

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 Regulation¹, 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 *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 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 Acts²; and
- compositional requirements that are relevant for both the Code³ and the false description of foods provisions of the application Acts.

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

² Section 18 of the model food provisions

³ Section 17 of the model food provisions

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 2.9.1 – Infant formula products

Division 1 Preliminary

New section 2.9.1—1 Name

This section establishes that the instrument is the *Australia New Zealand Food Standards Code – Standard 2.9.1 – Infant formula products*.

New section 2.9.1—2 Outline of Standard

New section 2.9.1—2 provides an outline of Standard 2.9.1.

New section 2.9.1—3 Definitions

This section has no operative part. It provides a note reference to the definitions of ‘follow-on formula’, ‘infant formula’, ‘infant formula product’, ‘medium chain triglycerides’, ‘pre-term formula’, ‘protein substitute’ and ‘soy-based formula’ that are in section 1.1.2—3.

New section 2.9.1—4 Interpretation

New subsection (1) repeats the current content of clause 2 of Standard 2.9.1.

New subsection (2) repeats the current content of clauses 3, 4 and 5 of Standard 2.9.1, which sets out the parameters for calculating energy content, protein content and potential renal solute load in infant formula product.

Division 2 General compositional requirements for infant formula products

New section 2.9.1—5 Use of substances as nutritive substances

New section 2.9.1—5 repeats the current provisions of clause 7 of Standard 2.9.1, which set out the conditions under which firstly, nutritive substances may be added to infant formula products and secondly, statements may be made on labels about the presence of a nutritive substance.

New section 2.9.1—6 Addition of lactic acid producing microorganisms

This new section 2.9.1—6 repeats the current permission in clause 9 of Standard 2.9.1 for lactic acid producing microorganisms to be added to infant formula products. The terms lactic acid producing microorganisms has been used to provide consistency in the Code, replacing lactic acid cultures and lactic acid producing cultures.

New section 2.9.1—7 Permitted quantities of added inulin-derived fructans and galacto-oligosaccharides

New section 2.9.1—7 re-states the current content of clause 9A of Standard 2.9.1. The provision sets out limits on the amount of inulin-derived fructans and galacto-oligosaccharides that may be added to infant formula product.

New section 2.9.1—8 Restriction on levels of other substances in infant formula product

New section 2.9.1—8 repeats the current content of subclause 6(2) and clauses 8 and 10 of Standard 2.9.1, which set out limits on the amount of gluten, nucleotide 5'-monophosphates (whether added or naturally occurring) and aluminium that can be in infant formula products.

Division 3 Infant formula and follow-on formula

New section 2.9.1—9 Infant formula and follow-on formula—composition

New section 2.9.1—9 re-states the current content of clause 21 of Standard 2.9.1, which sets out the compositional requirements for infant formula and follow-on formula.

New section 2.9.1—10 Infant formula and follow-on formula—protein—further requirements

New section 2.9.1—10 re-states the current content of clause 22 of Standard 2.9.1, which sets out the protein content requirements for infant formula and follow-on formula.

New section 2.9.1—11 Infant formula and follow-on formula—fat—further requirements

New section 2.9.1—11 re-states the current content of clause 23 of Standard 2.9.1, which sets out the fat requirements for infant formula and follow-on formula.

New section 2.9.1—12 Infant formula and follow-on formula—vitamins, minerals and electrolytes—further requirements

New section 2.9.1—12 re-states the current content of subclauses 24(2)–(4) of Standard 2.9.1, which sets out the requirements for infant formula and follow-on formula that relate to polyunsaturated fatty acids, the ratio of calcium to phosphorus and the ratio of zinc to copper.

Division 4 Infant formula products for special dietary use

New section 2.9.1—13 Products formulated for premature or low birthweight infants

New section 2.9.1—13 re-states the current content of clauses 25 and 26 of Standard 2.9.1, which require specific labelling of infant formula products that have been formulated for premature or low birthweight infants.

New section 2.9.1—14 Products for metabolic, immunological, renal, hepatic and malabsorptive conditions

New section 2.9.1—14 re-states the current content of clauses 27–30 of Standard 2.9.1, which require specific labelling of infant formula products for that are formulated for metabolic, immunological, renal, hepatic or malabsorptive conditions.

New section 2.9.1—15 Products for specific dietary use based on a protein substitute

New section 2.9.1—15 repeats the current content of clauses 31 and 32 of Standard 2.9.1, which set out the requirements for infant formula products that are based on a protein substitute.

Division 5 Labelling and packaging requirements

New section 2.9.1—16 Representations about food as infant formula product

New section 2.9.1—16 repeats the current requirement in clause 11 of Standard 2.9.1 that food can only be represented as infant formula product if it complies with the Division.

New section 2.9.1—17 Prescribed names

This new section repeats the current content of clause 12 of Standard 2.9.1, which lists 'infant formula' and 'follow-on formula' as prescribed names.

New section 2.9.1—18 Requirement for measuring scoop

New section 2.9.1—18 re-states the current requirement in clause 13 of Standard 2.9.1 that a package of infant formula product in powdered form must contain a scoop to enable mixing according to instructions. A scoop is not required for powdered infant formula product in single serve sachets.

New section 2.9.1—19 Requirement for warning statements and directions

New section 2.9.1—19 re-states the current content of clause 14 of Standard 2.9.1 which sets out labelling requirements for infant formula products.

New section 2.9.1—20 Print size

This new section repeats the current requirements in clause 15 of Standard 2.9.1 for print size on packages of infant formula product.

New section 2.9.1—21 Declaration of nutrition information

New section 2.9.1—21 sets out the requirements that are currently in clause 16 of Standard 2.9.1 for declaring nutrition information on a package of infant formula product.

New section 2.9.1—22 Date marking and storage instructions

New section 2.9.1—22 repeats the current content of clause 17 of Standard 2.9.1. The section provides that a use-by date does not have to be provided on a package of infant formula product. Instead, the label must provide storage instructions for the period after the package is opened. An editorial note that provides that the full range of climatic conditions that exist in Australia and New Zealand may need to be considered when determining valid and appropriate storage instructions, has been omitted.

New section 2.9.1—23 Statements of protein source and dental fluorosis

New section 2.9.1—23 re-states the current content of clauses 18 and 19 of Standard 2.9.1, which require statements about protein source and, in certain circumstances, dental fluorosis on the label of infant formula product.

New section 2.9.1—24 Prohibited representations

New section 2.9.1—24 repeats the current content of clause 20 of Standard 2.9.1, which prohibits a range of representations on packages of infant formula product.

Division 6 Guidelines

New section 2.9.1—25 Guidelines for infant formula product

New section 2.9.1—25 provides that guidelines in relation to the maximum amounts of vitamins and minerals in infant formula product, which are not legally binding, are repeated in section S29—10.