18 December 2025
373-25

Approval report – Application A1293

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

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Food Standards Australia New Zealand (FSANZ) has assessed an application submitted by Novozymes Australia Pty Ltd to amend the Australia New Zealand Food Standards Code to permit the use of the enzyme phosphoinositide phospholipase C as a processing aid in degumming vegetable fats and oils.

On 2 September 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 Application A1293 page on the FSANZ website[2]:

SD1 Risk and technical assessment report (unchanged at approval)

The published submissions from the call for submissions can be found on the Application A1293 Consultation Hub page.

[2] https://www.foodstandards.gov.au/food-standards-code/applications/a1293-phosphoinositide-plc-bacillus-licheniformis-processing-aid

Executive summary

Novozymes Australia Pty Ltd applied to Food Standards Australia New Zealand (FSANZ) to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of the enzyme phosphoinositide phospholipase C (EC 3.1.4.11) as a processing aid in degumming vegetable fats and oils. The enzyme is produced by *Bacillus licheniformis* containing the phosphoinositide phospholipase C gene from *Pseudomonas* sp. 62186.

FSANZ found that the enzyme is used in a way that is technologically justified. It does not perform a technological function in the food for sale, therefore functioning as a processing aid for the purposes of the Code. There are existing identity and purity specifications in the Code that the enzyme must meet when used in food or sold for use in food.

No public health and safety concerns were identified with the use of phosphoinositide phospholipase C produced by this *B. licheniformis* under the proposed conditions of use.

Following assessment, FSANZ called for submissions on a draft variation to the Code on 2 September 2025, with a four-week consultation period. Two submissions were received, one in support of the draft variation, and one from a private individual not in support of current labelling requirements that exempt processing aids from the requirement to be declared in the statement of ingredients.

Based on this information and other relevant considerations set out in this report, FSANZ has approved the draft variation proposed at the call for submissions.

The amendment will list phosphoinositide phospholipase C (EC 3.1.4.11), sourced from *B. licheniformis* containing the phosphoinositide phospholipase C gene from *Pseudomonas* sp. 62186 and its associated technological purpose in the table to subsection S18—9(3) of the Code. This table lists substances (including enzymes) permitted to be used as processing aids for specific technological purposes. The enzyme will have to be used at a level in accordance with Good Manufacturing Practice.

The effect of this amendment will be to permit the use of this enzyme as a processing aid in degumming vegetable fats and oils in accordance with the Code.

1 Introduction

1.1 The applicant

The applicant is Novozymes Australia Pty Ltd, an international biotechnology company.

1.2 The application

The purpose of the application was to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of the enzyme phosphoinositide phospholipase C (EC 3.1.4.11) as a processing aid in degumming vegetable fats and oils.

The enzyme is produced by *Bacillus licheniformis* containing the gene for phosphoinositide phospholipase C from *Pseudomonas* sp. 62186[3].

Phosphoinositide phospholipase C is used as a processing aid in hydrolysing phosphatidylinositol (a type of phospholipid) to form 1,2-diacylglycerol and inositol phosphate. 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 would be used in accordance with Good Manufacturing Practice (GMP).[4]

1.3 The current Standard

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

1.3.1 Permitted use

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 the use of that substance 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

[3]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.

[4]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, and
- it is a substance listed in Schedule 18 or identified in section S16—2 as an additive permitted at GMP.

Enzymes of microbial origin permitted to be used as processing aids are listed in the table to subsection S18—4(5) or table to subsection S18—9(3) of Schedule 18, 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.

Phosphoinositide phospholipase C from *B*. *licheniformis* containing the phosphoinositide phospholipase C gene from *Pseudomonas* sp. 62186 is not listed in the table to subsection S18—9(3) and so is not currently a permitted processing aid for use in food processing.

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 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 and the United States Pharmacopeial Convention Food Chemicals Codex. These include general specifications for enzyme preparations used in food processing for identity and purity parameters.

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. In terms of food safety, the relevant international standard setting body is the Codex Alimentarius Commission (Codex).

In contrast to food additives, there is no Codex ‘general standard’ for processing aids. However, as noted in section 1.3.2 of this report, there are internationally recognised specifications for enzyme preparations established by JECFA and Food Chemicals Codex.

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

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) provided a 'no questions' response to Novozyme's GRAS notification (GRN No. 728).

1.5 Reasons for accepting application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) and
- 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 drafted a variation amending the Code to permit the use of the enzyme as a processing aid in degumming vegetable fats and oils.

For the reasons outlined in this report and after consideration of submissions received during the consultation period, FSANZ approved the draft variation without change. The approved draft variation takes effect on gazettal and is at Attachment A.

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

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions on a draft variation to the Code from 2 September – 30 September 2025. Two submissions were received (see Table 1 below).

The submissions are publicly available on the FSANZ website Application A1293 Consultation Hub page.

Table 1: Summary of issues

Issue	Raised by	FSANZ response
Unsupportive. It should be mandatory for processing aids to be declared in the ingredient list of labels as traces remain, impacting highly sensitive people. Trust in labelling is not possible when processing aids do not need to be declared.	Individual (GS)	FSANZ understands that food allergies, intolerances and sensitivities are of concern for some individuals, and that food labels can be a useful source of information to assist these individuals in avoiding certain substances. Regarding allergies, as noted in Section 1.3.3 above, paragraphs 1.2.4—3(2)(d) and (e) of the Code exempt processing aids from the requirement to be declared in the statement of ingredients. However, this exemption does not apply if a processing aid contains an allergen (as well as cereals that contain gluten or added sulphites). In that case, paragraph 1.2.3—6(2)(a) of the Code requires the statement of ingredients to include the words 'processing aid' along with a declaration of the allergen. This protects the health and safety of consumers with a food allergy, so they can identify if an allergen is present in the food. A list of the food and ingredients that need to be declared in the ingredient list when they are present can be found on the FSANZ website[5]. FSANZ's assessment, based on the best available scientific evidence, is that use of this substance in the manner proposed will pose no public health and safety risk. This includes allergenic risk. See section 2.3 below. FSANZ remains attentive to consumer reports of food sensitivities and intolerances. Additional information on intolerances and allergies can be found on the FSANZ website[6].
Supportive.	New Zealand Food Safety	Noted.

2.2 Food technology assessment

FSANZ undertook a food technology assessment to determine whether the processing aid achieves its technological purpose as described in the application (see SD1).

FSANZ concluded:

- the proposed use of the enzyme was consistent with its function, specifically, the hydrolysis of phospholipids, facilitating the removal of gum impurities during vegetable fat and oil refining
- the enzyme functions as a processing aid for the purposes of the Code and does not perform a technological purpose in the food for sale
- the evidence presented to support its proposed use provides adequate assurance that its

[5] Allergen labelling for consumers | Food Standards Australia New Zealand
[6] Food allergies and intolerances | Food Standards Australia New Zealand

use, in the quantity and form proposed to be used (which must be consistent with GMP), is technologically justified.

There are relevant identity and purity specifications in the Code with which the enzyme will have to comply when it is added to food in accordance with the Code or sold for use in food.

2.3 Risk assessment

FSANZ assessed the public health and safety risks associated with the enzyme and its use as a processing aid (see SD1). A summary of this risk assessment is provided below.

The microbiological assessment undertaken by FSANZ did not identify any public health and safety concerns associated with the use of the production organism, *B. licheniformis,* as a source of phosphoinositide phospholipase C. It is neither pathogenic nor toxigenic. Analysis of the production strain confirmed the presence and stability of the inserted DNA.

Sufficient information was provided by the applicant to assess the safety of the enzyme. Bioinformatics analysis found no significant homology between it and any known toxins or allergens. The enzyme preparation is not expected to pose a food allergenicity concern under the proposed conditions of use.

The enzyme showed no evidence of genotoxicity *in vitro*. The no observed adverse effect level (NOAEL) in a 13-week oral toxicity study in rats was 194.5 mg total organic solids (TOS)/kg body weight (bw)/day.

The theoretical maximum daily intake (TMDI) of the TOS from the enzyme preparation was calculated to be 0.01 mg TOS/kg bw/day. A comparison of the NOAEL and the TMDI gave a Margin of Exposure (MOE) of approximately 19,000.

Based on the large MOE, FSANZ concluded that an acceptable daily intake (ADI) 'not specified' was appropriate.

2.4 Risk management

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

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

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

The conclusions from the technical and risk assessment were that the proposed use of phosphoinositide phospholipase C as a processing aid is technologically justified and there were no 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 (Attachment A).

Risk management considerations for this application relating to the regulatory approval, nomenclature, specifications and labelling 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 the enzyme as a processing aid in degumming vegetable fats and oils. The express permission also provides the permission for the enzyme's potential presence in the food for sale (Attachment A).

2.4.2 Enzyme nomenclature, source microorganism nomenclature and specifications

The International Union of Biochemistry and Molecular Biology (IUBMB) lists the accepted name 'phosphoinositide phospholipase C' for the enzyme EC 3.1.4.11 (see section 2.1 of SD1). This is the name used in the approved draft variation.

Nomenclature for the host and donor organisms – *Bacillus licheniformis* and *Pseudomonas* sp. 62186, respectively – is in accordance with accepted international norms for bacterial taxonomy.

There are relevant identity and purity specifications in primary sources of specifications listed in Schedule 3 of the Code for enzyme preparations used in food processing (refer to section 1.3.2 of this report).

2.4.3 Labelling

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

2.4.4 Risk management conclusion

The risk management conclusion is to permit the enzyme phosphoinositide phospholipase C (EC 3.1.4.11) produced by *B. licheniformis* containing the phosphoinositide phospholipase C gene from *Pseudomonas* sp. 62186 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 must be an amount consistent with GMP. The express permission for the enzyme to be used as a processing aid in Schedule 18 of the Code will also provide the permission for the enzyme's potential presence in the food for sale.

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 FSANZ 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 who made 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

2.6.1 Section 29

2.6.1.1 Consideration of costs and benefits

FSANZ assessed the costs and benefits of the proposed amendment to the Code to permit the use of the enzyme phosphoinositide phospholipase C (EC 3.1.4.11) and concluded the benefits are likely to outweigh the costs. The reasons for this conclusion are outlined below.

Background to the cost and benefit analysis

Section 29 of the FSANZ Act requires FSANZ to have regard to whether costs that would arise from a proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

The purpose of this consideration was to determine if the community, government and industry as a whole is likely to benefit, on balance, from a move from the status quo (where the *status quo* is rejecting the application).

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

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 is minor and deregulatory in nature. It seeks to permit the use of a processing aid found to be safe and that use is voluntary. This position is consistent with previous advice from the Office of Impact Analysis (OIA23-06225).

Costs and benefits of permitting the proposed use of this enzyme

Industry may benefit from several improvements and efficiencies from the use of this enzyme to refine fats and oils, in the process of manufacturing food. 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 that are already monitored for compliance.

Conclusions from cost benefit assessment

FSANZ's assessment at the call for submissions was that the direct and indirect benefits that would arise from permitting the proposed use of this enzyme as a processing aid would most likely outweigh any 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 as a result 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 processing aids 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 risk and technical assessment and concluded there were no public health and safety concerns associated with the proposed use of this enzyme (see section 2.3 of this report and SD1).

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 processing aid in accordance with the Code to enable consumers to make informed choices (see sections 1.3.3 and 2.4.3 of this report).

2.6.2.3 The prevention of misleading or deceptive conduct

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

2.6.3 Subsection 18(2) considerations

FSANZ also had regard to:

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

FSANZ used the best available scientific evidence to conduct the risk analysis, which is provided in SD1. The applicant submitted a dossier of information and scientific literature as part of their 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**

In terms of food safety, the relevant international standard setting body is Codex. There is no Codex 'general standard' for enzymes, however as noted in section 1.3.2 of this report, 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.

There is also a Codex guideline, *Guidelines on Substances used as Processing Aids* (CAC/GL 75-2010), which sets out general principles for the safe use of substances used as processing aids, including that substances used as processing aids shall be used under conditions of GMP (see section 1.4.1 of this report).

- **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 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, the 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 consideration.

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

The Ministerial Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*[7] includes specific order policy principles for substances added to achieve a solely technological function, such as processing aids. These specific order policy principles state that permission should be granted where:

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the 'stated purpose')
- the addition of the substance to food is safe for human consumption
- the amounts added are consistent with achieving the technological function
- the substance is added in a quantity and a form which is consistent with delivering the stated purpose
- no nutrition, health or related claims are to be made in regard to the substance.

FSANZ determined that permitting the proposed use of this enzyme is consistent with these specific order policy principles for 'technological function'. All other relevant requirements of the policy guideline are similarly met.

Attachments

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

[7] https://www.foodregulation.gov.au/resources/publications/policy-guideline-addition-substances-other-vitamins-and-minerals

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

Food Standards (Application A1293 – Phosphoinositide 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]

[To be signed by the 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 A1293 – Phosphoinositide 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:

Phosphoinositide phospholipase C (EC 3.1.4.11) sourced from *Bacillus licheniformis* containing the phosphoinositide phospholipase C gene from *Pseudomonas* sp. 62186	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 A1293 – Phosphoinositide 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 A1293 which sought to amend the Code to permit the use of the enzyme phosphoinositide phospholipase C (EC 3.1.4.11), from *Bacillus licheniformis* containing the phosphoinositide phospholipase C gene from *Pseudomonas* sp. 62186*,* 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 A1293 – Phosphoinositide 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 is a legislative instrument

The approved draft variation is a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and is publicly available on the Federal Register of Legislation (www.legislation.gov.au).

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

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the FMM. The FMM is established under the Food Regulation Agreement and the

international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has approved a draft variation amending the table to subsection S18—9(3) in Schedule 18 of the Code to permit the use of the enzyme phosphoinositide phospholipase C (EC 3.1.4.11) from this *Bacillus licheniformis* 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) and 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 A1293 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 from 2 September – 30 September 2025.

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. This position is consistent with previous advice from the Office of Impact Analysis (OIA23-06225).

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 A1293 – Phosphoinositide 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 will commence 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:

- 'Phosphoinositide phospholipase C (EC 3.1.4.11) sourced from *Bacillus licheniformis* containing the phosphoinositide phospholipase C gene from *Pseudomonas* sp. 62186'

The permitted technological purpose for this enzyme is prescribed in column 2 of the table i.e. 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 amendment is to permit the proposed use of the enzyme phosphoinositide phospholipase C (EC 3.1.4.11) from this *Bacillus licheniformis* as a processing aid in accordance with the Code.