

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 A1190 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 and formulated supplementary foods for young children (FSFYC). 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.

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 Authority has approved a draft variation to the Code to:

- amend Schedule 26 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
- insert prescribed specifications for this 2'-FL into Schedule 3.

The approved draft variation includes consequential amendments to the Code as a result of the above amendments.

3. 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.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of application A1190 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 22 July 2021 for a four-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).

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

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

Item [1]

Item [1] varies Standard 2.9.1 by omitting references to '2'-O-fucosyllactose' wherever occurring in subsection 2.9.1—7(2), and substituting them with references to '2'-fucosyllactose'. The revised reference reflects the preferred substance name for all permitted 2'-FL in the Code.

This amendment is a consequence of the amendments in **items [2]** and **[3]** below.

Item [2]

Item [2] sets out the following amendments to Schedule 3.

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)).

Sub-item [2.1] omits references to '2'-O-fucosyllactose' and 'section S3—40' in columns 1 and 2 respectively of the table to subsection S3—2(2), substituting them with, in alphabetical order, references to '2'-fucosyllactose sourced from *Escherichia coli* K-12' and 'section S3—40'.

This amendment reflects the preferred substance name and source; and distinguishes between the specifications for 2'-fucosyllactose from *Escherichia coli* K-12 and specifications for the new substance sought to be permitted by the applicant - 2'-fucosyllactose from *Escherichia coli* BL21 (see sub-items [2.2] and [2.5] below).

Sub-item [2.2] inserts into columns 1 and 2 of the table to subsection S3—2(2), in alphabetical order, new references to '2'-fucosyllactose from *Escherichia coli* BL21' and 'section S3—5' respectively. These new references relate to the new provision that is inserted by sub-item [2.5] below.

Sub-item [2.3] omits the heading for section S3—40, substituting it with '2'-fucosyllactose (2' FL) sourced from *Escherichia coli* K-12' (see sub-item [2.1] above).

Sub-item [2.4] omits the reference to '2'-O-fucosyllactose (2'-FL)' in section S3—40, substituting it with a reference to '2'-fucosyllactose (2' FL) sourced from *Escherichia coli* K-12' consistent the new heading for section S3—40 (see sub-items [2.1] and [2.3] above).

The effect of the amendments in sub-items [2.3] and [2.4] is that the specifications in section S3—40 will relate specifically to 2'-fucosyllactose (2' FL) sourced from *Escherichia coli* K-12.

Sub-item [2.5] inserts new section S3—45 which sets out the specifications relating specifically to 2'-fucosyllactose sourced from *Escherichia coli* BL21, the new substance sought to be permitted by the applicant.

Consequently, the permission for 2'-fucosyllactose sourced from *Escherichia coli* BL21 to be used as a nutritive substance in infant formula products (or sold for such use) will be subject

to the requirement in section 1.1.1—15 that the substance must comply with these specifications.

Item [3]

Item [3] sets out the following amendments to Schedule 26.

Schedule 26 relates to food produced using gene technology. 2'-fucosyllactose sourced from *Escherichia coli* BL21 is a food produced using gene technology (as defined in subsection 1.1.2—2(3)) 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.

Sub-item [3.1] omits item 1 in the table to subsection S26—3(7), substituting it with a revised item 1.

Revised item 1 refers to '2'-fucosyllactose' as the substance name in column 1 of the table instead of '2'-O-fucosyllactose' (see sub-item [2.1] above).

Revised item 1 also includes a new source (paragraph (b)) of 2'-fucosyllactose in column 2 of the table - *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *Escherichia coli* O126.

Revised item 1 also sets out the following new conditions in column 3 of the table, both of which 2'-fucosyllactose from source (b) must comply with:

- (a) 2'-fucosyllactose from source (b) may only be added to infant formula products; and
- (b) during the 'exclusive use period' (i.e. the period commencing on the date of gazettal of this approved draft variation, and ending 15 months after that date), 2'-fucosyllactose from source (b) may only be sold under the brand name 'CHR. HANSEN™ 2'-FL'.

Condition (b) means that the permission for 2'-FL from source (b) will apply exclusively to that substance under the brand 'CHR. HANSEN™ 2'-FL' in accordance with the Code. Once this period ends, the exclusive use permission will revert to a general permission, meaning that the permission will then apply to all brands of 2'-FL from source (b) in accordance with the Code.

The effect of the amendment in sub-item [3.1] is that 2'-fucosyllactose derived from *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *Escherichia coli* O126 will be permitted to be used as a nutritive substance in infant formula products:

- in accordance with the Code; and
- subject to the above exclusive use condition.

Sub-item [3.2] omits the reference to '2'-O-fucosyllactose' in item 2 in the table to subsection S26—3(7), substituting it with a reference to '2'-fucosyllactose'. This amendment is a consequence of the amendments in sub-item [3.1] above.

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

Item [4]

Item [4] varies Schedule 29 by omitting references to '2'-O-fucosyllactose' wherever occurring in the table to section 2.9.1—5, and substituting them with references to '2'-

fucosyllactose'. As stated above, the revised reference reflects the preferred substance name for all permitted 2'-FL.

This amendment is a consequence of the amendments in **items [2]** and **[3]** above.