

Attachment B – Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1277 – 2'-FL from GM Escherichia coli K-12 (gene donor: Helicobacter enhydrae) in infant formula products) 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 A1277 which sought to amend the Code to permit 2'-fucosyllactose (2'-FL) produced from a new genetically modified (GM) strain of *Escherichia coli* K-12 to be used as a nutritive substance in infant formula products. The application also sought a 15 month exclusive use permission. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation - the *Food Standards (Application A1277 - 2'-FL from GM Escherichia coli K-12 (gene donor: Helicobacter enhydrae) in infant formula products) 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).

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 to the Code to:

- Amend Schedule 26 of the Code to permit 2'-FL produced from a new genetically modified source i.e. *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter enhydrae*, to be used as a nutritive substance in infant formula products subject to an exclusive use permission for a period of 15 months linked to the applicant's brand name '2'-FL-Inbiose'.
- Amend the current specification in Schedule 3 of the Code for 2'-FL sourced from *Escherichia coli* K-12 (section S3—40) to include 2'-FL from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter enhydrae* in the list of substances to which the specifications in section S3—40 apply.

4. Documents incorporated by reference

The approved draft variation prepared by the Authority does not incorporate any documents by reference.

However, the approved draft variation varies Schedule 3 of the Code which does incorporate documents by reference. Section 1.1.1—15 of the Code requires certain substances (such as substances used as nutritive substances) to comply with any relevant identity and purity specifications listed in Schedule 3.

Schedule 3 incorporates documents by reference to set specifications for various substances in the circumstances specified in that Schedule. The documents incorporated include: the 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.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1277 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment reports. Submissions were called for on 10 October 2023 for a six-week consultation period. Further details of the consultation process, the issues raised during consultation and by whom, and the Authority's response to these issues are available in an approval report published on the Authority's website at www.foodstandards.gov.au.

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 FSANZ that a Regulatory Impact Statement was not required for the applications relating to nutritive substances and genetically modified food. This is

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

because applications relating to permitting the use of nutritive substances and genetically modified food that have been determined to be safe are considered to be 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 regulatory impact statement was 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 A1277 – 2'-FL from GM Escherichia coli K-12 (gene donor: Helicobacter enhydrae) in infant formula products) 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.

Items [1] and [2] of the Schedule to the variation amend Schedule 3 of the Code.

Schedule 3 contains specifications for the purposes of section 1.1.1—15 of the Code. Section 1.1.1—15 requires certain substances, e.g. substances used as nutritive substances, to comply with any relevant identity and purity specifications listed in Schedule 3 when added to food in accordance with the Code, or sold for use in food. Specifications include those set out in provisions which are listed in the table to subsection S3—2(2) (see paragraph S3—2(1)(a)).

Item [1] amends the table to subsection S3—2(2). This table lists entries consisting of substances for which there are specifications in Schedule 3; and their associated provisions.

In particular, item [1] amends the entry in the table to subsection S3—2(2), which is associated with section S3—40 by inserting *Helicobacter enhydrae* as a source of 2'-FL produced from *Escherichia coli* K-12 in that entry. This amendment is consequential to the amendment in item [2] below.

Item [2] amends section S3—40, which sets out the specification for 2'-FL produced from specific sources of *Escherichia coli* K-12.

In particular, item [2] inserts '*Helicobacter enhydrae*' in the list of sources of 2'-FL produced from *Escherichia coli* K-12 for the purposes of that specification.

The effect of the amendments in items [1] and [2] is that 2'-FL produced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter enhydrae* will have to comply with the specification set out in section S3—40 when added to infant formula products for use as a nutritive substance (or sold for such use).

Item [3] of the Schedule to the variation amends Schedule 26 of the Code.

Schedule 26 relates to food produced using gene technology. 2'-FL sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter enhydrae* is

a food produced using gene technology (as defined in subsection 1.1.2—2(3) of the Code) because it is produced from an organism modified using gene technology.

Paragraph 1.5.2—3(a) permits a food for sale to consist of, or have as an ingredient, a food produced using gene technology if the food produced using gene technology (other than a processing aid or food additive) is listed in Schedule 26 and complies with any corresponding conditions in that Schedule.

The table to subsection S26—3(7) lists food produced using gene technology of microbial origin.

Item [3] amends item 1 of that table by inserting new paragraph (d) into the column headed 'Source'. Item 1 of the table relates to 2'-FL. New paragraph (d) refers to:

'Escherichia coli K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter enhydrae*'.

Associated conditions of use for 2'-FL from this new source are set out in column 3 of the table as follows:

1. the substance may only be added to infant formula products
2. during the exclusive use period, the substance may only be sold under the brand 2'-FL-Inbiose and
3. for the purposes of condition 2, exclusive use period means the period commencing on the date of gazettal of the *Food Standards (A1277 - 2'-FL from GM Escherichia coli K-12 (gene donor: Helicobacter enhydrae) in infant formula products) Variation* and ending 15 months after that date.

Condition 2 means that 2'-FL sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter enhydrae* may only be sold under the brand '2'-FL-Inbiose' during the exclusive use period. 'Exclusive use period' is defined in condition 3 as the period commencing on gazettal of the draft variation and ending 15 months after that date.

The effect of the amendment in item [3] is that 2'-FL from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter enhydrae* is a 2'-FL permitted for use by Standard 1.5.2.is In other words, the sale and use of this 2'-FL as a food produced using gene technology is permitted, subject to the above conditions of use for the substance and in accordance with the Code.

Once the exclusive use period ends, the permission will revert to a general permission, meaning that the proposed permission will then permit the sale and use of 2'-FL sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter enhydrae* under any brand.

The amendments made by item [3] do not make any substantive change to *existing* permissions and to other requirements in the Code relating to food produced using gene technology.

The effect of the amendment in item [3] is also to permit 2'-FL sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter enhydrae* to be used as a nutritive substance in infant formula products in accordance with the Code.

This is because subsection 2.9.1—5(1) and section S29—5 permit a '2'-fucosyllactose permitted for use by Standard 1.5.2' to be used as a nutritive substances in infant formula products at an amount no greater than 96 mg/100 kJ.