EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1275 – Transglutaminase from GM Bacillus licheniformis *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 A1275 which sought to amend the Code to permit the use of the enzyme transglutaminase (EC 2.3.2.13) from genetically modified *Bacillus licheniformis* containing the transglutaminase gene from *Streptomyces mobaraensis* to be used as a processing aid. The enzyme was proposed for use during brewing and in the manufacture and/or processing of: bakery and other cereal-based products such as pasta and noodles; cheese; fermented dairy products; dairy analogues; egg substitutes; meat products; fish products; meat analogues; and fish analogues. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation - the *Food Standards (Application A1275 – Transglutaminase from GM* Bacillus licheniformis *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 the transglutaminase (EC 2.3.2.13) enzyme sourced from genetically modified *Bacillus licheniformis* containing the transglutaminase gene from *Streptomyces mobaraensis* as a processing aid. It is permitted for use during brewing and in the manufacture and/or processing of the above-mentioned foods. The 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 A1275 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 10 October 2023 for a 5-week consultation period.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)[1]. 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 food. This is because applications relating to permitting the use of processing aids and genetically modified 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 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

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

rights as it is a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1275 – Transglutaminase from GM* Bacillus licheniformis *as a processing aid) Variation*.

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

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

7.1 Item [1]

Item [1] of the Schedule to the variation inserts 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:

- 'Transglutaminase (EC 2.3.2.13) sourced from *Bacillus licheniformis* containing the transglutaminase gene from *Streptomyces mobaraensis'*

The permitted technological purpose for this enzyme is prescribed in column 2 of the table as use as a processing aid during brewing and in the manufacture and/or processing of the following types of food: bakery and other cereal-based products such as pasta and noodles; cheese; fermented dairy products; dairy analogues; egg substitutes; meat products; fish products; meat analogues; and fish analogues.

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 enzyme transglutaminase (EC 2.3.2.13) sourced from *Bacillus licheniformis* containing the transglutaminase gene from *Streptomyces mobaraensis* as a processing aid in accordance with the Code.