18 December 2025
373-25

Approval report – Application A1292

Phospholipase C from *Bacillus licheniformis* as a processing aid

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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 C from *Bacillus licheniformis* containing the phospholipase C gene from *Bacillus thuringiensis* as a processing aid in degumming vegetable fats and oils.

On 15 July 2025 FSANZ sought submissions on a draft variation and published an associated report. FSANZ received two submissions.

FSANZ approved the draft variation on 10 December 2025. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 18 December 2025.

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

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

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Supporting document

The following document which informed the assessment of this application is available on the FSANZ website[2]:

SD Risk and technical assessment report (at approval)[3]

The published submissions from the call for submissions can be found on the A1292 Consultation Hub page.

[2] https://www.foodstandards.gov.au/food-standards-code/applications/a1292-phospholipase-c-bacillus-licheniformis-processing-aid

[3] Minor editorial changes were made to the SD following the call for submissions.

Executive summary

Food Standards Australia New Zealand (FSANZ) received an application from Novozymes Australia Pty Ltd to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of the enzyme phospholipase C (EC 3.1.4.3) from a strain of *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 concluded there are no public health and safety concerns about phospholipase C from *B. licheniformis* under the proposed use conditions. 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 must comply when added to food in accordance with the Code or sold for use in food.

Following the assessment and the preparation of the draft variation, FSANZ called for submissions regarding the draft variation. FSANZ received two submissions, one from a jurisdiction and one from an individual. The jurisdiction supported approval of the draft variation. The individual did not support approval of the draft variation.

Based on the information above and on other relevant considerations set out in this report, FSANZ has approved the draft variation to the Code proposed at the call for submissions with certain amendments (see below).

The approved draft variation will amend Schedule 18 of the Code by listing this enzyme and its associated technological purpose in the table to subsection S18—9(3). This table lists substances (including enzymes) permitted for use as processing aids for specific technological purposes.

Removal of references to 'protein engineered' from the draft variation is required after recent Code changes under Proposal P1055 *Definitions for gene technology and new breeding techniques*, *a new definition for 'genetically modified food'*. Taking this into account, FSANZ has approved the draft variation proposed in the call for submissions, with these amendments:

- removing the reference to 'protein engineered' in item [1] of the draft variation proposed at the call for submissions, and
- removing item [2] of that draft variation, which would amend the dot point list of protein engineered variants of enzymes in the note after the table to subsection S18—9(3).

The effect of the approved draft variation will be to permit the use 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. This permission will be subject to the condition that the enzyme's maximum permitted level or amount in food must be an amount consistent with Good Manufacturing Practice.

1 Introduction

1.1 The applicant

The applicant is Novozymes Australia Pty 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 the enzyme phospholipase C (EC 3.1.4.3) from *Bacillus licheniformis*[4] containing the phospholipase C gene from *Bacillus thuringiensis* as a processing aid in the degumming of vegetable fats and oils.

Phospholipase C is used as a processing aid in hydrolysing phosphatides (phosphatidylcholine and phosphatidylethanolamine) to water-soluble esters (phosphorylcholine and phosphorylethanolamine, respectively). The latter hydrolysis product is subsequently solubilised in water and removed by centrifugation – a process known as degumming. Benefits of this process include increased oil yields, improved physical stability and processing cost reductions.

The applicant has indicated that the enzyme is to be used at minimum levels necessary to achieve the desired effect, according to Good Manufacturing Practice (GMP).[5]

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 cannot contain, 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

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[4] Under recent Code changes following Proposal P1055 – Definitions for gene technology and new breeding techniques, a new definition for 'genetically modified food' was adopted that excludes substances used as a processing aid. As a result of this change, enzyme processing aids produced from organisms that have been genetically modified to contain novel DNA are no longer subject to Code requirements for genetically modified food.

[5] GMP is defined in section 1.1.2—2 of the Code as follows: ***GMP*** *or* ***Good Manufacturing Practice****, with respect to the addition of substances used as food additives and substances used as processing aids to food, means the practice of:*

(a) limiting the amount of substance that is added to food to the lowest possible level necessary to accomplish its desired effect; and

(b) to the extent reasonably possible, reducing the amount of the substance or its derivatives that:

*(i) remains as a *component of the food as a result of its use in the manufacture, processing or packaging; and*

(ii) is not intended to accomplish any physical or other technical effect in the food itself;

(c) preparing and handling the substance in the same way as a food ingredient.

- 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 the table to section S18—9.

Phospholipase C is not listed in Schedule 18. Therefore, the proposed use of this enzyme 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)[6], 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 in the Code.

Paragraphs 1.2.4—3(2)(d) and (e) exempt processing aids from the requirement to be declared in the statement of ingredients, unless other requirements apply.

1.4 International standards

1.4.1 International

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

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

preparations established by JECFA and Food Chemicals Codex.

In addition, there is a Codex guideline—Guidelines on Substances used as Processing Aids (CAC/GL 75-2010)—which sets out general principles for the safe use of substances used as processing aids, including that these substances shall be used under GMP conditions.

1.4.2 Overseas regulations

The enzyme has been evaluated as safe under the intended conditions of use by the European Food Safety Authority (EFSA) and has been approved for use in Denmark, Mexico, Brazil and France. The United States Food and Drug Administration (US FDA) has responded that it has 'no questions' to Novozymes' Generally Recognized as Safe (GRAS) notification (GRN No. 698).

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 in accordance with the FSANZ Act.

1.7 Decision

Following assessment, FSANZ prepared a draft variation amending the Code to permit the use of 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. That permission was also made subject to the condition that the maximum permitted level or amount of enzyme that may be present in food must be consistent with GMP.

For the reasons outlined in this report and after consideration of submissions received during the consultation period, FSANZ decided to approve that draft variation with the following amendments:

- removing the reference to 'protein engineered' from item [1] of the draft variation, and
- removing item [2] of the draft variation, which would amend the dot point list of protein engineered variants of enzymes in the note after the table to subsection S18—9(3).

The above amendments to the draft variation reflect recent Code changes under Proposal P1055. Previously, the term 'protein engineered' was used to indicate that the enzyme's amino acid sequence had been changed to a sequence not found in nature, meaning the enzyme was considered a 'novel protein' for GM labelling. Given the exclusion of processing aids from the new definition for 'genetically modified food', GM labelling requirements do not apply; therefore, it is no longer necessary to refer to the enzyme as 'protein engineered'. In addition, the note to the table to subsection S18—9(3) has been removed as a result of P1055.

Despite those amendments, the approved draft variation will have the effect of permitting the use of this enzyme as a processing aid in degumming vegetable fats and oils.

The approved draft variation takes effect on gazettal and is in Attachment A.

The related explanatory statement is in Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

The draft variation to the Code (at the consultation stage) is in Attachment C.

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ received a total of two submissions to the call for submissions between 15 July 2025 and 26 August 2025. The submissions are publicly available on the FSANZ website A1292 Consultation hub page.

The first submission was from a private individual, who did not support approval of the draft variation because of a general objection to the use of genetically modified substances in food. FSANZ noted this objection, however, the issue or objection raised was out of scope for this application because the enzyme is not considered a GM food for Code purposes.

The second submission was made by New Zealand Food Safety, which supported the approval of the draft variation. They noted that the proposed draft variation will need to be amended following gazettal of changes to the Code under Proposal P1055. Accordingly, FSANZ has amended the draft variation to reflect these changes (see Section 1.7 above).

2.2 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 *B. licheniformis* containing the phospholipase C gene from *B. thuringiensis* performs its typical technological function in degumming vegetable fats and oils during processing. Crude oils contain phospholipids, which impart undesirable qualities to oils. Removing these through a degumming step improves clarity, flavour, and shelf life.

The enzyme does not perform a technological function in food for sale. Therefore, it functions as a processing aid for the purposes of the Code.

2.3 Safety assessment

FSANZ assessed the public health and safety risks associated with the proposed use of phospholipase C from *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.

Phospholipase C showed no evidence of genotoxicity. There were no treatment-related clinical signs or adverse effects in a 13-week oral toxicity study in rats. The no observed adverse effect level (NOAEL) in this study was 714 mg total organic solids (TOS)/kg bw/day, the highest dose tested. 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 of approximately 7100. The enzyme is not expected to pose a food allergenicity concern.

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.

2.4 Risk management

Following assessment, FSANZ prepared a draft variation and called for submissions on that draft variation for a period of six weeks.

The risk management options available to FSANZ following the call for submissions are to:

- approve the draft variation proposed following assessment, or
- approve that draft variation subject to such amendments as FSANZ considers necessary, or
- reject that draft variation.

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

Having regard to the submissions received and, for the reasons set out in this report, FSANZ considers it appropriate to approve the draft variation proposed following assessment, with amendments to:

- remove the reference to 'protein engineered' in item [1] of the draft variation proposed at the call for submissions, and
- remove item [2] of that draft variation, which contained an amendment to the dot point list of protein engineered variants of enzymes in the note after the table to subsection S18—9(3).

The effect of the approved draft variation will be to permit the proposed use of phospholipase C from *B. licheniformis* containing the phospholipase C gene from *B. thuringiensis*, as a processing aid in accordance with the Code.

The permission to use this phospholipase C is subject to the condition that the maximum permitted level or amount of enzyme that may be present in food must be consistent with GMP.

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

2.4.1 Regulatory approval for processing aids

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

2.4.2 Enzyme nomenclature, source microorganism nomenclature and specifications

The International Union of Biochemistry and Molecular Biology (IUBMB)[7] 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 will have to comply with those specifications when added to food in accordance with the Code or sold for use in food.

2.4.3 Labelling

The labelling provisions in the Code will apply to foods for sale that are manufactured using

[7] https://iubmb.org/

this enzyme as a processing aid (see section 1.3.3 above).

2.4.4 Risk management conclusion

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

The enzyme and its associated technological purpose will 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 will have to be an amount consistent with GMP.

2.5 Risk communication

2.5.1 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 and Food Standards News.

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

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

2.6 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.

2.6.1 Section 29

2.6.1.1 Consideration of costs and benefits

FSANZ had 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 (as per paragraph 29(2)(a) of the FSANZ Act).

FSANZ has assessed that a Regulation Impact Statement is not required for this application. This is because applications relating to permitting the use of processing aids that have been determined to be safe are considered to be minor in impact and deregulatory in nature as their use will be voluntary if the draft variation concerned is approved.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the potential positives and negatives of moving away from the status quo by permitting the use of phospholipase C from *B. licheniformis* containing the phospholipase C gene from *B. thuringiensis* as a processing aid in degumming vegetable fats and oils.

Costs and benefits of permitting the proposed use of this enzyme

If the draft variation is approved, industry might benefit from several improvements and efficiencies from the use of this enzyme. Due to the voluntary nature of the permission, industry would only use this enzyme as proposed where they believe a net benefit exists for

them.

If industry experiences cost savings because of using this enzyme, industry might pass on some of the cost savings to consumers.

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

Conclusions from cost benefit considerations

FSANZ's assessment at the call for submissions stage was that the direct and indirect benefits that would arise from permitting phospholipase C from *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. No further information was received during the consultation process that changed that assessment.

2.6.1.2 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.

2.6.1.3 Any relevant New Zealand standards

The standards in the Code that 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.

2.6.1.4 Any other relevant matters

Other relevant matters are considered below.

2.6.2 Subsection 18(1)

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

2.6.2.1 Protection of public health and safety

FSANZ undertook a safety assessment (see section 2.3 above and the SD), which concluded there were no public health and safety concerns with permitting the proposed use of this phospholipase C from *B. licheniformis* containing the phospholipase C gene from *B.* thuringiensis as a processing aid.

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

Existing labelling requirements will apply to this enzyme and its proposed use in accordance with the Code to enable consumers to make informed choices (see sections 1.3.3 and 2.4.3 above).

2.6.2.3 The prevention of misleading or deceptive conduct

There were no issues relevant to this objective.

2.6.3 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 information and 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 will have to comply when added to food in accordance with the Code or sold for use in food.

Also, as noted in section 1.4.1 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**

As stated in section 1.4.2 of this report, the enzyme has been evaluated as safe by EFSA, self-affirmed as GRAS in the USA and approved for use in several other countries. Australia and New Zealand food industries will remain competitive with international markets where approval for the use of the enzyme is granted. This will also help foster continued innovation and improvements in food manufacturing techniques and processes.

The conclusion of the risk and technical assessment was that there are no public health and safety concerns associated with the proposed use of this enzyme as a 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 for the applications proposed by the applicant. Ultimately, Australian and New Zealand food industries will make their own economic decisions, taking into account the costs and benefits of using the new enzyme, to determine if it is of benefit to their particular business.

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

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

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

The Ministerial Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*[8] 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 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.

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

Attachments

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

B. Explanatory Statement

C. Draft variation to the Australia New Zealand Food Standards Code (call for submissions).

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

Food Standards (Application A1292 – Phospholipase C from *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* 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 (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

Attachment B – Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1292 – Phospholipase C from* 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 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. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation—the *Food Standards (Application A1292 – Phospholipase C from* Bacillus licheniformis *as a processing aid) Variation* (the approved draft variation).

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

2. Variation will be 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.

The 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.

3. Purpose

The Authority has approved a draft variation to amend the table to subsection S18—9(3) of the Code to permit the use 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.

This permission is 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 approved 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 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 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 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary.

FSANZ called for submissions on the draft variation between 15 July and 26 August 2025. Further details of the consultation process, the issues raised during consultation and by whom, and the Authority's response to these issues are available in an approval report published on the Authority's website at www.foodstandards.gov.au.

A regulation impact statement (RIS) was not prepared. FSANZ's assessment was that a RIS was not required for this application. This was on the basis that the application was minor and deregulatory in nature. It sought to permit the use of a processing aid found to be safe and that use is voluntary.

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

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

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1292 – Phospholipase C from* 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 inserts a new entry, in alphabetical order, into the table to subsection S18—9(3) of the Code.

The new entry consists of the following enzyme in column 1 of the table:

- 'Phospholipase C (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 is prescribed in column 2 of the table. The prescribed purpose is 'For use in degumming vegetable fats and oils.'

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

The effect of the proposed amendment in item [1] is to permit the proposed use 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.

Attachment C – 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;