

## **EXPLANATORY STATEMENT**

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

#### ***Food Standards (Application A1278 – Beta-Fructofuranosidase from GM *Trichoderma reesei* 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 A1278 which sought to amend the Code to permit beta-fructofuranosidase (EC 3.2.1.26) from a genetically modified strain of *Trichoderma reesei* to be used as a processing aid in the production of short-chain fructooligosaccharides, and to produce a reduction in sugars levels in treated fruit and vegetable products. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation - the *Food Standards (Application A1278 – Beta-Fructofuranosidase from GM *Trichoderma reesei* 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) in Schedule 18 of the Code to permit beta-fructofuranosidase from genetically modified *Trichoderma reesei* to be used as a processing aid in the production of short-chain fructooligosaccharides, and to produce a reduction in sugar levels in treated fruit and vegetable products. 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 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 26 (2021)) and the United States Pharmacopeial Convention (2022) Food Chemicals Codex (13th edition). 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 A1278 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 six-week consultation period.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA). 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 required for the applications relating to processing aids and GM foods. This is because applications relating to permitting the use of processing aids and GM foods 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, FSANZ's assessment is that a RIS 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 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 A1278 – Beta-Fructofuranosidase from GM *Trichoderma reesei* 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 commences on the date of gazettal of the instrument.

**Item [1]** of the Schedule to the variation amends Schedule 18 of the Code by inserting a new entry, in alphabetical order, into column 1 of the table to subsection S18—9(3). The new entry consists of the following enzyme:

‘ $\beta$ -Fructofuranosidase (EC 3.2.1.26) sourced from *Trichoderma reesei* containing the  $\beta$ -fructofuranosidase gene from *Aspergillus niger*’

The International Union of Biochemistry and Molecular Biology uses the accepted name  $\beta$ -fructofuranosidase for the enzyme numbered EC 3.2.1.26 (IUBMB 2023). This is the name used in the variation and in Schedule 18 (subsection S18—4(5)). However, ‘beta-fructofuranosidase’ is referred to elsewhere in this Explanatory Statement to avoid using symbols in reports which can be hard to read on some platforms.

The permitted technological purpose for this enzyme is prescribed in column 2 of the table i.e., for use as a processing aid in the production of short chain fructooligosaccharides; and to produce a reduction in sugar levels in treated fruit and vegetable products.

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  $\beta$ -fructofuranosidase (EC 3.2.1.26) sourced from *Trichoderma reesei* containing the  $\beta$ -fructofuranosidase gene from *Aspergillus niger* as a processing aid in accordance with the Code.