation refers to "EC 3.1.4.3" in conjunction with "Phospholipase C" in the name of the substance."

There are relevant identity and purity specifications in primary sources of specifications listed in Schedule 3 for enzyme preparations used in food processing (refer to section 1.3.2 above). This enzyme would have to comply with those specifications when added to food in accordance with the Code or sold for use in food.

2.3.3 Labelling

The labelling provisions in the Code will apply to foods for sale that are manufactured using this enzyme as a processing aid (see section 1.3.3 above).

Labelling requirements in section 1.5.2—4 apply to processing aids where novel DNA or novel protein from the processing aid remains in the food for sale. As the processing aid is a protein engineered variant of phospholipase C, the enzyme preparation produced from *B. licheniformis* would contain novel DNA or novel protein. The labelling statement 'genetically modified' would be required in conjunction with the name of the processing aid if novel DNA or novel protein remains present in the final food for sale.

2.3.4 Risk management conclusion

The risk management conclusion is to permit this enzyme, a protein engineered variant of phospholipase C from a GM *B. licheniformis* containing the phospholipase C gene from *B. thuringiensis*, as a processing aid in degumming vegetable fats and oils.

If approved, the enzyme and its associated technological purpose would be listed in the table to subsection S18—9(3) of the Code, which includes enzymes permitted for a specific technological purpose. The maximum permitted level or amount of the enzyme that may be present in the food would have to be an amount consistent with GMP.

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[4] See section 1.3.4 of this report. The prepared draft variation is based on the provisions of the Code as at the date of this report. The draft variation, if approved, may require amendment if the P1055 amendments to the Code are endorsed and commence prior to it.

[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

[6] https://iubmb.org/

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 FSANZ notification circular, media release, FSANZ's digital channels and Food Standards News. Subscribers and interested parties are also notified about the availability of reports for public comment.

The process by which FSANZ considers standards development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on the draft variation. FSANZ will consider all submissions received through this call for submissions process before deciding on whether to approve the application.

2.4.2 World Trade Organization

As members of the World Trade Organization (WTO)[7], Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are not substantially the same as existing international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards and amending the Code to permit the use of phospholipase C 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.

2.5 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.

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

Changes have been made to the impact analysis requirements by the Office of Impact Analysis (OIA)[8]. Impact analysis no longer must be finalised with the OIA. Prior to these changes, the OIA advised FSANZ that a Regulation Impact Statement (RIS) was not needed for applications relating to permitting the use of processing aids and GM food (OIA23-06225). This is because applications relating to permitting the use of processing aids and GM food that have been determined to be safe are minor and deregulatory in nature, and their use will be voluntary if the draft variation concerned is approved. Under the new approach, FSANZ's assessment is that a RIS is not required for this application.

However, FSANZ has considered 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

[7] World Trade Organization - Home page - Global trade (wto.org)
[8] Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis (pmc.gov.au)

are likely to benefit, on balance, from a move from the status quo (where the status quo is rejecting the application). This analysis considers permitting the use of a protein engineered variant of phospholipase C from a GM *B. licheniformis* containing the phospholipase C gene from *B. thuringiensis* as a processing aid in degumming vegetable fats and oils.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures. In fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the positives and negatives of moving away from the status quo by approving the variation to the Code proposed by the application.

FSANZ's conclusions regarding the 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 a different outcome.

Costs and benefits of permitting the proposed use of this enzyme.

Industry may benefit from efficiency improvements from the proposed use of this enzyme. Due to the voluntary nature of the permission, industry will only use the enzyme as proposed where they believe a net benefit exists for them.

If industry were to experience cost savings because of using this enzyme, industry may pass on some of the cost savings to consumers.

Permitting the proposed use of this enzyme may result in a small, inconsequential cost to government in terms of an addition to the current range of processing aids monitored for compliance.

Conclusions from cost benefit considerations

FSANZ has assessed that the direct and indirect benefits of permitting a protein engineered variant of phospholipase C from a GM strain of *B. licheniformis* containing the phospholipase C gene from *B. thuringiensis* to be used as a processing aid in degumming vegetable fats and oils are likely to outweigh the associated costs.

Information received through this call for submissions process may result in FSANZ arriving at a different outcome.

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 because of the application.

2.5.1.3 Any relevant New Zealand standards

The standards in the Code which are relevant to the permitted use of the enzyme processing aid in question 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 section 2.2 above and the SD), which concluded there were no public health and safety concerns with permitting the proposed use of this phospholipase C from a GM *B. licheniformis* containing the phospholipase C gene from *B.* thuringiensis as a processing aid.

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 were no issues relevant to this objective.

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

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

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

In terms of food safety, the relevant international standard setting body is Codex. In contrast to food additives, there is no Codex 'general standard' for enzymes, however, as noted in section 1.3.2 above, there are internationally recognised specifications for enzyme preparations established by JECFA and Food Chemicals Codex, with which this enzyme would have to comply when added to food in accordance with the Code or sold for use in food.

Also, as noted in section 1.4 above, 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 these substances shall be used under conditions of GMP.

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

The conclusion of the risk assessment is that there are no public health and safety concerns associated with the proposed use of this 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 use of this enzyme as proposed by the applicant.

The domestic food industry will make their own economic decisions, considering the costs and benefits of using the new enzyme, to determine if it is of benefit to their 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*[9] 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

[9] Available on the Food regulation website

- 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 regarding the substance.

FSANZ determined that permitting the proposed 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 Draft variation

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

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

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 A1292 – Phospholipase C from GM *Bacillus licheniformis* 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 name and position of Delegate]
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 A1292 – Phospholipase C from GM* Bacillus licheniformis *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:

Phospholipase C, protein engineered variant, (EC 3.1.4.3) sourced from *Bacillus licheniformis* containing the gene for phospholipase C from *Bacillus thuringiensis*	For use in degumming vegetable fats and oils	GMP

[2] Subsection S18—9(3) (note after the table, dot point list of protein engineered variants of enzymes)

Omit:

- Maltogenic α-amylase, protein engineered variant;

substitute:

- Maltogenic α-amylase, protein engineered variant;
- Phospholipase C, protein engineered variant;

Attachment B – Draft Explanatory Statement

DRAFT EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1292 – Phospholipase C from GM* Bacillus licheniformis *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 A1292, which sought to amend the Code to permit the use of a protein engineered variant of the enzyme, phospholipase C from a genetically modified (GM) strain of *B. licheniformis* containing the phospholipase C gene from *B. thuringiensis*, as a processing aid in degumming vegetable fats and oils. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation – the *Food Standards (Application A1292 – Phospholipase C from GM* Bacillus licheniformis *as a processing aid) Variation* (the 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.

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 prepared a draft variation amending the table to subsection S18—9(3) of the Code to permit the use of a protein engineered variant of the enzyme phospholipase C from a GM strain of *B. licheniformis* containing the phospholipase C gene from *B. thuringiensis* as a processing aid in degumming vegetable fats and oils.

If approved, this permission would be subject to the condition that the maximum permitted level or amount of the enzyme that may be present in the food must be consistent with good manufacturing practice (GMP).

4. Documents incorporated by reference

The draft variation does not incorporate any documents by reference.

However, existing provisions of the Code incorporate documents by reference that would 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 when added to food in accordance with the Code or sold for use in food.

Section S3—2 of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Compendium of Food Additive Specifications (FAO/WHO 2021), the United States Pharmacopeial Convention (2022) Food Chemicals Codex (13th edition). These include general specifications for the identity and purity parameters of enzyme preparations used in food processing.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1292 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.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA) [10]. Impact analysis is no longer required to be finalised with the OIA. Prior to these changes, the OIA advised FSANZ that a Regulation Impact Statement (RIS) was not needed for applications relating to processing aids and GM food. This is because applications relating to permitting the use of processing aids and GM food that have been determined to be safe are minor and deregulatory in nature, as their use will be voluntary if the draft variation concerned is approved. Under this approach, FSANZ's assessment is that a RIS is not required for this application for those reasons

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*.

[10] Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis (pmc.gov.au)

7. Variation

References to 'variation' in this section are references to the draft variation.

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1292 – Phospholipase C from GM* Bacillus licheniformis*, as a processing aid) Variation*.

Clause 2 of the variation provides that the Code is amended by the Schedule to the variation.

Clause 3 of the variation provides that the variation commences on the date of gazettal of the instrument.

Schedule to the variation

Item [1] of the Schedule to the variation would insert a new entry, in alphabetical order, into column 1 of the table to subsection S18—9(3) of the Code.

The new entry consists of the following enzyme:

- 'Phospholipase C, protein engineered variant, (EC 3.1.4.3) sourced from *Bacillus licheniformis* containing the gene for phospholipase C from *Bacillus thuringiensis'*

The permitted technological purpose for this enzyme would be prescribed in column 2 of the table. The prescribed purpose would be 'For use in degumming vegetable fats and oils.'

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

If approved, the effect of the proposed amendment in item [1] would be to permit the proposed use of the protein engineered variant of the enzyme, Phospholipase C (EC 3.1.4.3) sourced from *Bacillus licheniformis* containing the phospholipase C gene from *Bacillus thuringiensis*, as a processing aid in accordance with the Code.

Item [2] of the Schedule to the variation would amend the dot point list of protein engineered variants of enzymes in the note after the table to subsection S18—9(3) by omitting the following entry in that list:

- Maltogenic α-amylase, protein engineered variant;

and substituting that entry with:

- Maltogenic α-amylase, protein engineered variant;
- Phospholipase C, protein engineered variant;

The Note after the table to subsection S18—9(3) relates to protein engineered variants of enzymes, which are listed in the table to subsection S18—9(3) as processing aids permitted to be used for specific technological purposes. The Note explains that if such an enzyme is used as a processing aid, the resulting food may have as an ingredient a food produced using gene technology, and the requirements relating to foods produced using gene technology in the Code will apply (see Standard 1.2.1 and Standard 1.5.2). The Note then lists the relevant enzymes.

If approved, the effect of the amendment proposed in item [2] would be to include 'Phospholipase C, protein engineered variant' in that list, in alphabetical order.