EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1252 – Glucoamylase from GM* Aspergillus niger *(gene donor:* Penicillium oxalicum*) 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 A1252 Glucoamylase from GM *Aspergillus niger* (gene donor: *Penicillium oxalicum*) as a processing aid which sought to amend the Code to permit the use of a protein engineered glucoamylase enzyme (EC 3.2.1.3) from a new genetically modified (GM) strain of *Aspergillus niger* as a processing aid in the manufacture of bakery products; brewing; and starch processing for the production of starch hydrolysates, including glucose syrups. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation - *Food Standards (Application A1252 – Glucoamylase from GM* Aspergillus niger *(gene donor:* Penicillium oxalicum*) 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 standard or draft variation of a standard.

2. Variation is a legislative instrument

The approved draft variation, Food Standards (Application A1252 – Glucoamylase from GM *Aspergillus niger* (gene donor: *Penicillium oxalicum*) as a processing aid) 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 the enzyme glucoamylase (EC 3.2.1.3) sourced from a GM strain of *Aspergillus niger,* containing a protein engineered variant of the glucoamylase gene from *Penicillium oxalicum*, as a processing aid in the manufacture of bakery products; brewing; and starch processing for the production of starch hydrolysates, including glucose syrups. 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 will prescribe identity and purity specifications for the processing aid 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) Combined Compendium of Food Additive Specifications (FAO JECFA Monographs 23 (2019)) and the United States Pharmacopeial Convention Food Chemicals Codex (12th edition, 2020). These include specifications for enzyme preparations used in food processing.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1252 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 28 September 2022 for a six-week period.

The Office of Impact Analysis[1] (OIA) granted the Authority a standing exemption from the requirement to develop a Regulatory Impact Statement for applications relating to permitting new processing aids and GM foods (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting new processing aids and GM foods is deregulatory as their use will be voluntary if the application concerned is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

6. Statement of compatibility with human rights

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

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

Item [1] of the Schedule to the approved draft variation inserts a new entry in alphabetical order, into the table to subsection S18—9(3) in Schedule 18. The new entry will consist of the following enzyme in column 1 of the table:

- 'Glucoamylase, protein engineered variant, (EC 3.2.1.3) sourced from *Aspergillus niger* containing the glucoamylase gene from *Penicillium oxalicum*'.

The permitted technological purpose for this enzyme prescribed in column 2 of the table is for use as a processing aid in:

- the manufacture of bakery products;
- brewing; and
- starch processing for the production of starch hydrolysates, including glucose syrups.

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 the approved draft variation is to permit the proposed use of the enzyme, glucoamylase (EC 3.2.1.3) sourced from *Aspergillus niger* containing a protein engineered variant of the glucoamylase gene from *Penicillium oxalicum* as a processing aid in accordance with the Code.