EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1268 – Steviol glycosides produced by bioconversion using new enzymes produced by GM Escherichia coli*) 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 A1268 which sought to amend the Code to permit the use of three new protein engineered enzymes from genetically modified (GM) *Escherichia coli* strain K-12 as processing aids in the bioconversion method of producing steviol glycosides – rebaudiosides I and M. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation - the *Food Standards (Application A1268 – Steviol glycosides produced by bioconversion using new enzymes produced by GM* Escherichia coli*) 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 will be 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 Code to include the applicant's bioconversion methods of producing the steviol glycosides: rebaudiosides I and M, using three new protein-engineered enzymes sourced from genetically modified *Escherichia coli* as processing aids, and to permit the use of those three enzymes for that specific use

In particular, the draft variation amends section S3—35 (Specification for steviol glycosides produced by enzymatic conversion) and the table to subsection S18—9(3) (permitted processing aids for various technological purposes) of the Code for the above purpose.

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 aids and food additives (the steviol glycosides rebaudiosides I and M produced by enzymatic conversion) to be permitted by the approved draft variation. Section 1.1.1—15 of the Code requires substances used as processing aids and food additives to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code. Subsection S3—2(1) of Schedule 3 incorporates by reference primary source specifications listed in the following: Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications (FAO JECFA Monographs 26 (2021)); the United States Pharmacopeial Convention (2022) Food chemicals codex (13th edition); and the Commission Regulation (EU) No 231/2012. These include general specifications for the identity and purity parameters of food additives and enzyme preparations used as processing aids in the production of those additives.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of application A1268 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 15 June 2023 for a six-week consultation period.

The Office of Impact Analysis[1] granted the Authority a standing exemption from the requirement to develop a Regulatory Impact Statement for applications relating to permitting new processing aids and genetically modified foods (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting new processing aids and genetically modified 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

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

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 A1268 – Steviol glycosides produced by bioconversion using new enzymes produced by GM* Escherichia coli*) 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 amends section S3—35 of the Code, which sets out specifications for steviol glycosides produced by the enzymatic conversion [bioconversion] method of production.

In particular, this item omits subparagraph S3—35(2)(d)(ii), and substitutes it with the following:

- a new subparagraph S3—35(2)(d)(ii) with a semi-colon at the end of the paragraph, instead of a full stop – this is a consequence of inserting new paragraphs S3—35(2)(e) and (f);

- new paragraphs S3—35(2)(e) and (f), which are inserted in alphabetical order:

  - new paragraph (e) refers to a process for the production of rebaudioside M by enzymatic conversion of purified stevia leaf extract by using these three protein engineered enzymes: UTP-glucose-1-phosphate uridylyltransferase (EC 2.7.7.9) sourced from *Escherichia coli* K-12, UDP-glucosyltransferase sourced from *Escherichia coli* K-12, and sucrose synthase (EC 2.4.1.13) sourced from *Escherichia coli* K-12

  - new paragraph (f) refers to a process for the production of rebaudioside I by enzymatic conversion of purified stevia leaf extract by using these two protein engineered enzymes: UTP-glucose-1-phosphate uridylyltransferase (EC 2.7.7.9) sourced from *Escherichia coli* K-12, and sucrose synthase (EC 2.4.1.13) sourced from *Escherichia coli* K-12.

7.2 Item [2]

Item [2] of the Schedule to the variation amends Schedule 18 of the Code by inserting new entries for three new enzymes into the table to subsection S18—9(3). The table lists substances permitted to be used as processing aids for specific technological purposes.

The following protein-engineered enzymes will each be inserted in alphabetical order into column 1 of the table:

- ‘Sucrose synthase, protein engineered variant, (EC 2.4.1.13) sourced from *Escherichia coli* K-12 containing the gene for sucrose synthase from *Glycine max*’;

- ‘Uridine diphosphate (UDP)-glucosyltransferase, protein engineered variant, sourced from *Escherichia coli* K-12 containing the UDP-glucosyltransferase gene from *Oryza sativa*’; and
- ‘Uridine triphosphate (UTP)-glucose-1-phosphate uridylyltransferase, protein engineered variant, (EC 2.7.7.9) sourced from *Escherichia coli* K-12, containing the gene for UTP-glucose-1-phosphate uridylyltransferase from *Bifidobacterium* bifidum’.

The permitted technological purpose for each enzyme is prescribed in column 2 of the table for the corresponding enzyme.

For both the sucrose synthase and UTP-glucose-1-phosphate uridylyltransferase enzymes, the technological purpose is ‘for the conversion of purified stevia leaf extract to produce one or more of the following: rebaudioside M and rebaudioside I’.

For the UDP-glucosyltransferase enzyme, the technological purpose is ‘for the conversion of purified stevia leaf extract to produce rebaudioside M’.

The maximum permitted level (MPL) at which each enzyme may be present in food is prescribed in column 3 of the table for the corresponding enzyme. For each enzyme inserted into the table in this variation, the MPL specified is GMP i.e. the MPL must be consistent with Good Manufacturing Practice (as defined by subsection 1.1.2—2(3) of the Code).

The cumulative effect of the amendments in items [1] and [2] above would be to permit the applicant’s bioconversion methods of producing the steviol glycosides: rebaudiosides I and M, using three new protein-engineered enzymes sourced from genetically modified *Escherichia coli* as processing aids, and the use of those three enzymes for that specific purpose, in accordance with the Code.