19 December 2022
[223-22]

Approval report – Application A1221

Phospholipase A1 from GM *Aspergillus niger* as a processing aid

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by Novozymes Pty Limited seeking to amend the Australia New Zealand Food Standards Code to permit phospholipase A1 from genetically modified *Aspergillus niger* to be used as a processing aid. This phospholipase A1 would be used in the processing of vegetable oils, specifically the degumming (removal of phosphatides) of those oils.

On 2 August 2022, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received three submissions.

FSANZ approved the draft variation on 14 December 2022. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 19 December 2022.

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

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

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Supporting document

The following supporting document (SD) which informed the assessment of this application is available on the FSANZ website:

SD Risk and Technical Assessment

Executive summary

Novozymes Australia Pty Limited 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 phospholipase A1 from genetically modified (GM) *Aspergillus niger,* as a processing aid during the manufacture of certain foods. The proposed use of this enzyme is in the processing of vegetable oils, specifically the degumming (removal of phosphatides) of those oils, which can then be used in the manufacture of fat-based products.

The phospholipase A1 enzyme is produced by submerged fermentation of *A. niger* containing the phospholipase A1 gene from *Evansstolkia leycettana* (basionym *Talaromyces leycettanus*). The phospholipase A1 gene donor was named in the application as *Talaromyces leycettanus. Talaromyces leycettanus* has however recently been reclassified to *Evansstolkia leycettana* (basionym *Talaromyces leycettanus*).

FSANZ undertook an assessment to determine whether the enzyme achieves the requested technological purpose in the quantity and form proposed to be used, and to evaluate public health and safety concerns associated with its use.

FSANZ concluded that the proposed use of the phospholipase A1 enzyme in the processing of vegetable oils is consistent with its typical function of catalysing the hydrolysis of phospholipids. This converts the phosphatides in vegetable oil to a hydrated gum that can easily be removed before further refining.

Analysis of the evidence provides adequate assurance that the use of the enzyme, in the form and requested amount (i.e. at a level not higher than necessary to achieve the desired enzyme reaction according to Good Manufacturing Practice (GMP)), is technologically justified and has been demonstrated to be effective in achieving the stated purpose.

Phospholipase A1 performs its technological purpose during the processing of vegetable oils and does not perform a technological purpose in the final food, therefore functioning as a processing aid for the purposes of the Code. Relevant general identity and purity specifications for enzyme preparations used in food processing are included in the Code. This enzyme will have to comply with those specifications.

No public health and safety concerns were identified in the assessment of phospholipase A1 from GM *A. niger* under the proposed conditions of use. A microbiological assessment concluded that *A. niger* has a long history of safe use in food and is neither pathogenic nor toxigenic. A biotechnology assessment confirmed the genetic modification is as described and that the inserted gene has been stably introduced. A toxicological assessment combined with a dietary exposure assessment concluded the enzyme is safe under the proposed conditions of use. In the absence of any identifiable hazard, an acceptable daily intake (ADI) 'not specified' is appropriate.

Following assessment and the preparation of a draft variation to the Code, FSANZ called for submissions regarding the draft variation from 2 August to 13 September 2022. FSANZ received three submissions, all supportive of the draft variation.

Based on the information above and on other relevant considerations set out in this report, FSANZ has approved a draft variation to the table to subsection S18—9(3) of the Code to permit the enzyme phospholipase A1 (EC 3.1.1.32) sourced from GM *A. niger* containing the phospholipase A1 gene from *E. leycettana* (basionym *T. leycettanus*) as a processing aid. The enzyme will be permitted for use in the degumming of vegetable oils. This permission is subject to the condition that the maximum permitted level of the enzyme that may be present

in the food is an amount consistent with GMP. The effect of the approved draft variation will be to permit the proposed use of this enzyme as a processing aid in accordance with the Code.

1 Introduction

1.1 The Applicant

The applicant is Novozymes Australia Pty Limited (Novozymes).

1.2 The Application

The applicant is seeking to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of the enzyme phospholipase A1 from genetically modified (GM) *Aspergillus niger,* as a processing aid. The phospholipase A1 enzyme is produced by submerged fermentation of *A. niger* containing the phospholipase A1 gene from *Evansstolkia leycettana* (basionym *Talaromyces leycettanus*). The phospholipase A1 gene donor named in the application is *Talaromyces leycettanus*. Food Standards Australia New Zealand (FSANZ) has assessed the taxonomy of the donor organism and determined the current legitimate name to be *Evansstolkia leycettana* (basionym *Talaromyces leycettanus*) (see Section 3.1.2 of the Supporting Document (SD)). The term 'basionym' means the original name on which the new name is based.

The stated purpose for the enzyme in the application is as a processing aid during the manufacture of edible vegetable oils and fats products. However following subsequent consultation with FSANZ, the applicant clarified that the technological purpose of this enzyme is as a processing aid in the processing of vegetable oils, specifically the degumming (removal of phosphatides) of those oils, which can then be used in the manufacture of fat-based products. The focus of FSANZ's assessment was therefore on the use of the enzyme in the processing of vegetable oils.

The applicant markets a liquid preparation containing this enzyme as the active constituent under the commercial name Quara in other countries where use of the enzyme is permitted (see Section 2.5.3).

The applicant has indicated that the enzyme is to be used at minimum levels necessary to achieve the desired effect, in accordance with Good Manufacturing Practice (GMP).

1.3 The current Standard

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

1.3.1 Permitted use

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

Paragraph 1.1.1—10(6)(c) provides that food for sale cannot contain, as an ingredient or component, a substance 'used as a processing aid' unless that substance's use as a processing aid is expressly permitted by the Code. Section 1.1.2—13 provides that a substance 'used as a processing aid' in relation to a food is a substance used during the course of processing that meets all of the following conditions:

- it is used to perform a technological purpose during the course of processing
- it does not perform a technological purpose in the food for sale, and

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

Standard 1.3.3 and Schedule 18 of the Code list the permitted processing aids. Enzymes of microbial origin permitted to be used as processing aids are listed in the table to subsection S18—4(5) or in the table to subsection S18—9(3) of Schedule 18, depending on whether a technological purpose has been specified. Enzymes of microbial origin listed in the table to subsection S18—4(5) are permitted for use as a processing aid to perform any technological purpose if the enzyme is derived from the corresponding source specified in the table. The table to subsection S18—9(3) lists those substances, including enzymes derived from particular sources, that are permitted to be used as processing aids for specific technological purposes in relation to:

- if a food is specified—that food; or
- if no food is specified—any food.

Additionally, paragraph 1.3.3—11(c) specifies that the substance may only be used as a processing aid if it is not present in the food at greater than the maximum permitted level for that substance indicated in the table to section S18—9.

Paragraph 1.1.1—10(6)(g) requires that the presence as an ingredient or component in a food for sale of a food produced using gene technology must be expressly permitted by the Code. Paragraph 1.5.2—3(b) provides that permission in the Code for use as a processing aid also constitutes the permission required by paragraph 1.1.1—10(6)(g).

Phospholipase A1, from a GM source, is approved for use as a processing aid (subsection S18—4(5)) however not from *A. niger* containing the phospholipase A1 gene from *E. leycettana* (basionym *T. leycettanus*) as requested by the applicant.

1.3.2 Identity and purity requirements

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

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

Section 1.5.2—4 of the Code requires a food for sale that consists of a *genetically modified food*[2] (GM food) or has a GM food as an ingredient to be labelled as 'genetically modified',

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

unless an exemption applies. The label 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. Standard 1.2.1 provides that the requirements imposed by section 1.5.2—4 apply only to foods for retail sale and to foods sold to a caterer.

1.4 International standards

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 Alimentarius 'general standard' for enzymes however, as noted above, there are internationally recognised specifications for enzyme 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 substances used as processing aids shall be used under conditions of GMP.

1.5 Reasons for accepting application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act)
- it related to a matter that warranted the variation of a food regulatory measure.

1.6 Procedure for assessment

The application was assessed under the General Procedure in the FSANZ Act.

1.7 Decision

For reasons set out in this report, FSANZ decided to approve a draft variation amending the Code to permit the use of this enzyme as a processing aid in the degumming of vegetable oils.

The draft variation as proposed following assessment was approved 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 sought public comments on the draft variation included in the call for submissions report between 2 August and 13 September 2022.

b) is listed in Section S26—3 as subject to the condition that its labelling must comply with this section' (*that being section 1.5.2—4*).

FSANZ received three submissions and had regard to all three submissions, all of which were supportive of the draft variation. The submissions were received from:

- New Zealand Food Safety
- New Zealand Food and Grocery Council
- the Victorian Departments of Health and of Jobs, Precincts and Regions.

2.2 Risk assessment

FSANZ has assessed the public health and safety risks associated with phospholipase A1 produced by GM *A. niger* and its proposed use as a processing aid. A summary of this risk assessment is provided below.

The proposed use of this phospholipase A1 as a processing aid in the production of vegetable oils is technologically justified.

No public health and safety concerns were identified in the assessment of phospholipase A1 from GM *A*. *niger* under the proposed conditions of use. A microbiological assessment concluded that *A*. *niger* has a long history of safe use in food and is neither pathogenic nor toxigenic.

A biotechnology assessment confirmed the genetic modification is as described and that the inserted gene has been stably introduced. A toxicological assessment combined with a dietary exposure assessment concluded the enzyme is safe under the proposed conditions of use.

In the absence of any identifiable hazard, an acceptable daily intake (ADI) of 'not specified' is appropriate.

For further details on the risk assessment, refer to the SD – Risk and Technical Assessment.

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.

The conclusions from the risk and technical assessment were that the proposed use of the enzyme is technically justified and there were no safety concerns associated with its proposed use at levels consistent with GMP.

FSANZ therefore considered it appropriate to prepare a draft variation amending the Code to permit the proposed use of this enzyme in the degumming of vegetable oils and called for submissions on the draft variation.

Following the call for submissions and having regard to all submissions received, for the reasons set out in this report, FSANZ considers it appropriate to approve the draft variation proposed following assessment without change (see Attachment A).

Risk management considerations for this application relating to the enzyme and source microorganism nomenclature, specifications and labelling are discussed below.

2.3.1 Regulatory approval for enzymes

FSANZ's assessment confirmed that phospholipase A1 performs its technological purpose during the processing of vegetable oils and it does not perform a technological purpose in the final food. On that basis, the enzyme would function as a processing aid for the purposes of the Code. From the food technology assessment, FSANZ concluded that the proposed use of this enzyme is consistent with its typical function of catalysing the hydrolysis of phospholipids during the processing of vegetable oils. This converts the phosphatides in vegetable oil to a hydrated gum that can easily be removed before further refining. This process is known as 'degumming'. As stated above (Section 1.7), FSANZ has approved a draft variation to permit the use of the enzyme as a processing aid in the degumming of vegetable oils.

The express permission for the enzyme to be used as a processing aid would also provide the permission for its potential presence in the food for sale as a food produced using gene technology. The enzyme is a food produced using gene technology according to the Code as it is derived from 'an organism that has been modified using gene technology' (see subsection 1.1.2—2(3) of the Code)[3].

2.3.2 Enzyme nomenclature, source microorganism nomenclature, and specifications

FSANZ notes that the International Union of Biochemistry and Molecular Biology (IUBMB) uses the accepted name 'phospholipase A_1'. This is the name used in the approved draft variation, explanatory statement, and in existing permissions for phospholipase A1 in Schedule 18. 'Phospholipase A1' has been used in this report and was used by the applicant in the application, without the subscript for the 1.

Nomenclature for the host and gene donor organisms (*A. niger* and *E. leycettana* (basionym *T. leycettanus*), respectively), is in accordance with accepted international norms (see Section 1.2 of this report).

There are relevant identity and purity general specifications for enzyme preparations in two of the primary sources of specifications listed in Schedule 3 of the Code, namely the JECFA Combined Compendium of Food Additive Specifications and the United States Pharmacopeial Convention Food Chemicals Codex (refer to Section 1.3.2 above). As noted in Section 2.2.3 of the SD, the enzyme will have to comply with those identity and purity specifications.

2.3.3 Labelling

The generic labelling provisions in the Code will apply to foods for sale that are manufactured using this processing aid. See Section 1.3.3 above.

2.3.4 Risk management conclusion

The risk management conclusion is to permit the enzyme phospholipase A1 (EC 3.1.1.32) sourced from GM *A. niger* containing the phospholipase A1 gene from *E. leycettana* (basionym *T. leycettanus*), for use as a food processing aid. The enzyme will be listed in the table to subsection S18—9(3) of the Code, which includes enzymes permitted for a specific

[3] 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'.

technological purpose. The technological purpose of this enzyme would be use as a processing aid in the degumming of vegetable oils. The maximum level at which the enzyme may be present in the food will 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 as a food produced using gene technology.

2.4 Risk communication

Consultation is a key part of FSANZ's standards development process.

FSANZ developed and applied a standard communication strategy to this application. The call for submissions was notified via the Food Standards Notification Circular, media release, FSANZ's social media tools and Food Standards News.

The process by which FSANZ considers standards development matters is open, accountable, consultative and transparent. Public submissions were called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options. FSANZ acknowledges the time taken by individuals and organisations to make a submission 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.

2.5 FSANZ Act assessment requirements

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

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

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

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

The purpose of this consideration was to determine if the community, government and industry as a whole is likely to benefit, on balance, from a move from the status quo. This analysis considered permitting the proposed use of the enzyme phospholipase A1 from GM *A. niger* to be used as a processing aid in the degumming of vegetable oils.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measure. In fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the

assessment sought to highlight the likely positives and negatives of moving away from the status quo by permitting the use of the enzyme phospholipase A1 produced from GM *A. niger.*

FSANZ's conclusions regarding costs and benefits of the proposed measure are set out below.

2.5.1.1.1 Costs and benefits of permitting the use of enzyme phospholipase A1 sourced from GM A. niger *as a processing aid*

Industry

The enzyme phospholipase A1 is already available to industry from other production sources. Due to the voluntary nature of the permission, industry will use phospholipase A1 from this additional source, GM *A. niger*, where businesses in the industry believe a net benefit exists for them. An additional source of this enzyme may help industry save on costs of processing vegetable oils.

The applicant advised that use of this enzyme from this source already has approval for various purposes in Denmark, France, Brazil and Mexico. On that basis, approval of this phospholipase A1 in the Code may help some of Australia's and New Zealand's sales in international markets. There may, however, be more competing imports in the domestic market from countries that use this enzyme into the future.

Consumers

Industry may pass cost savings to consumers, where it is cheaper to source phospholipase A1 from GM *A. niger* in production processes.

Government

Permitting the proposed use of this phospholipase A1 may result in a small cost to government in terms of an addition to the current range of processing aids that are monitored for compliance.

Conclusions from cost benefit considerations

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting the proposed use of the enzyme phospholipase A1 from GM *A. niger* as a processing aid in the degumming of vegetable oils most likely outweigh the associated costs. No further information was received during the consultation process that changed that assessment.

2.5.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the application.

2.5.1.3 Any relevant New Zealand standards

The relevant standards apply in both Australia and New Zealand. There are no relevant New Zealand only Standards.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2 Subsection 18(1)

FSANZ 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 the SD) and concluded there were no public health and safety concerns associated with the proposed use of this enzyme.

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 are no issues identified with this application 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 used the best available scientific evidence to conduct the risk analysis. The applicant submitted a dossier of information and scientific literature as part of its application. This dossier, together with other technical and scientific information, was considered by FSANZ in assessing the application. The risk assessment is provided in the SD.

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

There are relevant international specifications for enzyme preparations, being the JECFA Compendium of Food Additive Specifications and the Food Chemicals Codex specifications for enzymes referred to in Section 1.3 of this report, with which this enzyme must comply.

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

The applicant advised that their phospholipase A1 enzyme is currently approved for use as a processing aid in Denmark, France, Brazil and Mexico. Approval for its use will bring Australia and New Zealand into line with other jurisdictions where it is already authorised for use. In this way, Australia and New Zealand will remain competitive with other international markets. This would also help foster continued innovation and improvements in food manufacturing techniques and processes.

The conclusion of the risk assessment is there are no public health and safety concerns associated with the proposed use of the enzyme as a food processing aid. It is therefore appropriate that Australian and New Zealand food industries are given the opportunity to benefit from this alternative enzyme for the application proposed by the applicant.

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

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

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

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

The Ministerial Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*[4] 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

[4] Food regulation website

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

Food Standards (Application A1221 – Phospholipase A1 from GM *Aspergillus niger* 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 Delegate's name and position title]
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 A1221 – Phospholipase A1 from GM* Aspergillus niger *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 A_1 (EC 3.1.1.32) sourced from *Aspergillus niger* containing the phospholipase A_1 gene from *Evansstolkia leycettana* (basionym *Talaromyces leycettanus*)	For use in the degumming of vegetable oils	GMP

Attachment B – Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

The Authority accepted Application A1221 which sought to amend the Code to permit phospholipase A1 from genetically modified *Aspergillus niger* to be used as a processing aid. This phospholipase A1 would be used in the processing of vegetable oils, specifically the degumming (removal of phosphatides) of those oils. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation.

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

2. Variation is a legislative instrument

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

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

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

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 phospholipase A_1 (EC 3.1.1.32) sourced from *Aspergillus niger* containing the phospholipase A_1 gene from *Evansstolkia leycettana* (basionym *Talaromyces leycettanus*) in the degumming of vegetable 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 will prescribe identity and purity specifications for the processing aid to be permitted by the approved draft variation. Section 1.1.1—15 of the Code requires substances used as processing aids to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code. Section S3—2 of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications (FAO JECFA Monographs 23 (2019)) and the United States Pharmacopeial Convention (2020) Food Chemicals Codex (12th edition). These include general specifications for the identity and purity 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 A1221 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 2 August 2022 for a six-week consultation period.

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

6. Statement of compatibility with human rights

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

7. Variation

Item [1] of the Schedule to the variation inserts a new entry, in alphabetical order, into the table to subsection S18—9(3) in Schedule 18. The new entry would consist of the following enzyme in column 1 of the table:

- Phospholipase A_1 (EC 3.1.1.32) sourced from *Aspergillus niger* containing the phospholipase A_1 gene from *Evansstolkia leycettana* (basionym *Talaromyces leycettanus*).

The technological purpose for this enzyme prescribed in column 2 of the table is use in the degumming of vegetable oils. Specifically, the enzyme would be used to catalyse the hydrolysis of phospholipids during the processing of vegetable oils, converting the phosphatides in those oils to a hydrated gum that can be removed before further refining.

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 variation is to permit the proposed use of phospholipase A1 (EC 3.1.1.32) sourced from *Aspergillus niger* containing the phospholipase A_1 gene from *Evansstolkia leycettana* (basionym *Talaromyces leycettanus*) as a processing aid in accordance with the Code.