

## 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.

FSANZ had originally accepted application A1155 which sought to permit the voluntary addition of 2'-O-fucosyllactose (2'-FL) alone or in combination with Lacto-N-neotetraose (LNnT), produced by microbial fermentation, to infant formula products and formulated supplementary foods for young children. The Authority had considered the Application in accordance with Division 1 of Part 3, and had approved a draft variation to the Code.

Following review of the approved draft variation by the Food Ministers Meeting<sup>1</sup> in accordance with Division 3 of Part 3 of the FSANZ Act, the Food Ministers Meeting decided to amend the approved draft variation permitting the voluntary addition of 2'-O-fucosyllactose (2'-FL) alone or in combination with Lacto-N-neotetraose (LNnT), produced by microbial fermentation, to infant formula products only.

The Food Ministers Meeting provided the Authority with a copy of the amended approved draft variation. Subsection 90(3) of the FSANZ Act required the Authority to prepare and publish a notice under section 92 of that Act in relation to that variation.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislation Act 2003*.

## 2. Purpose

The purpose of the amended approved draft variation to the Code is to:

- Amend Schedule 26 to permit 2'-FL and LNnT derived from specific microbial sources for use in infant formula products; and to provide an exclusive use period of 15 months for the applicant's brand of 2'-FL and LNnT.
- Amend Schedule 29 to permit the same 2'-FL alone or combined with LNnT for use as nutritive substances in infant formula products, within specified maximum levels.
- Amend Standard 2.9.1 to prohibit certain representations (e.g. 'human milk identical oligosaccharide') on labels of infant formula products; and to prohibit the use of 2'-FL alone or with LNnT, in combination with existing permissions for ITF and GOS.
- Insert prescribed specifications for 2'-FL and LNnT into Schedule 3.
- Insert a new unit of measure, as used in the prescribed specifications, in Schedule 2.

## 3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

## 4. Consultation

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<sup>1</sup> Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation established by the

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of application A1155 included two rounds of public comment following an assessment and the preparation of a draft variation and associated assessment summaries. Submissions were first called for on 22 November 2018 for a six week consultation period. Submissions on a proposed draft variation were sought on 22 July 2019 for a six week consultation period.

A Regulation Impact Statement was not required because the proposed variations are likely to have a minor impact on business and individuals (OBPR ID 23349).

In reviewing the approved draft variation, the Food Ministers Meeting consulted with the Authority in accordance with Division 3 of Part 3 of the FSANZ Act.

## **5. 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 94 of the FSANZ Act.

## **6. Variation**

### ***Item [1]***

Item [1.1] varies Standard 2.9.1 by omitting the existing section 2.9.1–7 and substituting a new subsection. The new subsection restates the permitted quantities of ITF and GOS in the current subsection, and includes a new requirement which will prohibit an infant formula product to which ITF or GOS are added, from containing 2'-FL alone, or a combination of 2'-FL and LNnT.

Item [1.2] varies Standard 2.9.1 by inserting new subparagraphs 2.9.1–24(1)(ca) and (cb). These new subparagraphs will prohibit the use of the words 'human milk oligosaccharide', 'human milk identical oligosaccharide (or any word or words of similar effect)', and the use of abbreviations 'HMO' or 'HiMO' (or any abbreviation having the same or similar effect), on the label on a package of infant formula product (i.e. not used in associated with 'human milk' or 'human milk identical') on the label on a package of an infant formula product.

### ***Item [2]***

Item [2] varies Schedule 2 to insert a new unit of measurement EU/mg (endotoxin unit per milligram), as used in the new specifications in Schedule 3 (see Item [3] below).

### ***Item [3]***

Item [3] varies Schedule 3 to insert new specifications for 2'-FL (new section S3–40) and LNnT (new section S3–41).

### ***Item [4]***

Item [4] varies Schedule 26 to insert a new table under a new subsection (7) with the heading *Food produced using gene technology of microbial origin*. This new table lists 2'-FL and LNnT from permitted microbial sources. This amendment will not amend the existing approvals currently listed in the table to subsection (4), or change the requirements for pre-market assessment and approval of GM foods. The detailed amendments made to this Schedule are discussed below.

Item [4.1] omits subsections 26–3(1), (2), (2A) and (3) and substitutes these with new subsections. New subsection (1) specifies that the existing table to subsection (4) and the new table to subsection (7) lists permitted food produced using gene technology. New subsections (2), (2A) and (3) restate the existing labelling requirements, but now specify that these apply to the existing table to subsection (4).

Item [4.2] omits the words ‘gene technology’ from the heading of the existing table to subsection (4) and replaces this with the words ‘gene technology of plant origin’ (i.e. the full table heading will now be *Food produced using gene technology of plant origin*). This amendment clarifies that permissions in the existing table to subsection (4) relate to food of plant origin, to distinguish these from the new permissions for 2'-FL and LNnT which are food of microbial origin (new table to subsection (7)).

Item [4.3] inserts new subsections 26–3(5), (6) and (7). Subsection (7) inserts a new table (*Food produced using gene technology of microbial origin*) which lists 2'-FL and LNnT sourced from specific gene-gene donor information. Subsections (5) and (6) require that a food listed in this new table must comply with any corresponding conditions listed in the table, and that the source listed in the table may contain additional copies of genes from the same strain. The new table includes the condition that 2'-FL and LNnT are only permitted to be added to infant formula products. It also includes the condition that, during the ‘exclusive use period’, 2'-FL and LNnT from the permitted source listed may only be sold under the brand name ‘GlyCare’. ‘Exclusive use period’ is defined to be the period commencing on the date of gazettal of the variation, and ending 15 months after that date. This means that the new permission will apply exclusively to 2'-FL and LNnT as listed in Schedule 26, under the brand ‘GlyCare during this period’. Once this period ends, the exclusive use permission will revert to a general permission, meaning that the permission will apply to all brands of 2'-FL and LNnT that meet the specific source and associated specifications in Schedule 3.

#### **Item [5]**

Item [5] varies Schedule 29 by omitting section 29–5 and substituting a new section to add 2'-FL, and 2'-FL combined with LNnT, in the table to this section as new substances permitted for use as nutritive substances in infant formula products. 2'-FL and LNnT listed in this table are linked to these substances permitted for use by Standard 1.5.2 (*Food produced using gene technology*). This means that only 2'-FL and LNnT derived from the microbial sources listed in Schedule 26 (table to subsection 26–3(7)) are permitted for use in infant formula products. The permission in section 29–5 also lists permitted forms, and requires infant formula products to contain not more than 96 mg/100 kJ of 2'-FL; and not more than 96 mg/100 kJ of 2'-FL and LNnT combined (of which contains not more than 24 mg/100 kJ of LNnT). A minimum amount is not set, as this was not requested in the application and has not been determined by FSANZ.