16 February 2024
281-24

Approval report – 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.

On 20 September 2023, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received one submission.

FSANZ approved the draft variation on 2 February 2024. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 16 February 2024.

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 (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 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[2].

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. It is 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.

Following assessment and the preparation of a draft variation to the Code, FSANZ called for submissions regarding the draft variation from 20 September until 3 November 2023. FSANZ received one submission from a government agency supporting the draft variation.

Based on the information above and on other relevant considerations set out in the approval report, FSANZ has approved a draft variation amending the table to subsection S18—9(3) of the Code. The effect of the approved draft variation will be to 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 in accordance with the Code. The permission will 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.

[2] 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 was 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 referred to the production of 'distilled alcohol', the term 'potable alcohol' can be used as an alternative. The Code permits the use of certain enzymes as processing aids in the manufacture or production of '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 2.6.3).

The applicant 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*[3] (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

[3] 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*).

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 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 was assessed under the General Procedure in the FSANZ Act.

1.7 Decision

For the reasons outlined in this report, FSANZ decided to approve a draft variation amending the Code to permit a protein engineered variant of cellulase from genetically modified *A. niger* to be used as a processing aid in brewing and the production of potable alcohol.

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 called for submissions on a draft variation to the Code from 20 September to 3 November 2023, with one submission received. The submitter, New Zealand Food Safety, supported the amendment to permit the use of a protein engineered variant of cellulase from GM *A. niger* to be used as a processing aid in brewing and the production of distilled alcohol.

2.2 Food technology assessment

From the food technology assessment, FSANZ concluded that 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. For further details see the Supporting Document (SD).

2.3 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. Refer to the SD. 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.

2.4 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 technologically justified and there were no safety concerns associated with its proposed use.

For the reasons listed in the assessment summary at the call for submissions, 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 and called for submissions on the draft variation.

Following the call for submissions and having regard to the submission received, for the reasons set out in this report, FSANZ considers it appropriate to approve the draft variation proposed following assessment (see Attachment A).

The permission to use this protein-engineered variant of cellulase is subject to the condition that the maximum permitted level or amount of enzyme present in the food must be consistent with GMP. Other risk management considerations for this application are related to the enzyme and source microorganism nomenclature, specifications and labelling. These are discussed below.

2.4.1 Regulatory approval

As stated above, FSANZ has approved 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[4].

2.4.2 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 approved 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).

2.4.3 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.

2.4.4 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. The enzyme and its associated technological purpose will be listed in the table to subsection S18—9(3) of the Code, which includes enzymes permitted for a specific technological purpose. The maximum permitted level or amount of the enzyme that may be present in the food 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 also provides the permission for the enzyme's potential presence in the food for sale as a food produced using gene technology.

[4] 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'.

2.5 Risk communication

2.5.1 Consultation

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

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

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

2.6 FSANZ Act assessment requirements

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

2.6.1 Section 29

2.6.1.1 Consideration of costs and benefits

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)[5]. 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 (RIS) was not required for the applications relating to processing aids and GM foods. This is because applications relating to permitting the use of processing aids and GM foods that have been determined to be safe are minor and deregulatory in nature as their use will be voluntary if the draft variation concerned is approved. Under the new approach, FSANZ's assessment is that a RIS is not required for this application.

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 (where status quo is rejecting the application). This analysis considered 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 was 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 sought 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.

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

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

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 savings 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 at the call for submissions stage was that the direct and indirect benefits that would arise from permitting this cellulase enzyme from GM *A. niger* as a processing aid for use in brewing and the production of potable alcohol, most likely outweigh the associated costs. No further information was received during the consultation process that changed that assessment.

2.6.1.2 Other measures

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

2.6.1.3 Any relevant New Zealand standards

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

2.6.1.4 Any other relevant matters

Other relevant matters are considered below.

2.6.2 Subsection 18(1)

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

2.6.2.1 Protection of public health and safety

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

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

The labelling requirements relevant to this application are discussed in sections 1.3.3 and 2.4.3 of this report.

2.6.2.3 The prevention of misleading or deceptive conduct

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

2.6.3 Subsection 18(2) considerations

FSANZ 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. 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.

- **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 will 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 Food Ministers' Meeting**

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

Minerals[6] 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.

Attachments

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

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

Attachment A – Approved 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 – Explanatory Statement

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 approved a draft variation – the *Food Standards (Application A1271 – Cellulase from GM* Aspergillus niger *as a processing aid) 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 approved draft variation.

2. Variation is a legislative instrument

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

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

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

on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has approved a draft variation amending the table to subsection S18—9(3) in Schedule 18 of the Code to permit the use of 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. This permission is subject to the condition that the maximum permitted level or amount of the enzyme that may be present in the food must be consistent with good manufacturing practice (GMP).

4. Documents incorporated by reference

The approved draft variation does not incorporate any documents by reference.

However, existing provisions of the Code incorporate documents by reference that would prescribe identity and purity specifications for the processing aid to be permitted by the approved draft variation. Section 1.1.1—15 of the Code requires substances used as processing aids to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code. 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 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. Submissions were called for on 20 September for a 6-week and 2 day consultation period.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)[7]. Impact analysis is no longer required to be finalised with the OIA. Prior to these changes, the OIA advised the Authority that a Regulatory Impact Statement was not required for the applications relating to processing aids and genetically modified foods. This is because applications relating to permitting the use of processing aids and genetically modified foods that have been determined to be safe are minor and deregulatory in nature as their use will be voluntary if the draft variation concerned is approved. Under the new approach, the Authority's assessment is that a Regulatory Impact Statement is not required for this application.

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

7. Variation

Clause 1 provides that the name of the variation is the *Food Standards (Application A1271 – 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 variation amends the table to subsection S18—9(3) of the Code by inserting a new entry, in alphabetical order, into column 1 of the table. 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 is 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 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 item [1] of the Schedule to the variation is to 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 variation amends 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 includes 'Cellulase, protein engineered variant;' which is inserted, in alphabetical order, in the table by item [1] of the variation (see above).

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 enzymes.