FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

30 January 2024

279-24

Call for submissions – Application A1282

Subtilisin from GM *Bacillus subtillis* as a processing aid

Food Standards Australia New Zealand (FSANZ) has assessed an application made by IFF Australia Pty Ltd (trading as Danisco Australia Pty Ltd) to amend the Australia New Zealand Food Standards Code to permit the use of a protein engineered variant of subtilisin from genetically modified *Bacillus subtillis* as a processing aid to hydrolyse proteins in foods, 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 and 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) 14 March 2024

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.

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Supporting document

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

SD1 Risk and technical assessment – Application A1282 Subtilisin from GM Bacillus subtillis as a processing aid

Executive summary

Food Standards Australia New Zealand (FSANZ) received an application from IFF Australia Pty Ltd (trading as Danisco Australia Pty Ltd) to vary the Australia New Zealand Food Standards Code (the Code) to permit the use of a protein engineered variant of the enzyme subtilisin (EC 3.4.21.62). Subtilisin is sourced from a genetically modified *Bacillus subtillis* containing the gene for subtilisin from *Bacillus clausii* as a processing aid for hydrolysing proteins in foods containing proteins.

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 subtilisin as an enzyme processing aid in the quantity and form presented is consistent with its typical function of hydrolysing proteins. This enzyme performs its technological purpose during processing of proteins in food and does not perform its technological purpose in the food for sale, therefore functioning as a processing aid for the purposes of the Code. The enzyme meets relevant identity and purity specifications in the Code.

There are no safety concerns from the use of subtilisin from a GM strain of *B. subtilis* containing the subtilisin gene from *Bacillus clausii*. A microbiological assessment concluded that the host organisms 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 according to the proposed use. In the absence of any identifiable hazard, an acceptable daily intake (ADI) of 'not specified' is appropriate.

Following assessment, for reasons set out in this report, FSANZ prepared a draft variation to the Code to permit a protein engineered variant of the enzyme subtilisin (EC 3.4.21.62) from a genetically modified strain of *B. subtilis* containing the subtilisin gene from *B. clausii*, as a processing aid for hydrolysing proteins in foods containing proteins. If approved, the draft variation would amend Schedule 18 by listing this enzyme and its associated technological purpose in the table to subsection S18—9(3). This table lists substances (including enzymes) permitted as processing aids for specific technological purposes. The amount of enzyme used would have to be consistent with good manufacturing practice (GMP).

FSANZ invites submissions on the draft variation.

1 Introduction

1.1 The Applicant

The applicant is IFF Australia Pty Ltd (trading as Danisco Australia Pty Ltd). Information about the applicant is provided in the application.

1.2 The Application

This application seeks to modify Schedule 18 of the Australia New Zealand Food Standards Code (the Code) to permit the use of a protein engineered variant of the enzyme subtilisin from genetically modified (GM) *Bacillus subtilli*s containing the gene for subtilisin from *Bacillus clausii* as a processing aid. The intended use is for hydrolysing proteins in foods containing protein. Typical processes which may employ subtilisin from GM *B. subtillis* include baking and dairy, egg, meat and fish processing. Subtilisin from GM *B. subtillis* would be used at minimum levels necessary to achieve the desired effect and according to requirements for normal production following Good Manufacturing Process (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.

Paragraph 1.1.1—10(6)(c) provides that a food for sale must not have, as an ingredient or a component, a substance that is used as a processing aid unless that substance's use as a processing aid is expressly permitted.

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 the course of processing
- it does not perform a technological purpose in the food for sale
- 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), depending on whether a technological purpose has been specified.

An enzyme of microbial origin listed in the table to subsection S18—4(5) is permitted for use as a processing aid to perform *any* technological purpose if the enzyme is derived from the corresponding source specified in the table.

The table to subsection S18—9(3) lists those substances, including enzymes derived from particular sources, that are permitted to be used as processing aids for specific technological purposes in relation to:

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

Additionally, paragraph 1.3.3—11(c) specifies that the substance may only be used as a processing aid if it is not present in the food at greater than the maximum permitted level for that substance indicated in the table to section S18—Paragraph 1.1.1—10(6)(g) requires that the presence of a food produced using gene technology as an ingredient or component in a

food for sale 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).

Serine proteinases of microbial origin (*Aspergillus oryzae, Bacillus amyloliquefaciens, Bacillus halodurans, Bacillus licheniformis,* and *Bacillus subtilis*) are currently permitted enzymes in the Code (see the respective tables to subsections S18—4(5) and S18—9(3)).

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) 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 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 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 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] 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*).

1.5 Reasons for accepting the 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 of the FSANZ Act.

2 Summary of the assessment

2.1 Food Technology assessment

FSANZ has undertaken a food technology assessment to determine whether the enzyme achieves its technological purpose in the quantity and form proposed (see SD1). A summary of this assessment is provided below.

Subtilisin 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 Safety Assessment

No public health and safety concerns were identified in the assessment of this subtilisin under the proposed use conditions (see SD1). The 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 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 subtilisin from a GM *B. subtillis* containing the gene for subtilisin from *B. clausii* as a processing aid in hydrolysing proteins in foods containing protein. 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 public health and safety concerns associated with its proposed use.

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

2.3.1 Regulatory approval for processing aids

As stated above, FSANZ has prepared a draft variation to permit the proposed use of this enzyme as a processing aid.

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[2].

2.3.2 Enzyme nomenclature, source microorganism nomenclature and specifications

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

Nomenclature for the host and gene donor organisms – *Bacillus subtillis* and *Bacillus clausii* respectively – is in accordance with accepted international norms for 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

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 subtilisin (EC 3.4.21.62) sourced from a GM *B. subtillis* containing the gene for subtilisin from *B. clausii* as a processing aid in hydrolysing proteins in foods containing protein. If approved, the enzyme and its associated technological purpose 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 considers standards development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on the draft variation. FSANZ will consider all submissions received through this call for submissions process before making a decision on whether to approve the draft variation.

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[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'.

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 and amending the Code to permit the use of this subtilisin from genetically modified *B. subtillis* as a processing aid for hydrolysing proteins in foods containing protein. The proposed amendment is unlikely to have a significant effect on international trade as there is no general standard for enzymes used as processing aids in the Codex Alimentarius. 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)[3]. Impact analysis no longer must be finalised with the OIA. Prior to these changes, the OIA advised FSANZ that a Regulatory Impact Statement (RIS) was not needed for the applications relating to processing aids and GM food. This is because applications relating to permitting the use of processing aids and GM food that have been determined to be safe are considered to be minor and deregulatory in nature, as their use will be voluntary if the draft variation concerned is approved. Under this approach, FSANZ's assessment is that a RIS is not needed for this application.

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 decide if the community, government and industry is likely to benefit, on balance, from a move from the *status quo* (where the status quo is rejecting the application). This analysis considers permitting the proposed use of this protein engineered variant of subtilisin from genetically modified *B. subtillis* as a processing aid for hydrolysing proteins in foods containing protein.

The consideration of the costs and benefits in this section is not an exhaustive, quantitative economic analysis of the proposed measure. In fact, most of the effects considered cannot easily be assigned a dollar value. Rather, the assessment highlights the likely positives and negatives of moving away from the status quo by approving the proposed variation to the Code.

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.

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

Costs and benefits of permitting the proposed use of this enzyme

Industry may benefit from several improvements and efficiencies from the use of this enzyme. Due to the voluntary nature of the permission, industry will only use the enzyme as proposed where they believe a net benefit exists for them.

If industry were to experience cost savings because of using this enzyme, industry may pass on some of the cost savings to consumers.

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

Conclusions from cost benefit considerations

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting the proposed use of this protein engineered variant of subtilisin from genetically modified *B. subtillis* as a processing aid for protein processing 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 standards in the Code which are relevant to the permitted use of the enzyme processing aid in question apply in both Australia and New Zealand. There are no relevant New Zealand only standards.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2 Subsection 18(1)

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

2.5.2.1 Protection of public health and safety

FSANZ undertook a safety assessment (SD1) and concluded there are no public health and safety concerns associated with permitting the proposed use of this protein engineered variant of subtilisin from a genetically modified *B. subtillis* as a processing aid for hydrolysing proteins in foods containing protein

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

Existing labelling requirements related to subtilisin are detailed in sections 1.1.3 and 2.2.3 of the report. FSANZ considers existing requirements would enable consumers to make informed choices.

2.5.2.3 The prevention of misleading or deceptive conduct

There were no issues 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 has used the best available scientific evidence to conduct the risk analysis. The risk assessment is provided in SD1. The applicant submitted a dossier of scientific studies as part of the application. This dossier, together with other technical information including scientific literature, was considered by FSANZ in assessing the application.

- **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**

Subtilisin 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[4].

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.

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[4] Pariza MW, Foster EM (1983) Determining the Safety of Enzymes Used in Food Processing. Journal of Food Protection 46(5):453-468.

Pariza MW, Johnson EA (2001) Evaluating the Safety of Microbial Enzyme Preparations Used in Food Processing: Update for a New Century. Regulatory Toxicology and Pharmacology 33:173-186.

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

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 in regard to the substance.

FSANZ determined that permitting the proposed use of this enzyme as a processing aid is consistent with the specific order policy principles for 'Technological Function'. All other relevant requirements of the policy guideline are similarly met.

[5] Available on the Food regulation website

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 A1282 – Subtilisin from GM *Bacillus subtilis* 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]

[Name and position of Delegate]

Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1282 – Subtilisin from GM* Bacillus subtilis *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:

Subtilisin, protein engineered variant, (EC 3.4.21.62) sourced from *Bacillus subtilis* containing the gene for subtilisin from *Bacillus clausii*	For use in hydrolysing proteins in foods containing proteins.	GMP

[2] Subsection S18—9(3) (note after the table, dot point list of protein engineered variants of enzymes)

Omit:

Protein engineered enzymes used in the manufacture of various steviol glycosides.

substitute:

Protein engineered enzymes used in the manufacture of various steviol glycosides;
Subtilisin, protein engineered variant.

Attachment B – Draft Explanatory Statement

DRAFT EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1282 – Subtilisin from GM* Bacillus subtillis *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 A1282 which sought to amend the Code to permit the use of a protein engineered variant of the enzyme subtilisin from GM *Bacillus subtillis* as a processing aid to hydrolyse proteins in foods containing proteins. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation – the *Food Standards (Application A1282 – Subtilisin from GM* Bacillus subtillis *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) of the Code to permit the use of a protein engineered variant of the enzyme subtilisin (EC 3.4.21.62) sourced from Ba*cillus subtilis* containing the gene for subtilisin from *Bacillus clausii* as a processing aid for use in hydrolysing proteins in foods containing proteins.

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 A1282 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.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)[6]. Impact analysis no longer must be finalised with the OIA. Prior to these changes, the OIA advised FSANZ that a Regulatory Impact Statement (RIS) was not needed for the applications relating to processing aids and GM food. This is because applications relating to permitting the use of processing aids and GM food that have been determined to be safe are considered to be minor and deregulatory in nature, as their use will be voluntary if the draft variation concerned is approved. Under this approach, FSANZ's assessment is that a RIS is not needed 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 A1282 — Subtilisin from GM* Bacillus subtillis *as a processing aid) Variation*

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

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

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:

> 'Subtilisin, protein engineered variant, (EC 3.4.21.62) sourced from *Bacillus subtilis* containing the gene for subtilisin from *Bacillus clausii*'.

The permitted technological purpose for this enzyme would be prescribed in column 2 of the table

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 subtilisin (EC 3.4.21.62) sourced from genetically modified *Bacillus subtilis* containing the gene for subtilisin from *Bacillus clausii* as a processing aid in accordance with the Code.

Item [2] of the Schedule to the draft variation would amend the dot point list of protein engineered variants of enzymes in the note after the table to subsection S18—9(3).

That note 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.

Item [2] would omit the last entry in the dot point list of protein engineered variants of enzymes in the note after the table to subsection S18—9(3) i.e.:

- Protein engineered enzymes used in the manufacture of various steviol glycosides.

and replace that entry with:

- Protein engineered enzymes used in the manufacture of various steviol glycosides;
- Subtilisin, protein engineered variant.

The effect of the amendment in item [2] would be to include this protein engineered variant of subtilisin in that list, in alphabetical order.