8 February 2023
230-23

Call for submissions – Application A1227

Alpha-arabinofuranosidase from GM *Trichoderma reesei* as a processing aid

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by Novozymes Australia Pty Limited seeking to amend the Australia New Zealand Food Standards Code to permit alpha-arabinofuranosidase from a genetically modified strain of *Trichoderma reesei* as a processing aid in grain processing and potable alcohol production. FSANZ has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

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

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published as soon as possible after the end of the submission period.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at information for submitters.

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

Submissions should be made in writing; be marked clearly with the word 'Submission.' You also need to include the correct application or proposal number and name. Electronic submissions can be made by emailing your submission to submissions@foodstandards.gov.au. FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 22 March 2023

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.
Questions about making a submission or application and proposal processes can be sent to standards.management@foodstandards.gov.au.

Submissions in hard copy may be sent to the following addresses:

Food Standards Australia New Zealand

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Supporting document

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

SD Risk and technical assessment - Application A1227

Executive summary

Novozymes Australia Pty Limited applied to Food Standards Australia New Zealand (FSANZ) to amend Schedule 18 of the Australia New Zealand Food Standards Code (the Code) to include alpha-arabinofuranosidase (EC 3.2.1.55) as a processing aid for use in grain processing and potable alcohol production. The enzyme is sourced from a genetically modified (GM) strain of *Trichoderma reesei (T. reesei)* containing the alpha-arabinofuranosidase gene from *Talaromyces pinophilus (T. pinophilus).*

FSANZ has undertaken an assessment to determine whether the enzyme achieves its technological purpose in the quantity and form proposed to be used and to evaluate any public health and safety concerns that may arise from the use of this enzyme.

FSANZ concludes that the proposed use of alpha-arabinofuranosidase in grain processing and potable alcohol production is technologically justified for use at levels consistent with Good Manufacturing Practice (GMP). Analysis of the evidence provides adequate assurance that the use of this enzyme, in the quantity and form proposed, is justified.

No public health and safety concerns were identified in the assessment under the proposed conditions of use. In the absence of any identifiable hazard, an acceptable daily intake (ADI) of 'not specified' is appropriate.

FSANZ has therefore prepared a draft variation to the Code which, if approved, would list the enzyme alpha-arabinofuranosidase (EC 3.2.1.55) sourced from *T. reesei* containing the alpha-arabinofuranosidase gene from *T. pinophilus* in the table to subsection S18—9(3) of the Code as a permitted processing aid. The enzyme would be permitted for use in grain processing and potable alcohol production. This permission would be subject to the condition that the maximum permitted level of the enzyme used is an amount consistent with GMP.

FSANZ seeks submissions on the draft variation.

1 Introduction

1.1 The applicant

The applicant is Novozymes Australia Pty Limited (Novozymes), a manufacturer of enzymes, microorganisms and precision proteins.

1.2 The application

The applicant is seeking to amend the the Australia New Zealand Food Standards Code (the Code) to include alpha-arabinofuranosidase (EC 3.2.1.55) from a genetically modified (GM) strain of *Trichoderma reesei (T. reesei)* as a processing aid. The enzyme is sourced from a GM *T. reesei* containing the alpha-arabinofuranosidase gene from *Talaromyces pinophilus (T. pinophilus).*

The intended purpose for use of the enzyme is in grain processing and potable alcohol production.

The applicant has stated the enzyme is to be used at minimum levels necessary to achieve the intended technological purpose, 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) of the Code 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 processing that meets all the following conditions:

- it is used to perform a technological purpose during processing
- it does not perform a technological purpose in the food for sale, 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).

Alpha-arabinofuranosidase from *Aspergillus niger* is already permitted to be used as a processing aid by the Code, but not from *T. reesei* containing the alpha-arabinofuranosidase gene from *T. pinophilus* 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 for identity and purity parameters.

1.3.3 Labelling requirements

Subsection 1.1.1—10(8) of the Code 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*[1] (GM food) or has a GM food as an ingredient to be labelled as 'genetically modified' 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. In these circumstances, the requirements imposed by section 1.5.2—4 apply only to foods for retail sale and to foods sold to a caterer in accordance with Standard 1.2.1.

[1] Section 1.5.2—4(5) defines ***genetically modified food*** to mean a '*food produced using gene technology that
a) contains novel DNA or novel protein; or
b) is listed in Section S26—3 as subject to the condition that its labelling must comply with this section' (*that being section 1.5.2—4*).

1.4 International standards

In developing food regulatory measures, Food Standards Australia New Zealand (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 is being assessed under the general procedure in the FSANZ Act.

2 Summary of the assessment

2.1 Risk assessment

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

The proposed use of this alpha-arabinofuranosidase as a processing aid in grain processing and potable alcohol production is technologically justified.

No public health and safety concerns were identified in the assessment under the proposed conditions of use. A microbiological assessment concluded that the GM *T. reesei* host strain is neither pathogenic nor toxigenic, and a biotechnology assessment confirmed the presence and stability of the inserted DNA.

A toxicological assessment combined with a dietary exposure assessment concluded the enzyme is safe under the proposed conditions of use. Bioinformatics analysis confirmed that the produced enzyme has no significant similarity with known toxins or food allergens.

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 Supporting Document (SD) – Risk and Technical Assessment Application A1227.

2.2 Risk management

The risk management options available to FSANZ after assessment were to either:

- reject the application, or
- prepare a draft variation of the Code.

For the reasons set out in this report and the SD, FSANZ decided to prepare a draft variation to the Code (Attachment A) to permit the enzyme alpha-arabinofuranosidase (EC 3.2.1.55) from a GM strain of *T. reesei* containing the alpha-arabinofuranosidase gene from *T. pinophilus* to be used as a processing aid in grain processing and potable alcohol production.

If approved, the proposed permission would be subject to the condition that the maximum permitted level of this enzyme that may be present in the food is consistent with GMP.

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

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

2.2.1 Regulatory approval for enzymes

Alpha-arabinofuranosidase performs its technological purpose during grain processing and potable alcohol production and does not perform a technological purpose in the final food. On that basis, if the draft variation is approved, the enzyme would function as a processing aid for the purposes of the Code. Based on the food technology assessment, FSANZ concluded that the proposed use of this enzyme is consistent with its typical function of catalysing the hydrolysis of arabinosidic linkages in arabinoxylan chains for further processing.

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)[2].

2.2.2 Nomenclature and specifications

The International Union of Biochemistry and Molecular Biology (IUBMB) uses the accepted name 'Non reducing end α-L-arabinofuranosidase.' The name used in the existing permission in s18-4(5) of the Code is 'α-Arabinofuranosidase'. Arabinofuranosidase was used by the applicant. Although 'α-Arabinofuranosidase' is another name listed in IUBMB and used for the existing permission, alpha-arabinofuranosidase is the name used in this report for ease of reading and accessibility considerations. The proposed draft variation includes the name α-Arabinofuranosidase as used for the existing permission in subsection S18-4(5).

Nomenclature for the host and gene donor organisms (*Trichoderma reesei* and *Talaromyces pinophilus*) is in accordance with accepted international norms (see Section 1.2 of this report).

[2] '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'.

There are relevant identity and purity specifications for the enzyme in two of the primary sources of specifications listed in Schedule 3, 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).

2.2.3 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 above).

2.2.4 Risk management conclusion

The risk management conclusion is to permit the enzyme alpha-arabinofuranosidase (EC 3.2.1.55) sourced from a GM strain of *T. reesei* containing the alpha-arabinofuranosidase gene from *T. pinophilus* for use as a food processing aid. If the draft variation is approved, the permission would be listed in the table to subsection S18—9(3) of the Code, which includes enzymes permitted for a specific technological purpose. The technological purpose of this enzyme would be as a processing aid in grain processing and for potable alcohol production. The maximum level at which the enzyme may be present in the food would 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 would also provide the permission for the enzyme's potential presence in the food for sale as a food produced using gene technology.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a standard communication strategy to this application. All calls for submissions are notified via the Food Standards Notification Circular, media release, FSANZ's social media channels and Food Standards News.

The process by which FSANZ approaches standards development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options.

The draft variation will be considered for approval by the FSANZ Board taking into account all public comments received from this call for submissions.

2.3.2 World Trade Organization (WTO)

As members of the WTO, Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

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

Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

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

2.4.1 Section 29

2.4.1.1 Consideration of costs and benefits

The Office of Impact Analysis[3] granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for the applications relating to processing aids (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting new processing aids is deregulatory as their use will be voluntary if the application is approved. This standing exemption relates to the introduction of a food to the food supply that have been determined to be safe.

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

The purpose of this consideration is to determine if the community, government, and industry is likely to benefit, on balance, from a move from the status quo (i.e., rejecting the application). This analysis considers permitting the use of the enzyme alpha-arabinofuranosidase, sourced from the GM strain of *T. reesei* in the processing of grains and potable alcohol production.

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 proposed use of the enzyme sourced from the GM strain of *T. reesei.*

FSANZ's conclusions regarding the costs and benefits of the proposed measure are set out below. However, information received from this Call for Submissions, may result in FSANZ arriving at a different conclusion.

2.4.1.1.1 Costs and benefits of permitting the use of an alpha-arabinofuranosidase enzyme sourced from this GM strain of T. reesei *as a processing aid*

Consumers

Consumers may benefit from a greater availability of foods. Industry may pass on some of any cost reductions onto consumers through lower prices.

Industry

Due to the voluntary nature of the permission, industry will only use the enzyme where they believe a net benefit exists for them. Industry may benefit from having additional choice available to them in the processing of grains, and potable alcohol production.

The enzyme is approved in other countries including Brazil, Denmark, and Mexico, which

[3] Formerly known as the Office of Best Practice Regulation (OBPR)

may be an opportunity for Australia and New Zealand industries, although there may be competing imports from these countries into the domestic market.

Government

Permitting the proposed use of this arabinofuranosidase enzyme may result in a small and inconsequential cost to government in terms of adding it to the current range of processing aids that are monitored for compliance.

Conclusions from cost benefit considerations

The direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the application outweigh the costs to the community, Government or industry that would arise from the development or variation of the food regulatory measure.

2.4.1.2 Other measures

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

2.4.1.3 Any relevant New Zealand standards

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

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2. Subsection 18(1)

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

2.4.2.1 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.

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

The labelling requirements for this enzyme are discussed in Section 2.2.3 of this report.

2.4.2.3 The prevention of misleading or deceptive conduct

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

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ used the best available scientific evidence to conduct the risk analysis. 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.

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

The applicant advised that their alpha-arabinofuranosidase preparation is currently used in a range of countries, where there are no restrictions on the use of enzyme processing aids or where the enzyme is covered by a country positive list or specific approval. They also advised that their enzyme preparation has been approved for use in Brazil, Denmark and Mexico.

Approval for use of the applicant's alpha-arabinofuranosidase would bring Australia and New Zealand into line with other jurisdictions where it is already permitted for use. In this way, Australia and New Zealand would remain competitive with other international markets. This would also help support 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 use at levels and for the purpose as proposed by the applicant.

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

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

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

- **any written policy guidelines formulated by the Forum on Food Regulation**

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

[4] Food regulation website

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.

3 Draft variation

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

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

Attachments

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

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

Food Standards (Application A1227 – Alpha-arabinofuranosidase from GM *Trichoderma reesei* 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 A1227 – Alpha-arabinofuranosidase from GM* Trichoderma reesei *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:

α-Arabinofuranosidase (EC 3.2.1.55) sourced from *Trichoderma reesei* containing the α-arabinofuranosidase gene from *Talaromyces pinophilus*	For use in: (a) grain processing; and (b) the production of potable alcohol.	GMP

Attachment B – Draft Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1227 – Alpha-arabinofuranosidase from GM* Trichoderma reesei *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 A1227 which seeks to permit a new source microorganism, being alpha-arabinofuranosidase from a genetically modified strain of *Trichoderma reesei* containing the alpha-arabinofuranosidase gene from *Talaromyces pinophilus.* The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation – the *Food Standards (Application A1227 – Alpha-arabinofuranosidase from GM* Trichoderma reesei *as a processing aid) Variation*.

2. Variation will be a legislative instrument

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

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

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

3. Purpose

The Authority has prepared a draft variation amending the table to subsection S18—9(3) in Schedule 18 of the Code to permit the use of the enzyme alpha-arabinofuranosidase (EC 3.2.1.55) sourced from a GM strain of *Trichoderma reesei* containing the containing the alpha-arabinofuranosidase gene from *Talaromyces pinophilus* as a processing aid in grain processing and potable alcohol production. If approved, this permission would be subject to the condition that the maximum permitted level or amount of the enzyme that may be present in the food must be consistent with Good Manufacturing Practice (GMP).

4. Documents incorporated by reference

The draft variation does not incorporate any documents by reference.

However, existing provisions of the Code incorporate documents by reference that will prescribe identity and purity specifications for the processing aid to be permitted by the draft variation. Section 1.1.1—15 of the Code requires substances used as processing aids to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code. Section S3—2 of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications (FAO JECFA Monographs 23 (2019)) and the United States Pharmacopeial Convention Food Chemicals Codex (12th edition, 2020). These include specifications for enzyme preparations used in food processing.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1227 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) will be open for a six-week period.

The Office of Impact Analysis[5] granted the Authority a standing exemption from the requirement to develop a Regulatory Impact Statement for applications relating to permitting new processing aids and GM foods (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting new processing aids and GM foods is deregulatory as their use will be voluntary if the application 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

If approved, this instrument would be 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 draft variation would insert 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:

- 'α-Arabinofuranosidase (EC 3.2.1.55) sourced from *Trichoderma reesei* containing the α-arabinofuranosidase gene from *Talaromyces pinophilus*'

[5] Formerly known as the Office of Best Practice Regulation (OBPR).

The permitted technological purpose for this enzyme would be prescribed in column 2 of the table for use as a processing aid in grain processing and potable alcohol production.

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

If approved, the draft variation would permit the proposed use of α-Arabinofuranosidase (EC 3.2.1.55) sourced from *Trichoderma reesei* containing the α-arabinofuranosidase gene from *Talaromyces pinophilus* as a processing aid in accordance with the Code.