20 September 2023
262-23

Call for submissions – Application A1271

Cellulase from GM *Aspergillus niger* as a processing aid

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Novozymes Australia Pty Ltd to amend the Australia New Zealand Food Standards Code to permit a protein-engineered variant of cellulase from genetically modified *Aspergillus niger* to be used as a processing aid in brewing and the production of distilled alcohol, and 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. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 3 November 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
PO Box 5423
KINGSTON ACT 2604

Food Standards Australia New Zealand
PO Box 10559
WELLINGTON 6140

AUSTRALIA
Tel +61 2 6271 2222

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Tel +64 4 978 5630

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Supporting document (SD)

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

SD Risk and Technical Assessment

Executive summary

Novozymes Australia Pty Ltd has applied to Food Standards Australia New Zealand (FSANZ) to amend the Australia New Zealand Food Standards Code (the Code) to permit the enzyme cellulase to be used as a processing aid in brewing and the production of distilled alcohol[1]. The enzyme is a protein engineered variant of cellulase (EC 3.2.1.4) sourced from genetically modified (GM) *Aspergillus niger* containing the cellulase gene from *Trichoderma reesei*. The enzyme would be used at minimum levels necessary to achieve the desired effect, in accordance with Good Manufacturing Practice (GMP).

The proposed use of this enzyme as a processing aid in brewing and the production of potable alcohol is consistent with its function of catalysing the endohydrolysis of (1→4)-β-D-glucosidic linkages in cellulose, lichenin and cereal β-D-glucans.

Cellulase performs the above technological purpose during brewing and the production of potable alcohol and is not performing the technological purpose in the food for sale, therefore functioning as a processing aid for the purposes of the Code. Relevant identity and purity specifications for the enzyme are included in the Code.

No public health and safety concerns were identified in the assessment of the cellulase produced by GM *A. niger* under the proposed use. A microbiological assessment concluded that *A. niger* has a long history of safe use in food and is not pathogenic or toxigenic. A toxicological assessment combined with a dietary exposure assessment concluded the enzyme is safe under the proposed use.

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

FSANZ has therefore prepared a draft variation to subsection S18—9(3) of the Code. The draft variation, if approved, would permit the use of the protein engineered variant of the enzyme cellulase (EC 3.2.1.4) produced from GM *A. niger* containing the cellulase gene from *T. reesei* to be used as a processing aid in brewing and the production of potable alcohol. The 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 an amount consistent with GMP.

FSANZ seeks submissions on the draft variation.

[1] The term 'potable alcohol' is used in this report. See section 1.2 for further information.

1 Introduction

1.1 The applicant

The applicant is Novozymes Australia Pty Ltd (Novozymes).

1.2 The application

The purpose of the application is to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of a protein engineered variant of the enzyme cellulase as a processing aid in brewing and the production of distilled alcohol. Although the application refers to the production of 'distilled alcohol', the term 'potable alcohol' can be used as an alternative term. The Code permits the use of certain enzymes in 'potable alcohol' rather than 'distilled alcohol' and the applicant confirmed that 'potable alcohol' is appropriate in this case. Hereinafter the term 'potable alcohol' will be used.

The enzyme is produced from genetically modified (GM) *Aspergillus niger* containing the cellulase gene from *Trichoderma reesei.* Thus *A. niger* is the host (source) species and *T. reesei* is the donor for the gene.

The applicant markets a liquid preparation containing this enzyme as the active constituent under the commercial name Ultraflo Key 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

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 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).

Cellulase sourced from non-GM *A. niger* is currently permitted for use as a processing aid in subsection S18—4(5), however there is no permission for a protein engineered variant of cellulase from GM *A. niger* containing the cellulase gene from *T. reesei.*

1.3.2 Identity and purity requirements

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

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 26 (2021)), and the United States Pharmacopeial Convention (2022) Food chemicals codex (13th 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) 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 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' unless an exemption applies. The statement 'genetically modified' must be made in conjunction with the name of the GM food. If the GM food is used as a processing aid, this statement may be included in the statement of ingredients. The requirements imposed by section 1.5.2—4 apply to foods for retail sale and to foods sold to a caterer in accordance with Standard 1.2.1.

1.4 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 in Section 1.3.2 above, there are internationally recognised specifications

[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
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*).

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), and
- 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 Food technology assessment

The proposed use of the cellulase enzyme as a processing aid in brewing and the production of potable alcohol is consistent with its typical function of catalysing the endohydrolysis of (1→4)-β-D-glucosidic linkages in cellulose, lichenin and cereal β-D-glucans.

Cellulase performs its technological purpose during the production of food and is not performing the technological purpose in the food for sale. It is therefore functioning as a processing aid for the purposes of the Code.

2.2 Risk assessment

FSANZ has assessed the public health and safety risks associated with a protein engineered variant of a cellulase from GM *A. niger* containing the cellulase gene from *T. reesei* and its proposed use as a processing aid. A summary of this risk assessment is provided below.

No public health and safety concerns were identified in the assessment of cellulase enzyme from GM *A. niger* under the proposed use conditions.

The *A. niger* host is neither pathogenic nor toxigenic. Analysis of the GM production strain 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.

Based on the reviewed data it is concluded that in the absence of any identifiable hazard an Acceptable Daily Intake (ADI) ‘not specified’ is appropriate.

2.3 Risk management

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

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

For the reasons listed in this report, FSANZ decided to prepare a draft variation to the Code permitting the use of a protein-engineered variant of cellulase produced from GM *A. niger* containing the cellulase gene from *T. reesei* as a processing aid in brewing and the production of potable alcohol. If approved, this permission would be subject to the condition that the maximum permitted level or amount of enzyme present in the food must be 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 source microorganism nomenclature, specifications, and labelling. These are discussed below.

2.3.1 Regulatory approval

As stated above, FSANZ has prepared a draft variation to permit the use of the enzyme as a processing aid in brewing and the production of potable alcohol.

The express permission for the enzyme to be used as a processing aid also provides the permission for its potential presence in food for sale as a food produced using gene technology (see Section 1.3.1 above). The enzyme is a food produced using gene technology for Code purposes as it is derived from an organism that has been modified using gene technology[3].

2.3.2 Enzyme nomenclature, source microorganism nomenclature and specifications

The International Union of Biochemistry and Molecular Biology (IUBMB) uses the accepted name cellulase. This is the name used in the proposed draft variation and the name used in existing permissions for cellulase in Schedule 18.

Nomenclature for the host and gene donor organisms – *Aspergillus niger* and *Trichoderma reesei* respectively – is in accordance with accepted international norms for fungal taxonomy.

There are relevant identity and purity specifications in primary sources of specifications listed in Schedule 3 for enzyme preparations used in food processing (refer to Section 1.3.2 above).

2.3.3 Labelling requirements

Relevant 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, a protein-engineered variant of cellulase (EC 3.2.1.4) produced from GM *A. niger* containing the cellulase gene from *T. reesei* as a processing aid in brewing and the production of potable alcohol. If approved, the

[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'.

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

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a standard communication strategy to this application. All calls for submissions are notified via the 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 the draft variation.

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

2.4.2 World Trade Organization (WTO)

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

There are no relevant international standards (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.

2.5 FSANZ Act assessment requirements

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

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)[4]. Impact analysis is no longer required to be finalised with the OIA. Prior to these changes, the OIA advised FSANZ that a Regulatory Impact Statement was not required for the applications relating to processing aids and GM. This is because applications relating to permitting the use of processing aids and GM that have been determined to be safe are minor and deregulatory in nature as their use will be voluntary if the application is approved. Under the new approach, FSANZ's assessment is that a Regulatory Impact Statement is not required for this application.

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

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 as a whole is likely to benefit, on balance, from a move from the status quo (where status quo is rejecting the application). This analysis considers permitting the use of a protein engineered variant of the enzyme cellulase from GM *A. niger* as a processing aid in brewing and the production of potable alcohol.

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 this cellulase from GM *A. niger* as a processing aid.

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

The food industry may benefit from improvements and efficiencies from the use of this enzyme in brewing and the production of potable alcohol. Use of the enzyme is voluntary, and therefore industry will use the enzyme only where a commercial net benefit exists for them.

There is not expected to be any significant costs or benefits for consumers. However, if some production efficiencies are achieved some of the saving may be passed on to consumers depending on the structure and competitiveness of the market.

Permitting the proposed use of this processing aid may result in a small cost to government in terms of an addition to the current range of sources 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 this cellulase from GM *A. niger* as a processing aid for in brewing and the production of potable alcohol, most likely outweigh the associated costs.

2.5.1.2 Other measures

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

2.5.1.3 Any relevant New Zealand standards

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

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2 Subsection 18(1)

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

2.5.2.1 Protection of public health and safety

FSANZ undertook a safety assessment (see Section 2.2 above and the SD) 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 Sections 1.3.3 and 2.3.3 of this report.

2.5.2.3 The prevention of misleading or deceptive conduct

There were 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 as referred to in Section 1.3.2 of this report, with which this enzyme would have to comply.

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

Novozymes stated that this cellulase enzyme is used as processing aid 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.

Approval for its use would bring Australia and New Zealand into line with other jurisdictions where it is already able to be used. In this way, Australia and New Zealand will remain competitive with other international markets. This will also help foster continued innovation and improvements in food manufacturing techniques and processes.

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

Ultimately, the domestic food industry will make their own economic decisions, considering

the costs and benefits of using the new enzyme, to determine if it is of benefit to their business.

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

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

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

The Ministerial Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*[5] includes specific order policy principles for substances added to achieve a solely technological function, such as processing aids. These specific order policy principles state that permission should be granted where:

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

FSANZ determined that permitting the proposed use of this enzyme 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

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

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

Food Standards (Application A1271 – Cellulase 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 A1271 – Cellulase 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:

Cellulase, protein engineered variant, (EC 3.2.1.4) sourced from *Aspergillus niger* containing the cellulase gene from *Trichoderma reesei*	For use in brewing and the production of potable alcohol	GMP

[2] Subsection S18—9(3) (note after the table)

Omit the dot point list of protein engineered variants of enzymes in the note, substitute:

- Cellulase, protein engineered variant;
- Endo-1,4-ß-xylanase, protein engineered variant;
- Fructan β-fructosidase, protein engineered variant;
- Glucoamylase, protein engineered variant;
- Maltogenic α-amylase, protein engineered variant;
- Protein engineered enzymes used in the manufacture of various steviol glycosides.

Attachment B

DRAFT Explanatory Statement

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1271 – Cellulase from GM* Aspergillus niger *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 A1271 which sought to amend the Code to permit the use of a protein engineered variant of the enzyme cellulase (EC 3.2.1.4) from genetically modified *Aspergillus niger* containing the cellulase gene from *Trichoderma reesei* to be used as a processing aid in brewing and the production of potable alcohol. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation - the *Food Standards (Application A1271 – Cellulase from GM* Aspergillus niger *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 a protein-engineered variant of the cellulase enzyme (EC 3.2.1.4) sourced from genetically modified *Aspergillus niger* containing the cellulase gene from *Trichoderma reesei,* as a processing aid in brewing and the production of potable alcohol. If approved, this permission would be subject to the condition that the maximum permitted level or amount of the enzyme that may be present in the food must be consistent with good manufacturing practice (GMP).

4. Documents incorporated by reference

The draft variation does not incorporate any documents by reference.

However, existing provisions of the Code incorporate documents by reference that would prescribe identity and purity specifications for the processing aid to be permitted by the draft variation. Section 1.1.1—15 of the Code requires substances used as processing aids to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code. 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 A1271 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 occur for a six-week consultation period.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA) [6]. Impact analysis is no longer required to be finalised with the OIA. Prior to these changes, the OIA advised FSANZ that a Regulatory Impact Statement was not required for the applications relating to processing aids and genetic modification. This is because applications relating to permitting the use of processing aids and genetic modification that have been determined to be safe are considered to be minor and deregulatory in nature as their use will be voluntary if the application is approved. Under the new approach, FSANZ's assessment is that a Regulatory Impact Statement is not required for this application.

6. Statement of compatibility with human rights

If approved, this instrument would be exempt from the requirements for a statement of compatibility with human rights as it would be a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

Clause 1 provides that the name of the variation is the *Food Standards (Application A1271 –*

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

Cellulase from GM Aspergillus niger *as a processing aid) Variation*

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

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

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

- 'Cellulase, protein engineered variant, (EC 3.2.1.4) sourced from *Aspergillus niger* containing the cellulase gene from *Trichoderma reesei'*

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

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, item [1] of the draft variation would permit the proposed use of the protein-engineered variant of the enzyme cellulase (EC 3.2.1.4) sourced from genetically modified *Aspergillus niger* containing the cellulase gene from *Trichoderma reesei* as a processing aid in accordance with the Code.

Item [2] of the Schedule to the draft variation would amend the Note after the table to subsection S18—9(3) by omitting the existing dot point list in the Note (the dot point list) and substituting it with a new dot point list. The dot point list is a list of protein-engineered variants of enzymes that are listed in the table to subsection S18—9(3) as permitted processing aids for specific technological purposes; and the new list would include 'Cellulase, protein engineered variant;' which would be inserted, in alphabetical order, in the table by item [1] of the draft variation (see above).

The existing protein-engineered variants of enzymes, which are not currently in alphabetical order, would be relisted in alphabetical order in the new dot point list.

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

The new dot point list contains a substance that is not listed in the Note to subsection S18—9(3) of the existing Code. This substance is ''Fructan β-fructosidase, protein engineered variant", and a proposed permission for its use as a processing aid is currently being consulted on by the Authority in Application A1267. If the draft variation proposed in Application A1267 is not approved prior to the approval of this draft variation, the entry for Fructan β-fructosidase will be omitted from the dot point list in this draft variation.