**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]](#footnote-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 C*o*de.

**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 2—Food standards for specific foods, Part 9—Special purpose foods)**

Chapter 2 of the *Australia New Zealand Food Standards Code* establishes:

* prescribed standards for the purposes of the false description of foods provisions of the application Acts [[2]](#footnote-2); and
* compositional requirements that are relevant for both the Code[[3]](#footnote-3) and the false description of foods provisions of the application Acts.

Definitions are provided in a Chapter 2 standard, also referred to as a commodity standard, if they can be justified on the grounds of protecting public health and safety, preventing misleading practices or facilitating market access.

Definitions may be included in a Chapter 2 standard to define the scope of the standard and to assist enforcement officers in their assessment of the provisions of the standard; to avoid confusion. When specific definitions are not included in a Chapter 2 standard, enforcement officers and manufacturers may refer to dictionaries for clarification.

Compositional requirements are stated when it is necessary that a food that is sold on the basis that it is a defined food have a particular composition.

***Standard 2.9.5 – Food for special medical purposes***

*Division 1 Preliminary*

New section 2.9.5 —1 Name

This section establishes that the instrument is the *Australia New Zealand Food Standards Code* – Standard 2.9.5 – Food for special medical purposes.

New section 2.9.5—2 Definitions

This section has no operative part. It provides a note reference to the definitions of ‘inner package’, ‘responsible institution’ and ‘package’ that are in subsection 1.1.2—2(3) and the definition of ‘food for special medical purposes’ that is in section 1.1.2—5.

New section 2.9.5—3 Application of other Standards

New section 2.9.5—3 repeats the current content of clause 3 of Standard 2.9.5.

New section 2.9.5—4 Claims must not be therapeutic in nature

New section 2.9.5—4 repeats the current content of clause 4 of Standard 2.9.5.

*Division 2 Sale of food for special medical purposes*

New section 2.9.5—5 Restriction on the persons by whom, and the premises at which, food for special medical purposes may be sold

New section 2.9.5—5 repeats the current content of clause 5 of Standard 2.9.5.

*Division 3 Composition*

New section 2.9.5—6 Permitted forms of particular substances

New section 2.9.5—6 repeats the current content of clause 6 of Standard 2.9.5.

New section 2.9.5—7 Compositional requirements for food represented as being suitable for use as a sole source of nutrition

New section 2.9.5—7 repeats the current provisions of content of clause 7 of Standard 2.9.5.

*Division 4 Labelling*

New section 2.9.5—8 Labelling and related requirements

New section 2.9.5—8 repeats the current content of clause 8 of Standard 2.9.5.

New section 2.9.5—9 Mandatory labelling information

New section 2.9.5—9 re-states the current content of part of clause 9 and clause 16 of Standard 2.9.5.

New section 2.9.5—10 Advisory and warning statements—food for special medical purposes

New section 2.9.5—10 re-states the current content of clauses 10 and 11 of Standard 2.9.5.

New section 2.9.5—11 Information relating to ingredients—food for special medical purposes

New section 2.9.5—11 repeats the current content of clause 12 of Standard 2.9.5.

New section 2.9.5—12 Date marking information—food for special medical purposes

New section 2.9.5—12 repeats the current content of clause 13 of Standard 2.9.5.

New section 2.9.5—13 Nutrition information—food for special medical purposes

New section 2.9.5—13 re-states the current content of parts of clause 9 of Standard 2.9.5.

New section 2.9.5—14 Claims in relation to lactose content

New section 2.9.5—14 re-states the current content of clause 14 of Standard 2.9.5.

New section 2.9.5—15 Claims in relation to gluten content

New section 2.9.5—15 re-states the current content of clause 15 of Standard 2.9.5.

New section 2.9.5—16 Labelling requirement—food for special medical purposes in inner package

New section 2.9.5—16 repeats the current content of clause 17 of Standard 2.9.5.

New section 2.9.5—17 Labelling requirement—food for special medical purposes in transportation outer

New section 2.9.5—17 repeats the current content of clause 18 of Standard 2.9.5.

1. Previously known as the Australia and New Zealand Food Regulation Ministerial Council [↑](#footnote-ref-1)
2. Section 18 of the model food provisions [↑](#footnote-ref-2)
3. Section 17 of the model food provisions [↑](#footnote-ref-3)