## Explanatory Statement

**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 accepted Application A1055, in which the Applicant seeks amendments to the Code to permit the optional addition of short chain FOS produced from sucrose by enzymatic action (short chain FOSsucrose) to Infant Formula Products (Standard 2.9.1), Foods for Infants (Standard 2.9.2) and Formulated Supplementary Foods for Young Children (Standard 2.9.3 Division 4).

The Code currently permits ‘inulin-derived substances’ (IDS), alone or in combination with galacto-oligosaccharides (GOS), to be added to these food categories up to a maximum amount. The definition of IDS in the Code incorporates short chain FOS derived from inulin (short chain FOSinulin). The Applicant proposes short chain FOSsucrose be used as an alternative to IDS at the same levels as currently permitted.

The Applicant also requested amending Standard 1.3.3 to permit the use of a new microbial source of β-fructofuranosidase (also called invertase) (EC 3.2.1.26) enzyme from a strain of the fungus *Aspergillus niger* (*A. niger*) as a processing aid (enzyme) to be used in the production of short chain FOSsucrose.

The Authority considered Application A1055 in accordance with Division 1 of Part 3 and has approved a draft variation setting out amendments to Standards 1.1.1, 1.3.3, 2.9.1, 2.9.2 and 2.9.3.

Following consideration by the COAG Legislative and Governance Forum on Food Regulation[[1]](#footnote-1), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the draft 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 sunsetting under the *Legislative Instruments Act 2003*.

**2. Purpose and operation**

The purpose of the draft variation is to amend the following Standards in the Code:

* Standard 1.1.1
* Standard 1.3.3
* Standards 2.9.1 to 2.9.3.

The proposed amendments are as follows:

* replacing the term ‘inulin-derived substances’ (IDS) and its definition with a new term ‘inulin-type fructans’ (ITF) and its definition (Standard 1.1.1);
* replacing references to IDS with the new term ITF throughout the Code (Standards 1.1.1, 2.9.1 to 2.9.3); and
* adding *Aspergillus niger* as an additional source of the enzyme β-fructofuranosidase (EC3.2.1.26) (Table to clause 17 in Standard 1.3.3).

Replacing the reference to IDS with ITF in Standards 2.9.1, 2.9.2 and 2.9.3 would enable both short chain FOSsucrose and IDS, alone or in combination with each other and/or GOS, to be added to infant formula products, infant foods and formulated supplementary foods for young children.

In addition, the Code currently states that IDS are taken not to be nutritive substances. This principle would apply to the new term, ITF. This means that the use of ITF, including short chain FOSsucrose, would not be prohibited in general foods.

Amending Standard 1.3.3 – Processing Aids, would enable manufacturers to produce short chain FOSsucrose using the invertase enzyme from a natural, genetically unmodified strain of the fungus *A. niger* as a processing aid.

**3. Documents incorporated by reference**

The variation to food regulatory measures does not incorporate any documents by reference.

**4. Consultation**

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority’s consideration of Application A1055 included one round of public consultation following an assessment of A1055, the preparation of a draft variation setting out amendments to Standards 1.1.1, 1.3.3, 2.9.1, 2.9.2 and 2.9.3 and associated report.  Submissions were called for in December 2012 for an eight-week consultation period. As a result of submissions received, some amendments were made to the draft variation.

An expert group, the Infant and Child Health Scientific Advisory Group (ICHSAG), was established with representatives from the fields of paediatrics, child nutrition research, gastroenterology and clinical nutrition to provide advice to the Authority throughout the standard development process. The ICHSAG contributed a broad spectrum of knowledge and expertise in the field of infant and young children’s nutrition.

A Regulation Impact Statement (RIS) was not required because the proposed variation provides only for the optional, as opposed to mandatory, addition of an ingredient and is unlikely to have a major impact on business and individuals.

**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. Variations**

***Subitem [1.1]***

Subitem [1.1] amends clause 2 of Standard 1.1.1 to replace the current term IDS and its definition with the new term ITF and its definition. Although not specified in the definition itself, the mixtures referred to in the definition of ‘inulin-type fructans’ would include but is not limited to substances described as -

1. FOS; or
2. short-chain FOS; or
3. oligofructose; or
4. inulin.

***Subitem [1.2]***

Subitem [1.2] amends clause 9A of Standard 1.1.1 to replace the reference to IDS with a reference to ITF. This amendment means that ITF would be taken not to be nutritive substances and, consequently, the use of ITF in general foods would not be prohibited.

***Subitem [2.1]***

Subitem [2.1] amends the Table to clause 17 of Standard 1.3.3 to omit the invertase enzyme (EC3.2.1.26) sourced from *Saccharomyces cerevisiae* from the list of permitted enzymes of microbial origin that may be used as a processing aid.

***Subitem [2.2]***

Subitem [2.2] amends the Table to clause 17 of Standard 1.3.3 by inserting a reference to the enzyme β-fructofuranosidase (EC3.2.1.26) sourced from both *Saccharomyces cerevisiae and A. niger* into the list of permitted enzymes of microbial origin that may be used as a processing aid.

***Subitem [3.1] and items [4] and [5]***

Subitem [3.1] and items [4] and [5] amend Standards 2.9.1, 2.9.2 and 2.9.3 respectively toreplacethe termIDS wherever this term occurs within those Standards with the term ITF. This is in line with the amendments made to Standard 1.1.1 above. These amendments permit ITF, which includes short chain FOSsucrose, to be added to infant formula products, infant foods and formulated supplementary foods for young children, alone or in combination with each other and/or GOS, at the maximum amounts currently prescribed in relation to IDS or IDS and GOS in these Standards.

***Subitem [3.2]***

Subitem [3.2] amends the Table of contents of Standard 2.9.1 so that clause 9A, which is currently not in the Table of contents, will be added to it with the new heading “Permitted inulin-type fructans and galacto-oligosaccharides.”

1. Previously known as the Australia and New Zealand Food Regulation Ministerial Council [↑](#footnote-ref-1)