

## 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 A1233 which sought to permit the voluntary addition of 2'-fucosyllactose (2'-FL) from a new microbial source, as a nutritive substance, to infant formula products. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a 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 standard or draft variation of a standard.

## 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 Food Ministers Meeting (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 purpose of the approved draft variation is to :

- amend Schedule 26 of the Code to permit the addition of 2'-FL derived from a new microbial source in infant formula products subject to certain conditions, including an exclusive use period of 15 months for the applicant's brand of 2'-FL; and
- amend Schedule 3 of the Code to set a new specification for 2'-FL sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from either *Helicobacter pylori* or *Bacteroides vulgatus*.

### **4. Documents incorporated by reference**

The approved draft variation 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 A1233 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 6 December 2021 for an eight-week consultation period.

A Regulation Impact Statement (RIS) was not required because the Office of Best Practice Regulation (OBPR) granted the Authority a standing exemption, permitting the voluntary use of genetically modified food (OBPR correspondence dated 24 November 2010, reference 12065), and the voluntary addition of nutritive substances to foods (OBPR correspondence dated 16 April 2013, reference 14943).

### **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**

The amendments in the Schedule take effect in numerical order i.e. according to item and sub-item numbers.

**Item [1]** of the Schedule varies 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. The specifications listed in Schedule 3 include those set out in provisions which are listed in the table to subsection S3—2(2) (see paragraph S3—2(1)(a)).

Item [1.1] amends the table to subsection S3—2(2). It amends the entry in that table for section S3—40 by replacing the words ‘2'-fucosyllactose sourced from *Escherichia coli* K-12' with ‘2'-fucosyllactose sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from either *Helicobacter pylori* or *Bacteroides vulgatus*'. This amendment is a consequence of the amendment made by item [1.2] below.

Item [1.2] repeals and replaces section S3—40 with a new section S3—40. The new section lists a specification for 2'-fucosyllactose sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from either *Helicobacter pylori* or *Bacteroides vulgatus*'.

**Item [2]** 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 *Bacteroides vulgatus* 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.

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 [2] will amend item [1] of that table to provide a permission for the use of 2'-FL sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus*.

In order to add the new permission to the table, item [2] will repeal and then restate the entire entry in the table for 2'-FL but with the new source permission included in the restated entry as sub-item (c) in column 2, and its associated 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;
2. during the exclusive use period, the substance may only be sold under the brand Aequival® 2'FL; and
3. for the purposes of condition 2, exclusive use period means the period commencing on the date of gazettal of the *Food Standards (Application A1233 – 2'-FL from new GM source for infant formula) Variation* and ending 15 months after that date.

Condition 2 will mean that 2'-FL sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* may only be sold under the brand 'Aequival® 2'FL' during the exclusive use period. 'Exclusive use period' will be defined in condition 3 as the period commencing upon gazettal of the draft variation and ending 15 months after that date

Once this period ends, the permission will revert to a general permission, meaning that the permission will then permit the sale of 2'-FL sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* to be sold under any brand.

The amendments made by **item [2]** do not make any substantive change to *existing* permissions and to other requirements in the Code relating to food produced using gene technology.