

## **EXPLANATORY STATEMENT**

### *Food Standards Australia New Zealand Act 1991*

#### ***Food Standards (Application A1282 – Subtilisin from GM Bacillus subtilis 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 genetically modified (GM) *Bacillus subtilis* 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 approved a draft variation: the *Food Standards (Application A1282 – Subtilisin from GM Bacillus subtilis 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 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](http://www.legislation.gov.au)).

This instrument is not subject to the disallowance or sunset 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 sunset 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 sunset 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) of the Code to permit the use of a protein engineered variant of the enzyme subtilisin (EC 3.4.21.62) sourced from *Bacillus subtilis* containing the gene for subtilisin from *Bacillus clausii* as a processing aid for use in hydrolysing proteins in foods containing proteins.

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 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 (13<sup>th</sup> 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 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. FSANZ called for submissions on a draft variation to the Code from 30 January to 14 March 2024.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)<sup>1</sup>. 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 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 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**

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

#### **7. Variation**

Clause 1 provides that the name of the variation is the *Food Standards (Application A1282 — Subtilisin from GM Bacillus subtilis 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 inserts a new entry, in alphabetical order, into column 1 of the table to subsection S18—9(3) of the Code.

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<sup>1</sup> [Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis \(pmc.gov.au\)](https://www.pmc.gov.au/regulatory-impact-analysis-guide)

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 is prescribed in column 2 of the table.

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 draft variation is to 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 amends 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] omits 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] is to include this protein engineered variant of subtilisin in that list, in alphabetical order.