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 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

FSANZ prepared Proposal P1025 to revise the Code. The Authority considered the Proposal in accordance with Division 2 of Part 3 and has approved a draft revised Code.

Following consideration by the Legislative and Governance Forum on Food Regulation[1], 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 sunsetting under the *Legislative Instruments Act 2003*.

2. Purpose

The Authority has approved variations of Chapters 1 and 2 of the Code.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference. The variations update some references to documents that are incorporated by reference.

4. Consultation

In accordance with the procedure in Subdivision F of Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1025 included two rounds of public comment following an assessment and the preparation of a draft Standard and associated reports. Submissions were called for on 23 May 2013 for a 12-week period, and on 10 July 2014 for an eight-week period.

A Regulation Impact Statement was not required, because the proposed variations to the Code are likely to have a minor 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. Variation (Chapter 1—Introduction and standards that apply to all foods, Part 1—Preliminary)

Standard 1.1.2 – Definitions used throughout the Code

New section 1.1.2—1 Name

This section establishes that the instrument is the *Australia New Zealand Food Standards Code* – Standard 1.1.2 – Definitions used throughout the Code.

[1] Previously known as the Australia and New Zealand Food Regulation Ministerial Council

New section 1.1.2—2 Definitions—general

This section provides definitions for the Code, or signposts to those definitions, for terms that do not describe foods. Food definitions are in the following section 1.1.2—3.

A few definitions, that have an application only in a single section of the Code, are set out in those sections.

Section 1.1.2—2 addresses an issue raised in the legislative audit about the placement of definitions throughout the Code. The new section places all definitions that have a non-food, Code-wide application in the one place, where they can be located conveniently.

Definitions that have specific relevance in a Division of the Code are placed within that Division. In most cases a signpost to the relevant definition is included in new section 1.1.2—2. However, some definitions that have only a local function within a section are not signposted.

New section 1.1.2—3 Definitions—particular foods

Definitions that currently provide standards for foods in Standard 1.1.1 or in Chapter 2, are now in new section 1.1.2—3 (either as a stand-alone definition or as a signpost to a definition that is expressed later in the Code). The compositional requirements for foods are stated independently of the definition.

The separation of definitions and compositional elements is a response to concerns expressed in consultation that the form of drafting adopted in the current Code is out-dated. Also, it is said that the current drafting style creates difficulty for enforcement agencies because the inclusion of both identifying and compositional elements in the definition means that a food product that does not comply with the compositional element cannot be considered as a food of the type identified.

Some definitions include characterising information that might appear to be a compositional requirement. Characterising information is not a compositional requirement.

The current drafting style relies on clause 14 of Standard 1.1.1 which provides that when a definition of food includes a compositional element the definition is taken to be a standard for the composition of that food. The application of requirements is implicit rather than explicit. New section 1.1.1—13 provides, explicitly, that if the Code provides that food that is sold with a representation that it is a specified food must comply with any requirements for that type of food, the requirements must be complied with. This style of drafting clarifies the requirement to comply with all standards.

New section 1.1.2—4 Definitions of *characterising component* and *characterising ingredient*

This provision re-states the definitions of characterising ingredient and characterising component that are currently in clause 1 of Standard 1.2.10.

New section 1.1.2—5 Definition of *food for special medical purposes*

This provision re-states the definition of food for special medical purposes that is currently in clause 1 of Standard 2.9.5.

New section 1.1.2—6 Definition of *formulated caffeinated beverage*

The current definition of formulated caffeinated beverage has been revised to clarify the nature of the beverage as a type of formulated beverage that contains caffeine. The revisions do not alter the compositional requirements.

New section 1.1.2—7 Definition of *medical institution*

New section 1.1.2—7 provides a definition of medical institution. This provision re-states the content of clause 8 of Standard 1.2.1. Clause 8 appears to be an inclusive definition. However, in the Code, it is used as an exclusive definition. The defined medical institutions are the 'other similar institutions' for the purpose of provisions such as the definition of package in the current Code.

New section 1.1.2—8 Definition of *novel food*

The definitions of novel food and non-traditional food that are currently in clause 1 of Standard 1.5.1 have been revised to improve readability. The term non-traditional food is now used in the definition for 'used as a food additive' to address the concept of common usage.

New section 1.1.2—9 Definition of *nutrition content claim*

This new section repeats the definition of nutrition content claim that is in clause 2 of Standard 1.2.7 and the provisions in subclauses 19(2)—(4) of Standard 1.2.8. The provision has been redrafted to avoid a need to define either voluntary item or mandatory item: terms that are now in subclause 19(1).

New section 1.1.2—10 *RDIs* and *ESADDIs*

This new section describes where the Recommended Dietary Intake or the ESADDI levels of vitamins and minerals are specified in the Code. RDIs and ESADDIs for infants and children aged one to three years are set out in columns 4 and 5 respectively of sections S1—2 and S1—3. RDIs and ESADDIs for all other purposes are set out in column 3 of sections S1—2 and S1—3.

New section 1.1.2—11 Definition of *used as a food additive*

New section 1.1.2—11 provides a definition of used as a food additive. In the current Code, a form of a definition of 'food additive' is provided in the Purpose statement for Standard 1.3.1, but there is no operative definition of 'food additive'. For the purposes of the current Code, a food additive is considered to be any substance that is not normally consumed as a food or an ingredient that is added to a food to perform one or more of a range of designated technological functions.

New subsection (1) formalises the elements of 'substance' and 'addition for a technological purpose' as a substantive part of the Code. The relevant substances are those described in subsection (2) and the relevant technological purposes are those described in Schedule 14.

New subsection (2) provides that the substances that are regulated by this Section are, firstly, the substances listed in Schedules 15 and 16 and, secondly, any other substance that has been selectively concentrated or refined or are synthesised and is a food or ingredient that does not have a history of use. The revision of this provision has the objective of limiting the range of substances that might be considered to be food additives to, firstly, those substances that have been recognised internationally as food additives and secondly, a limited range of substances that have been selectively extracted or refined or have been synthesised and may require a safety assessment before being used as food additives.

Other definitions
New subsection (3) provides definitions of terms that describe the Schedules. FSANZ has elected to use the terms 'additive permitted at GMP', 'colouring permitted at GMP' and colouring permitted to a maximum level' to describe the three categories of additive that are currently listed in Schedules 2, 3 and 4 of Standard 1.3.1.

Colours and their aluminium and calcium lakes
New subsection (4) clarifies that a reference to a colour listed in Schedule 15, a *colouring permitted at GMP or a *colouring permitted to a maximum level includes a reference to the aluminium and calcium lakes prepared from that colour.

New section 1.1.2—12 Definition of *used as a nutritive substance*

This section defines 'used as a nutritive substance' in similar terms to the current definition of nutritive substance in clause 2 of Standard 1.1.1. The definition focusses attention on the purpose of addition of the substance to a food, ie to achieve a nutritional purpose.

The substances that are subject to the provision are substances that, firstly, are identified in the Code as a substance that may be used as a nutritive substance[2] or, secondly, substances that are selectively extracted or refined or are synthesised and are not normal foods or ingredients[3]. Thirdly, the provisions in new paragraph (2)(c) restate the descriptive part of the current definition of nutritive substance and operate to make it clear that inulin-type fructans, GOS and substances that are basic foodstuffs are not regulated as nutritive substances. Some submitters expressed concern about the use of terms relating to 'normal use' and sale to consumers. We are satisfied that the terms are well understood in the context of food regulation in Australia, New Zealand and internationally, and should continue to be used notwithstanding any lack of precision.

This definition operates with new section 1.1.1—10 to prohibit the addition of substances that are not normal foods or ingredients (including vitamins and minerals) for a nutritional purpose, unless there is a specific permission in the Code. Other provisions of the Code establish limits for the addition of such substances.

New section 1.1.2—13 Definition of *used as a processing aid*

This new section provides a definition that describes what a reference to a substance or a food that is used as a processing aid means.

The definitions for dairy ingredient, EC number and maximum permitted level that are currently in Standard 1.3.3 have not been repeated. They are unnecessary in the new Code.

New subsection (1) provides that a reference to a substance used as a processing aid is to a substance listed in Schedule 18 or an additive permitted at GMP (that is, a substance listed in section S16—2) when that substance is used to perform a technological purpose in processing but does not perform a technological in the food when it is sold.

References to foods that are used as a processing aid
New subsection (2) provides that a reference to a food used as a processing aid is to a food that is used to perform a technological purpose in processing but does not perform a technological purpose in the food when it is sold, but only to so much of the food as is necessary to perform the technological purpose.

Note 1 makes it clear that the Code does not prohibit the use of foods as processing aids, unless they are foods referred to in the relevant schedules in which case the use will be subject to conditions.

New section 1.1.2—14 Calculation and expression of amount of vitamin or mineral

This new section sets out how the amount of certain vitamins is to be calculated. This information is currently provided in the Code, partially, in a footnote and, additionally, in the definitions of RDI and ESADDI.

In the revision, the forms of vitamin A that were formerly referred to as carotenoid forms are described as provitamin A forms, following current international practice.

[2] e.g. in Schedule S29—5.
[3] This is a very broad range of substances. The current definition makes it clear that the range of substances that might be used for a nutritive purpose includes vitamins, minerals, amino acids, electrolytes and nucleotides. An example of the substances that are within the scope of this arm of the definition is the list of substances in Schedules S30.19 and S30.20.

Niacin is to be calculated after excluding niacin provided from the conversion of tryptophan. Vitamin C is calculated by adding the amounts of L-ascorbic acid and dehydroascorbic acid.

The new provision clarifies uncertainty in the current Standard about the manner in which naturally occurring and added amounts of a vitamin or mineral should be included in the calculation and expression of an average or aggregate amount.

The table to section S1—3 resolves an anomaly in the current Code in relation to the ESADDIs for biotin and pantothenic acid. At present different, ESADDIs are set for adult populations in, on the one hand, Standards 2.9.3 and 2.9.4, and, on the other, the rest of the Code. The lower ESADDI recognises more recent nutrient reference values. Manufacturers of formulated sports foods and formulated meal replacements may have to alter labelling in the period after commencement of the revision. There are no health or safety concerns posed by the use of either ESADDI level.