

## **EXPLANATORY STATEMENT**

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

#### ***Food Standards (Application A1265 – 2'-FL/DFL, LNT, 6'-SL sodium salt and 3'-SL sodium salt as nutritive substances 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 A1265 which sought to permit the use of four human-identical milk oligosaccharide products, each derived from a specific genetically modified *Escherichia coli* (*E.coli*) strain, as nutritive substances in infant formula products. The four products or substances are:

- a mixture of 2'-fucosyllactose (2'-FL) and difucosyllactose (DFL) (2'-FL/DFL);
- lacto-N-tetraose (LNT);
- 6'-sialyllactose (6'-SL) sodium salt; and
- 3'-sialyllactose (3'-SL) sodium salt.

The Application also sought a 15 month exclusive use permission.

The Authority assessed the Application in accordance with Division 1 of Part 3 of the FSANZ Act.

During that assessment, the Authority identified a need to amend the Code to remove the current prohibition on the addition to infant formula products of galacto-oligosaccharides and/or inulin-type fructans in combination with lacto-N-neotetraose (LNT). Removal of this prohibition was not requested in Application A1265, but was considered warranted by the Authority.

Based on that assessment, the Authority prepared a draft variation - the *Food Standards (Application A1265 – 2'-FL/DFL, LNT, 6'-SL sodium salt and 3'-SL sodium salt as nutritive substances in infant formula products) Variation* and consulted on that draft variation.

Following consultation, the Authority has further considered the application in accordance with Division 1 of Part 3, amended the draft variation, and approved the amended draft variation (approved draft variation).

Following consideration by the Food Ministers' Meeting, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the approved 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 the amended draft variation to the Code to:

- amend Schedule 29 of the Code to permit each of the four substances to be used in infant formula products, either alone or in combination, as a nutritive substance up to a specified maximum permitted amount;
- amend Schedule 26 of the Code to permit each of the four substances, as substances derived from a new genetically modified microbial source, to be added to infant formula products subject to certain conditions, including an exclusive use period of 15 months for the applicant's brand of each substance;
- amend Schedule 3 of the Code to include identity and purity specifications for each of the four substances; and
- remove the current prohibition in Standard 2.9.1 on the use of galacto-oligosaccharides and/or inulin-type fructans with lacto-N-neotetraose.

### **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 will vary 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) Compendium of Food Additive Specifications (FAO/WHO 2019);
- the United States Pharmacopeial Convention (2020);
- Food Chemicals Codex (12th 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 A1265 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 8 June 2023 for a 4-week consultation period.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)<sup>14</sup>. 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. This is because applications relating to permitting the use of nutritive substances that have been determined to be safe are considered to be minor and deregulatory in nature as their use will be voluntary if the application is approved. Under the new approach, FSANZ's assessment is that a regulatory impact statement 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 provides that the name of the variation is the *Food Standards (Application A1265 – 2'-FL/DFL, LNT, 6'-SL sodium salt and 3'-SL sodium salt as nutritive substances in infant formula products) Variation*

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

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

Item [1] of the Schedule to the variation amends Standard 2.9.1 by repealing subsection 2.9.1—7(2). The effect of this amendment is to remove the current prohibition on the addition to infant formula products of galacto-oligosaccharides and/or inulin-type fructans in combination with lacto-N-neotetraose.

Items [2] and [3] of the Schedule amends 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. Specifications include those set out in provisions which are listed in the table to subsection S3—2(2) (see paragraph S3—2(1)(a)).

The amendments made by items [2] and [3] set – for the purposes of section 1.1.1—15 of the Code - a specification for each of the four substances listed above.

Item [2] amends the table to subsection S3—2(2) by inserting in alphabetical order new entries for:

- '2'-fucosyllactose and difucosyllactose sourced from *Escherichia coli K-12*' and a corresponding reference to new section S3—47 (see item [3] below)
- 'lacto-N-tetraose sourced from *Escherichia coli K-12*' and a corresponding reference to

- new section S3—48 (see item [3] below)
- ‘6'-sialyllactose sodium salt sourced from *Escherichia coli K-12*' and a corresponding reference to new section S3—49 (see item [3] below)
- ‘3'-sialyllactose sodium salt sourced from *Escherichia coli K-12*' and a corresponding reference to new section S3—50 (see item [3] below)

Item [3] inserts new sections S3—47, S3—48, S3—49 and S3—50 into Schedule 3 in numerical order after S3—46.

New section S3—47 lists a specification for 2'-fucosyllactose and difucosyllactose sourced from *Escherichia coli K-12*.

New section S3—48 lists a specification for lacto-N-tetraose sourced from *Escherichia coli K-12*.

New section S3—49 lists a specification for 6'-sialyllactose sodium salt sourced from *Escherichia coli K-12*.

New section S3—50 lists a specification for 3'-sialyllactose sodium salt sourced from *Escherichia coli K-12*.

Item [4] of the Schedule amends Schedule 26 of the Code.

Schedule 26 relates to food produced using gene technology. Each of the four substances listed above is a food produced using gene technology (as defined in subsection 1.1.2—2(3) of the Code) because it is derived from an organism modified using gene technology. That is, from a genetically modified *Escherichia coli (E.coli) K-12* strain.

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 [4] amends that table by adding new table items 4 to 7 to provide a permission for the use of each of the four substances.

Each permission is subject to conditions of use set out in column 3. These conditions of use are 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 name specified by and for that permission; and
3. for the purposes of condition 2, exclusive use period means the period commencing on the date of gazettal of the variation and ending 15 months after that date.

Condition 2 means that each substance, as a permitted food produced using gene technology, may only be sold under the specified brand during the exclusive use period. 'Exclusive use period' is defined in condition 3 as the period commencing upon gazettal of the variation and ending 15 months after that date

Once this period ends, each permission will revert to a general permission, meaning that the proposed permission will then permit the four substances sourced from the specified genetically modified *Escherichia coli (E.coli)* strain to be sold under any brand.

The amendments made by item [4] do not make any substantive change to *existing* permissions and to other requirements in the Code relating to food produced using gene technology.

Item [5] of the Schedule amends Schedule 29 of the Code.

The item amends the table to section S29—5. The table lists the new substances permitted for use as nutritive substances in infant formula products. The item amends the table by inserting into that table in alphabetical order a separate new permission for each of the following:

- 3'-sialyllactose sodium salt, with a specified maximum permitted amount of 8 mg/100 kJ;
- 6'-sialyllactose sodium salt, with a specified maximum permitted amount of 16 mg/100 kJ;
- a combination of 2'-fucosyllactose and difucosyllactose, with a specified maximum permitted amount of 96 mg/100 kJ; and
- lacto-N-tetraose, with a specified maximum permitted amount of 32 mg/100 kJ.

A minimum amount is not set for each permission or substance as this was not requested in the Application and has not been determined by the Authority.

Each permission prescribes a permitted form for the permitted substance. This means that the substance must be used in that form.

Each permission is also expressly linked to these substances as permitted for use by Standard 1.5.2 (*Food produced using gene technology*). This means that only those substances derived from the relevant microbial source listed in Schedule 26 (table to subsection 26—3(7)) for that substance will be permitted for use as a nutritive substance in infant formula products.