

## **EXPLANATORY STATEMENT**

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

#### ***Food Standards (Application A1266 – Endo-1,4-beta-xylanase from GM Trichoderma reesei (gene donor: Fusarium verticillioides) 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 A1266 which sought to amend the Code to permit the use of a protein-engineered endo-1,4-beta-xylanase enzyme (EC 3.2.1.8) from a genetically modified strain of *Trichoderma reesei* as a processing aid in starch processing and the production of potable alcohol. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation – *Food Standards (Application A1266 – Endo-1,4-beta-xylanase from GM Trichoderma reesei (gene donor: Fusarium verticillioides) 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 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) in Schedule 18 of the Code to permit the use of a protein-engineered endo-1,4-beta-xylanase enzyme (EC 3.2.1.8) from a genetically modified strain of *Trichoderma reesei* as a processing aid in starch processing and the production of potable alcohol. This permission is 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 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 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 (12<sup>th</sup> 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 A1266 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 24 May 2023 for a six-week consultation period.

The Office of Impact Analysis<sup>1</sup> 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**

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 A1266 – Endo-1,4-beta-xylanase from GM Trichoderma reesei (gene donor: Fusarium verticillioides) 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 will commence on the date of gazettal of the instrument.

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<sup>1</sup> Formerly known as the Office of Best Practice Regulation (OBPR).

**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:

‘Endo-1,4- $\beta$ -xylanase, protein engineered variant, (EC 3.2.1.8) sourced from *Trichoderma reesei* containing the endo-1,4- $\beta$ -xylanase gene from *Fusarium verticillioides*’

The International Union of Biochemistry and Molecular Biology uses the accepted name ‘endo-1,4- $\beta$ -xylanase’. This is the name used in the variation. However, the word ‘beta’ has been used instead of its symbol in the name of the variation and in this Explanatory Statement.

The permitted technological purpose for this enzyme is prescribed in column 2 of the table i.e. for use as a processing aid in starch processing and the manufacture of potable alcohol.

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 variation is to permit the proposed use of the enzyme, endo-1,4-beta-xylanase (EC 3.2.1.8) sourced from a genetically modified strain of *Trichoderma reesei* containing a protein-engineered variant of the endo-1,4-beta-xylanase gene from *Fusarium verticillioides*, as a processing aid in accordance with the Code.