

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1245 – Alpha-glucosidase from GM *Trichoderma reesei* as a processing aid in brewing) 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 A1245 which sought to amend the Code to permit an additional use of the enzyme alpha-glucosidase (α -glucosidase) from a genetically modified (GM) strain of *Trichoderma reesei* containing the α -glucosidase gene from *Aspergillus niger* as a processing aid in brewing of beer. The Code currently permits this enzyme to be used as a processing aid in the manufacture and/or processing of certain foods but not including beer, subject to the condition that the maximum permitted level or amount of this enzyme that may be present in the food must be consistent with good manufacture practice (GMP). The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation – the *Food Standards (Application A1245 – Alpha-glucosidase from GM *Trichoderma reesei* as a processing aid in brewing) 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 standard or 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 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) in Schedule 18 of the Code to permit the use of the enzyme α -glucosidase (EC 3.2.1.20) sourced from a GM strain of *Trichoderma reesei* containing the α -glucosidase gene from *Aspergillus niger* as a processing aid in the manufacture and/or processing of beer. This permission is subject to the existing condition that the maximum permitted level or amount of this enzyme that may be present in the food must be consistent with 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 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) 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 general specifications for the identity and purity 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 A1245 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 9 March 2023 for a 6-week consultation period.

The Office of Impact Analysis¹ granted the Authority a standing exemption from the requirement to develop a Regulatory Impact Statement for applications relating to permitting processing aids and GM foods (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting 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

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*.

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

7. Variation

Clause 1 provides that the name of the variation is the *Food Standards (Application A1245 – Alpha-glucosidase from GM Trichoderma reesei as a processing aid in brewing) Variation*.

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

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

Item [1] of the Schedule to the variation amends the table item dealing with ‘ α -Glucosidase (EC 3.2.1.20) sourced from *Trichoderma reesei* containing the α -glucosidase gene from *Aspergillus niger*’ (the enzyme) in the table to subsection S18—9(3) of the Code by:

- repealing existing paragraph (e) in the column headed ‘Technological purpose and food’ in relation to that table item; and
- substituting existing paragraph (e) with a new paragraph (e) with ‘; and’ at the end of it, followed by new paragraph (f) listing ‘beer’ as a food.

Paragraph (e) is currently the final listing of food in which the enzyme may be used as a processing aid and, as such, the paragraph has a full stop at the end of it. Therefore, paragraph (e) needs to be repealed and substituted with the new paragraph (e) for the purposes of adding ‘beer’ to the existing list.

The permission to use the enzyme as a processing aid in the manufacture and/or processing of beer is subject to the existing condition 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 variation is to permit the proposed use of the enzyme, α -glucosidase (EC 3.2.1.20) sourced from *Trichoderma reesei* containing the α -glucosidase gene from *Aspergillus niger*, as a processing aid in the manufacture and/or processing of beer in accordance with the Code.