

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Proposal P1028 – Infant Formula) Variation

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.

The Authority prepared Proposal P1028 to revise and clarify standards relating to infant formula products. The Authority has considered the Proposal in accordance with Division 2 of Part 3 and has approved two draft variations – the *Food Standards (Proposal P1028 – Infant Formula) Variation* and the *Food Standards (Proposal P1028 – Infant Formula – Consequential Amendments) Variation*.

This Explanatory Statement relates to the *Food Standards (Proposal P1028 – Infant Formula) Variation* (the approved draft variation).

Following consideration by the Food Ministers Meeting (FMM), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the approved draft variation.

2. Variation is a legislative instrument

The approved draft variation is a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and is publicly available on the Federal Register of Legislation (www.legislation.gov.au).

This instrument is not subject to the disallowance or sunset provisions of the *Legislation Act 2003*. Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunset if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunset legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the FMM. The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State

and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority approved the *Food Standards (Proposal P1028 – Infant Formula) Variation* and the *Food Standards (Proposal P1028 – Infant Formula – Consequential Amendments) Variation*. The purpose of both instruments is to amend the Code to revise and clarify the Code's provisions relating to infant formula products, including those relating to category definitions, composition, labelling and representation of infant formula products.

4. Documents incorporated by reference

Section 14 of the *Legislation Act 2003* provides that a legislative instrument may:

- apply, adopt or incorporate provisions of a Commonwealth disallowable legislative instrument, with or without modification, as in force at a particular time or as in force from time to time; and
- incorporate any other document in writing which exists at the time the legislative instrument commences or a time before its commencement.

The Code currently contains provisions that incorporate other legislative instruments and other written documents by reference in accordance with the above section.

The approved draft variation contains one section that will incorporate a document by reference. New section 2.9.1—51 lists the information relating to ingredients that must be stated on the label of a special medical purpose product for infants. It provides that that information may be:

- information that complies with Articles 18, 19 and 20 of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers; or
- information that complies with 21 CFR § 101.4. That is, section 101.4 of Title 21 of the United States Code of Federal Regulations.

A copy of the EU Regulation is freely and publicly available online at various websites. These include <https://eur-lex.europa.eu/homepage.html> and <https://www.legislation.gov.uk/eur/2011/1169/contents>

A copy of the United States Code of Federal Regulations is freely and publicly available online at <https://www.govinfo.gov/app/collection/cfr>

5. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1028 included two rounds of public comment following an assessment and the preparation of draft variations and associated assessment summaries. The first call for submissions was issued on 4 April 2022 for an 11 week consultation period. The second call for submissions (including draft variations) was issued on 26 April 2023 for a 10-week consultation period.

The Authority also released a number of consultation papers prior to the issue of the first call for submissions, with each consultation paper focused on a key aspect of infant formula regulation.

A decision Regulation Impact Statement was prepared by the Authority and has been approved by The Office of Best Practice Regulation (Reference - OBPR 25089)

6. 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 44 of the *Legislation Act 2003*.

7. Variation

In this section, references to ‘the variation’ are references to the approved draft variation.

Clause 1 provides that the name of the variation is the *Food Standards (Proposal P1028 – Infant Formula) Variation*.

Clause 2 provides that the Code is amended by the Schedule to the variation.

Clause 3 provides that the variation will commence on the date of gazettal of the instrument.

Clause 4 sets out how the variations made by the instrument take effect

The Note to clause 4 explains that New Zealand has under Annex D of the *Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System* opted out of Standard 2.9.1.

Subclauses 4(1) to (3) provide a transitional arrangement,

Subclause 4(1) provides that the stock-in-trade exemption provided by section 1.1.1—9 of Standard 1.1.1 does not apply to any of the amendments made by the variation.

Instead, subclauses 4(2) and (3) provide a transitional arrangement where during a five year transition period commencing on the date of gazettal of the variation, an infant formula product may be sold if the product complies with either: the Code as in force without the amendments made by the variation and the *Food Standards (Proposal P1028 – Infant Formula – Consequential Amendments) Variation*; or the Code as amended by those two instruments.

Schedule of the Variation

The Schedule of the variation amends Standard 2.9.1 of the Code.

Item [1] of the Schedule repeals sections 2.9.1—2 to 2.9.1—25 and substitutes them with new provisions as follows.

Section 2.9.1—2: This provision provides an outline for the new Standard 2.9.1. The outline explains that the Standard regulates various types of infant formula products and then what each division of the new Standard 2.9.1 covers. Division 1 deals with preliminary matters. Division 2 sets out the compositional requirements for infant formula and follow-on formula, while Division 3 sets out their labelling and packaging requirements. Division 4 sets out sale, compositional and labelling requirements for special medical purpose product for infants.

Section 2.9.1—3: The Note to this provision sets out definitions for certain key words used in the Standard. These definitions are contained within sections 1.1.2—2 and 1.1.2—3 of the Code and are restated in Standard 2.9.1 for convenience. The Note includes a definition for *Special medical purpose product for infants*, which is a newly defined term in the Code. The

definition of that term is inserted into Standard 1.1.2 by the *Food Standards (Proposal P1028 – Infant Formula Products – Consequential Amendments) Variation*.

Section 2.9.1—4: This provision provides that, unless expressly stated otherwise, the compositional requirements contained in the Standard apply to: a powdered or concentrated form of infant formula product that has been reconstituted with water in accordance with the relevant directions; and an infant formula product in ‘ready to drink’ form. The section also prescribes how energy, protein and vitamin A content must be calculated for the purposes of the Standard.

Division 2: Division 2 contains the compositional requirements for infant formula and follow-on formula. Division 2 comprises sections 2.9.1—5 to 2.9.1—13.

The Note to the heading for Division 2 alerts readers to subsection 1.5.1—3(2). That provision provides that an infant formula product for retail sale may consist of, or have as an ingredient or a component, a novel food only when and if each condition specified in that subsection is met. The terms ‘component’ of a food and ‘novel food’ are defined in subsection 1.1.2—2(3) and section 1.1.2—8 of the Code respectively.

Subsection 1.5.1—3(2) is a new provision inserted into Standard 1.5.1 by the *Food Standards (Proposal P1028 – Infant Formula Products – Consequential Amendments) Variation*.

Section 2.9.1—5: This section sets general compositional requirements for infant formula and follow-on formula.

Subsection 2.9.1—5(1) provides that infant formula and follow-on formula must have an energy content of no less than 2510 kJ/L and no more than 2930 kJ/L.

Subsection 2.9.1—5(2) provides that, subject to subsections 2.9.1—5(3) and (4), infant formula and follow-on formula must not contain added fructose and/or added sucrose.

Subsection 2.9.1—5(3) provides an exception to the prohibition imposed by subsection 2.9.1—5(2). This exception applies only to infant formula and follow on formula manufactured from partially hydrolysed protein. The subsection provides that these types of formula may contain added fructose and/or added sucrose provided that: that fructose and/or sucrose is added to the formula to provide a source of carbohydrate; and the sum of the added fructose and/or sucrose in the formula does not exceed 20% of available carbohydrates in that formula.

Subsection 2.9.1—5(4) also provides an exception to the prohibition imposed by subsection 2.9.1—5(2). Subsection (4) provides that the prohibition does not apply to added fructose and/or added sucrose that is present in infant formula or follow-on formula as a result of: the addition of inulin-type fructans to the infant formula or follow-on formula in accordance with Standard 2.9.1; and/or the use of a substance as a processing aid in accordance with the Code in the manufacture of the infant formula or follow-on formula. The phrase ‘used as a processing aid’ in relation to a food is defined in section 1.1.2—13 of the Code.

Subsection 2.9.1—5(5) provides that the fluoride content of infant formula and follow-on formula must not exceed 17 µg/100 kJ if in a powdered or concentrated form; and 24 µg/100 kJ if in a ready-to-drink form.

Subsection 2.9.1—5(6) provides that the limits set by subsection 2.9.1—5(5) apply to the infant formula and follow-on formula as sold.

Section 2.9.1—6: This section sets out the protein requirements for infant formula and follow-on formula.

Subsection 2.9.1—6(1) provides that infant formula and follow-on formula must be derived only from one or more of the proteins listed in that subsection.

Subsection 2.9.1—6(2) provides mandatory protein content requirements for infant formula. Milk-based infant formula must have a protein content of no less than 0.43 g/100 kJ and no more than 0.72 g/100 kJ. Infant formula that is not a milk-based infant formula must have a protein content of no less than 0.54 g/100 kJ and no more than 0.72 g/100 kJ. Subsection 2.9.1—6(4) defines what is a 'milk-based infant formula' for the purposes of subsection 2.9.1—6(2).

Subsection 2.9.1—6(3) provides mandatory protein content requirements for follow-on formula. Milk-based follow-on formula must have a protein content of no less than 0.38 g/100 kJ and no more than 0.72 g/100 kJ. Follow-on formula that is not a milk-based follow-on formula must have a protein content of no less than 0.54 g/100 kJ and no more than 0.72 g/100 kJ. Subsection 2.9.1—6(4) defines what is a 'milk-based follow-on formula' for the purposes of subsection 2.9.1—6(3).

Subsection 2.9.1—6(4) defines what is a milk-based infant formula and a milk-based follow-on formula for the purposes of subsections 2.9.1—6(2) and (3) respectively. Paragraph 2.9.1—6(4)(a) defines **milk-based infant formula** to mean infant formula that is derived only from one or more of the following proteins: cow milk; goat milk; sheep milk; a partially hydrolysed protein of one or more of cow milk, goat milk and sheep milk. Paragraph 2.9.1—6(4)(b) defines **milk-based follow-on formula** to mean follow-on formula that is derived only from one or more of the following proteins: cow milk; goat milk; sheep milk; a partially hydrolysed protein of one or more of cow milk, goat milk and sheep milk.

Subsection 2.9.1—6(5) requires that the L-amino acids listed in the table to section S29—3 must be present in infant formula and follow-on formula at or above the minimum levels specified in that table.

Subsection 2.9.1—6(6) provides an exception to the requirement imposed by subsection 2.9.1—6(5). This exception applies only to the minimum levels specified in the table to section S29—3 for cysteine and for methionine. Subsection 2.9.1—6(6) provides that these minimum levels do not apply to infant formula and follow-on formula when both the following conditions are met: the minimum amount of combined cysteine and methionine in the infant formula and follow-on formula is not less than 15 mg per 100 kJ; and the ratio of methionine to cysteine in the infant formula and follow-on formula is less than 2 to 1.

Subsection 2.9.1—6(7) provides another exception to the requirement imposed by subsection 2.9.1—6(5). This exception applies only to the minimum levels specified in the table to section S29—3 for phenylalanine and for tyrosine. Subsection 2.9.1—6(7) provides that these minimum levels do not apply to infant formula and follow-on formula when both the following conditions are met: the minimum amount of combined phenylalanine and tyrosine in the infant formula and follow-on formula is not less than 37 mg per 100 kJ; and the ratio of tyrosine to phenylalanine in the infant formula and follow-on formula is less than 2 to 1.

Subsection 2.9.1—6(8) provides that, despite the above-mentioned requirement that the L-amino acids listed in the table to section S29—3 must be present in infant formula and follow-on formula at levels in accordance with subsections (5), (6) and (7), these L-amino acids must only be added to infant formula and follow-on formula in an amount necessary to improve protein quality.

Section 2.9.1—7: This section sets out the fat requirements for infant formula and follow-on formula.

Paragraph 2.9.1—7(1)(a) requires that infant formula and follow-on formula must have a fat content of no less than 1.1 g/100 kJ and no more than 1.4 g/100 kJ.

Paragraph 2.9.1—7(1)(b) requires that infant formula and follow-on formula must have a ratio of linoleic acid to α -linolenic acid of no less than 5 to 1 and no more than 15 to 1.

Paragraph 2.9.1—7(1)(c) requires that infant formula and follow-on formula must contain no less than 90 mg/100 kJ of linoleic acid and no less than 12 mg/100 kJ of α -linolenic acid.

The Note to paragraph 2.9.1—7(1)(c) identifies and explains that it is recommended that infant formula and follow-on formula contain not more than 335 mg of linoleic acid. This is not a mandatory or binding maximum limit. This amount or Guidance Upper Level is provided as guidance only and a recommended upper level for this nutrient which poses no significant risks on the basis of current scientific knowledge. The level is a value derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. It is recommended that the amount specified not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formula and follow-on formula or due to technological reasons.

Paragraph 2.9.1—7(1)(d) requires that infant formula and follow-on formula must have an arachidonic acid (20 to 4 n-6) content of equal to or more than docosahexaenoic acid (22 to 6 n-3) content.

Paragraph 2.9.1—7(1)(e) requires that infant formula and follow-on formula must contain no less than 0.5 mg of vitamin E per gram of polyunsaturated fatty acids.

Paragraph 2.9.1—7(1)(f) requires that any long chain polyunsaturated fatty acids that are present in infant formula or follow-on formula must have an eicosapentaenoic acid (20:5 n-3) content that is not more than the docosahexaenoic acid (22 to 6 n-3) content.

Paragraph 2.9.1—7(1)(g) lists requirements for certain fatty acids present in infant formula and follow-on formula. The paragraph provides that, if a fatty acid listed in Column 1 of the table to section S29—4 is present in infant formula or follow-on formula, that formula must contain not more than the maximum amount (if any) of that fatty acid that is specified in Column 2 of that table.

Subsection 2.9.1—7(2) provides that infant formula and follow-on formula may only contain medium chain triglycerides that contain predominantly the saturated fatty acids designated by 8 to 0 and 10 to 0 and are either: a natural constituent of a milk-based ingredient of that formula; or for a fat soluble vitamin that is specified in either section S29—5 (in the case of infant formula) or section S29—6 (in the case of follow-on formula), a substance that was used as a processing aid in the preparation of that permitted fat soluble vitamin for use in the formula. The phrase 'used as a processing aid' in relation to a food is defined in section 1.1.2—13 of the Code.

Subsection 2.9.1—7(3) provides that infant formula and follow-on formula must not have a phospholipid content of more than 72 mg/100 kJ.

Section 2.9.1—8: This section provides that infant formula and follow-on formula must contain certain nutritive substances.

Subsection 2.9.1—8(1) provides that infant formula must contain each substance listed in Column 1 of the table to section S29—5 in an amount (including any naturally occurring amount) complying with the corresponding minimum amount and any corresponding maximum amount specified in Columns 2 and 3 respectively of that table.

The Note to subsection 2.9.1—8(1) identifies and explains for readers the operation of Column 4 of the table to section S29—5. This Note explains that it is recommended that infant formula contain a substance listed in Column 1 of the table to section S29—5 in an amount that is not more than the amount (if any) specified for that substance in Column 4. This is not a mandatory or binding maximum limit. The amounts or Guidance Upper Levels are provided as guidance only and are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. It is recommended that the amounts specified in Column 4 not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formulas or due to technological reasons. Guidance Upper Levels are listed for substances where no maximum limit is set.

Subsection 2.9.1—8(2) provides that follow-on formula must contain each substance listed in the table to section S29—6 in an amount (including any naturally occurring amount) complying with the corresponding minimum amount and any corresponding maximum amount specified in Columns 2 and 3 respectively of that table.

The Note to subsection 2.9.1—8(2) identifies and explains for readers the operation of Column 4 of the table to section S29—6. This Note explains that it is recommended that follow-on formula contain a substance listed in Column 1 of the table to section S29—6 in an amount that is not more than the amount (if any) specified for that substance in Column 4. This is not a mandatory or binding maximum limit. The amounts or Guidance Upper Levels are provided as guidance only and are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. It is recommended that the amounts specified in Column 4 not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of follow-on formulas or due to technological reasons. Guidance Upper Levels are listed for substances where no maximum limit is set.

Subsection 2.9.1—8(3) provides that the ratio of calcium to phosphorus in infant formula and follow-on formula must be no less than 1 to 1 and no more than 2 to 1.

Section 2.9.1—9: This section provides that certain substances may be used as a nutritive substance in infant formula and in follow-on formula. The phrase ‘used as a nutritive substance’ in relation to a food is defined in section 1.1.2—12 of the Code.

Subsection 2.9.1—9(1) provides that a substance listed in Column 1 of the table to section S29—7 may be used as a nutritive substance in infant formula, provided that the amount of the substance in the formula (including any naturally-occurring amount) is: no less than the minimum amount (if any) specified in Column 2 of the table; and no more than the maximum amount (if any) specified in Column 3 of the table.

Subsection 2.9.1—9(2) provides that a substance listed in Column 1 of the table to section S29—8 may be used as a nutritive substance in follow-on formula, provided that the amount of the substance (including any naturally-occurring amount) is: no less than the minimum amount (if any) specified in Column 2 of the table; and no more than the maximum amount (if any) specified in Column 3 of the table.

The Note to subsection 2.9.1—9(2) identifies and explains for readers the operation of Column 4 of the table to section S29—8. This Note explains that it is recommended that follow-on formula contain a substance listed in Column 1 of the table to section S29—8 in an amount that is not more than the amount (if any) specified for that substance in Column 4. This is not a mandatory or binding maximum limit. The amounts or Guidance Upper Levels are provided as guidance only and are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. It is recommended that the amounts specified in Column 4 not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of follow-on formulas or due to technological reasons.

Section 2.9.1—10: This section requires that any substance used in either infant formula or follow-on formula in accordance with section 2.9.1—8 or 2.9.1—9 must be in the permitted form listed in the table to section S29—23 (for vitamin, mineral or electrolytes) or the table to section S29—9 (in all other cases).

Section 2.9.1—10A: This section sets conditions of use for certain substances used as a nutritive substance in an infant formula product.

The section refers to the table to subsection S29—9A(2) (the table) and provides that a substance that is:

- used as a nutritive substance in an infant formula product; and
- listed in Column 1 of the table; and
- in a permitted form listed in Column 2 of the table for that substance,

must comply with any corresponding conditions specified in Column 3 of the table for that substance in that permitted form.

At present -

- 'Lactoferrin' is the only substance listed in Column 1 of the table.
- 'Bovine lactoferrin' is listed in Column 2 of the table as the permitted form for that substance.
- Two conditions (providing a time limited exclusive use permission) are listed in Column 3 for that permitted form.

Section 2.9.1—11: This section permits the addition of L(+) lactic producing microorganisms to infant formula and follow-on formula.

Section 2.9.1—12: This section restricts the addition of inulin-type fructans and galacto-oligosaccharides in infant formula and follow-on formula. The terms 'inulin-type fructans' and 'galacto-oligosaccharides' are defined in subsection 1.1.2—2(3) of the Code.

Section 2.9.1—12 lists the requirements that must be met if an inulin-type fructan or a galacto-oligosaccharide is added to infant formula or follow-on formula. The requirements are that, following the addition of the latter, the product must contain (taking into account both the naturally-occurring and added substances) no more than:

- (a) if only inulin-type fructans are added—110 mg/100 kJ of inulin-type fructans; or
- (b) if only galacto-oligosaccharides are added—290 mg/100 kJ of galacto-oligosaccharides; or
- (c) if both inulin-type fructans and galacto-oligosaccharides are added:
 - (i) no more than 110 mg/100 kJ of inulin-type fructans; and

- (ii) no more than 290 mg/100 kJ of combined inulin-type fructans and galactooligosaccharides.

Section 2.9.1—13: This section provides that infant formula and follow-on formula must not contain: detectable gluten; and/or more than 3.8 mg/100 kJ of free nucleotide-5'-monophosphates.

Note 1 to section 2.9.1—13 refers the reader to section S19—4 which sets out the maximum levels of contaminants permitted in infant formula products.

Note 2 to section 2.9.1—13 refers the reader to Standard 1.3.1 and Schedule 15, which permit the use of certain substances as food additives in infant formula products. The phrase 'used as a food additive' in relation to a food is defined in section 1.1.2—11 of the Code.

Division 3: Division 3 contains the labelling and packaging requirements for infant and follow-on formula. Division 3 comprises sections 2.9.1—14 to 2.9.1—28.

The Note to Division 3 refers to Standard 1.2.7 and, in particular, paragraph 1.2.7—4(b), which provides that a nutrition content claim or health claim must not be made about infant formula products. The Note also explains that paragraph 1.2.7—6(a) provides that this prohibition does not apply to claims that are expressly permitted by the Code, including by Division 3 of Standard 2.9.1.

Section 2.9.1—14: This section provides that a food may only be represented as infant formula or follow-on formula if that food complies with Standard 2.9.1.

Section 2.9.1—15: This section provides that the label on a package of infant formula or follow-on formula must differentiate that infant formula or follow-on formula from other foods through the use of text, pictures and/or colour. The example provided explains that the text, pictures and/or colours used on a label of infant formula must differentiate that product from, among other things, follow-on formula, a special medical purpose product for infants, or a formulated supplementary food for young children.

Section 2.9.1—16: This section sets out the prescribed names for infant formula and follow-on formula for the purposes of the Code. Subsection 2.9.1—16(1) provides that 'Infant formula' is the prescribed name for infant formula. Subsection 2.9.1—16(2) provides that 'Follow-on formula' is the prescribed name for follow-on formula.

The Note to section 2.9.1—16 explains to readers that, under the labelling provisions in Standard 1.2.1 and section 1.2.2—2 of the Code, if a food has a prescribed name, that prescribed name must be used in the labelling of the food, i.e. wherever the Code requires the name of that food to be stated or used.

Section 2.9.1—17: This section sets out the requirement for a measuring scoop in some packages of infant formula and follow-on formula in powdered form.

Subsection 2.9.1—17(1) requires that a package of infant formula or follow-on formula in a powdered form must contain a scoop to enable the use of the formula in accordance with the directions contained in the label on the package.

Subsection 2.9.1—17(2) provides that subsection 2.9.1—17(1) does not apply to single serve sachets, or packages containing single serve sachets, of formula in a powdered form.

Section 2.9.1—18: This section requires that, for the Code's labelling provisions, the storage instructions for infant formula and follow-on formula must cover the period after the package is opened.

The Note to section 2.9.1—18 advises that the labelling provisions are set out in Standard 1.2.1.

Section 2.9.1—19: This section provides that, for the Code's labelling provisions, the name of the food must be stated on the front of a package of infant formula or follow-on formula. The effect of the section is that, while the name of the food may also appear elsewhere on the package, the name must appear on the front of the package at least once.

In accordance with section 2.9.1—16, the name of the food is the prescribed name (for example, 'Infant formula' or 'Follow-on formula').

The ordinary meaning of 'front of a package' will apply (for example, the surface that is displayed or visible to the purchaser under customary conditions of sale or use).

The Note to section 2.9.1—19 advises the reader that the labelling provisions are set out in Standard 1.2.1.

Section 2.9.1—20: This section sets out requirements related to the statement of the protein source or sources in infant formula and follow-on formula.

Subsection 2.9.1—20(1) provides that, for the Code's labelling provisions, the specific animal or plant source or sources of protein in the infant formula or follow-on formula must be included in the statement of the name of the food required by section 2.9.1—19 (see above). Three examples are provided to assist readers: 'Infant formula based on cow milk'; 'Follow-on formula based on goat milk'; and 'Infant formula based on 'soy protein'.

The effect of the subsection is that the specific protein source must be included in the statement of the name of the food (the prescribed name) required by section 2.9.1—19 and that both the statement of protein source and name of the food must appear on the front of the package of infant formula or follow-on formula.

The first Note to subsection 2.9.1—20(1) advises the reader that the permitted protein sources for infant formula and follow-on formula are listed in subsection 2.9.1—6(1).

The second Note to subsection 2.9.1—20(1) advises the reader that the labelling provisions are set out in Standard 1.2.1.

Subsection 2.9.1—20(2) provides that, if infant formula and follow-on formula are derived solely or in part from a partially hydrolysed protein, the words 'partially hydrolysed' must be used immediately adjacent to the statement of protein source required by subsection 2.9.1—20(1). An example is provided to assist readers: 'Infant formula based on partially hydrolysed cow milk'.

The effect of subsection 2.9.1—20(2) is that the words 'partially hydrolysed' must appear together with the statement of protein source and the name of the food on the front of the package of infant formula or follow-on formula if the infant formula and follow-on formula are derived solely or in part from a partially hydrolysed protein.

Subsection 2.9.1—20(3) provides that the statement of protein source required by subsection 2.9.1—20(1) must not use the word 'milk' as the sole descriptor of the protein source.

The example to subsection 2.9.1—20(3) illustrates that protein source statements such as ‘Infant formula based on milk’ or ‘Infant formula sourced from milk’ are not permitted.

The Note to subsection 2.9.1—20(3) refers to sub-paragraph 2.9.1—28(1)(j)(i) (see below) in relation to the use of the word ‘milk’ on the label separately and in addition to in a statement of protein source.

Section 2.9.1—21: This section sets out requirements related to warning statements, statements on use, and directions for infant formula and follow-on formula.

Subsection 2.9.1—21(1) provides that, for the Code’s labelling provisions, both of the following warning statements are required for infant formula and follow on formula:

- ‘Warning – follow instructions exactly. Prepare bottles and teats as directed. Incorrect preparation can make your baby very ill.’ (paragraph 2.9.1—21(1)(a)); and
- A heading that states ‘Important Notice’ (or words to that effect), with under it the warning statement—‘Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice.’ (paragraph 2.9.1—21(1)(b)).

The term ‘warning statement’, in relation to a food for sale, is defined in subsection 1.1.2—2(3) of the Code.

The Note to subsection 2.9.1—21(1) explains that the labelling provisions are set out in Standard 1.2.1.

Subsection 2.9.1—21(2) provides that, for the Code’s labelling provisions, the required statements on use for infant formula and follow-on formula are ones indicating that:

- for infant formula—the infant formula may be used from birth (paragraph 2.9.1—21(2)(a)); and
- for follow-on formula—the follow-on formula should not be used for infants aged under the age of 6 months (paragraph 2.9.1—21(2)(b)); and
- for infant formula and follow-on formula—it is recommended that infants from the age of 6 months should be offered foods in addition to the infant formula or follow-on formula (paragraph 2.9.1—21(2)(c)).

The Note to subsection 2.9.1—21(2) advises the reader that the labelling provisions are set out in Standard 1.2.1.

Subsection 2.9.1—21(3) provides that the statements required by paragraphs 2.9.1—21(2)(a) and (b) must appear on the front of the package of the product.

Subsection 2.9.1—21(4) provides that, notwithstanding subsection 2.9.1—21(3), a statement required by subsection 2.9.1—21(2) may appear more than once on the label.

Subsection 2.9.1—21(5) sets out, for the Code’s labelling provisions, requirements relating to the directions on preparation and use that are required for infant formula and follow-on formula.

The directions must instruct in words and pictures that:

- each bottle must be prepared individually (paragraph 2.9.1—21(5)(a)); and
- if a bottle of prepared formula is to be stored prior to use, it must be refrigerated and used within 24 hours (paragraph 2.9.1—21(5)(b)); and
- previously boiled and cooled potable water must be used (paragraph 2.9.1—21(5)(c));

and

- if a package contains a measuring scoop—only the enclosed scoop must be used (paragraph 2.9.1—21(5)(d)); and
- for powdered or concentrated formula—do not change proportions of the powder or concentrate or add other food except on medical advice (paragraph 2.9.1—21(5)(e)); and
- for ready-to-drink formula—do not dilute or add other food except on medical advice (paragraph 2.9.1—21(5)(f)); and
- formula left in the bottle after a feed must be discarded within 2 hours (paragraph 2.9.1—21(5)(g)).

The Note to subsection 2.9.1—21(5) advises the reader that the labelling provisions are set out in Standard 1.2.1.

Subsection 2.9.1—21(6) provides that paragraphs 2.9.1—21(5)(a), (b) and (c) do not apply to ready-to-drink formula.

Subsection 2.9.1—21(7) provides that paragraph 2.9.1—21(5)(d) does not apply to concentrated formula and to ready-to drink formula.

Subsection 2.9.1—21(8) provides that, for the Code's labelling provisions, both of the following must be declared for infant formula and follow-on formula:

- for a product in powdered or concentrated form—the proportion of powder or concentrate required to reconstitute the formula according to directions (paragraph 2.9.1—21(8)(a)); and
- for a product in powdered form—for a product in powdered form—the weight of one scoop (paragraph 2.9.1—21(8)(b)).

The Note to subsection 2.9.1—21(8) advises the reader that the labelling provisions are set out in Standard 1.2.1.

Section 2.9.1—22: This section prescribes the print size for the warning statements required by subsection 2.9.1—21(1).

If the package of infant formula or follow-on formula has a net weight of more than 500 g, paragraph 2.9.1—22(a) requires that the statements must be in a size of type of at least 3 mm. If the package of infant formula or follow-on formula has a net weight of 500 g or less, paragraph 2.9.1—22(b) requires that the statements must be in a size of type of at least 1.5 mm. The term 'size of type' is defined by subsection 1.1.2—2(3) of the Code.

Section 2.9.1—23: This section provides an optional format to declare added vitamins and minerals in the statement of ingredients for infant formula and follow-on formula.

Subsection 2.9.1—23(1) provides an exception to section 1.2.4—5 of the Code. Section 1.2.4—5 requires a statement of ingredients to list each ingredient in descending order of ingoing weight. Subsection 2.9.1—23(1) provides that, where a vitamin or mineral is added to infant formula or follow-on formula in accordance with section 2.9.1—8, the statement of ingredients need not list the added vitamin and mineral in descending order of ingoing weight, provided that that statement of ingredients lists all added vitamins together under the subheading 'Vitamins', and lists all added minerals together under the subheading 'Minerals'.

The Note to subsection 2.9.1—23(1) refers to Standard 1.2.4 for all other ingredient labelling requirements.

Subsection 2.9.1—23(2) provides that section 1.2.4—8 of the Code does not apply to a statement of ingredients referred in subsection 2.9.1—23(1). Section 1.2.4—8 permits a vitamin or mineral that has been added to a food to be declared in accordance with section 1.2.4—7 using the class name ‘vitamin’ or ‘mineral’. Subsection 1.2.4—7(1) provides that a substance (including a vitamin or mineral) used as a food additive must be listed in a statement of ingredients by specifying:

- if the substance can be classified into a class of additives listed in Schedule 7 (whether prescribed or optional)—that class name, followed in brackets by the name or *code number of the substance as indicated in Schedule 8; or
- otherwise—the name of the substance as indicated in Schedule 8.

The phrase ‘used as a food additive’ in relation to a food is defined in section 1.1.2—11 of the Code.

Section 2.9.1—24: This section sets out requirements related to the declaration of nutrition information for infant formula and follow-on formula.

Subsection 2.9.1—24(1) provides that, for the Code’s labelling provisions, a statement of nutrition information is required for infant formula and follow-on formula.

Subsection 2.9.1—24(2) provides that a reference in this section to ‘the statement’ is the statement required by subsection 2.9.1—24(1).

Subsection 2.9.1—24(3) provides that the statement must contain all of the following information:

- The average energy content expressed in kilojoules per 100 mL of formula (paragraph 2.9.1—24(3)(a)).
- The average quantity of protein, fat and carbohydrate expressed in grams per 100 mL of formula and as ‘protein’, ‘fat’ and ‘carbohydrate’, respectively (paragraph 2.9.1—24(3)(b)).
- The average quantity of each vitamin or mineral expressed in micrograms or milligrams per 100 mL of formula (including any naturally-occurring amount) (paragraph 2.9.1—24(3)(c)).
- For infant formula only—the average quantity of choline, inositol and L-carnitine expressed in milligrams per 100 mL of formula (including any naturally-occurring amount) (paragraph 2.9.1—24(3)(d)).
- The average quantity of the following if added: any substance used as a nutritive substance (including any naturally occurring amount); inulin-type fructans; galacto-oligosaccharides; or a combination of inulin-type fructans and galacto-oligosaccharides (paragraph 2.9.1—24(3)(e)). These amounts must be expressed in grams, micrograms or milligrams per 100 mL of formula.

The terms ‘average quantity’, ‘carbohydrate’, ‘inulin-type fructans’, and ‘galacto-oligosaccharides’ are defined in subsection 1.1.2—2(3) of the Code.

The phrase ‘used as a nutritive substance’ in relation to a food is defined in section 1.1.2—12 of the Code.

The Note to subsection 2.9.1—24(3) explains that the labelling provisions are set out in Standard 1.2.1.

Subsection 2.9.1—24(4) permits the statement to include the average quantity of each of the following substances that is present in the infant formula or follow-on formula, expressed in grams per 100 mL of formula (including any naturally occurring amount):

- whey (paragraph 2.9.1—24(4)(a)); and
- casein (paragraph 2.9.1—24(4)(b)).

The term ‘average quantity’ is defined in subsection 1.1.2—2(3) of the Code.

Subsection 2.9.1—24(5) permits the statement to include the average quantity of each of the following substances that is present in the infant formula or follow-on formula, expressed in milligrams per 100 mL of formula (including any naturally occurring amount):

- docosahexaenoic acid (paragraph 2.9.1—24(5)(a)); and
- eicosapentaenoic acid (paragraph 2.9.1—24(5)(b)); and
- arachidonic acid (paragraph 2.9.1—24(5)(c)).

Subsection 2.9.1—24(6) requires that, if the infant formula or follow-on formula is in a powdered or concentrated form, information included in the statement in accordance with subsection 2.9.1—24(3), (4) or (5) (see above) must be expressed in terms of per 100 mL of formula as reconstituted according to the directions on the package.

Subsection 2.9.1—24(7) permits information included in the statement in accordance with subsection (3), (4) or (5) to also be expressed:

- if sold in a concentrated form —per 100 mL of the formula as sold (paragraph 2.9.1—24(7)(a)); or
- if sold in a powdered form —per 100 g of formula as sold (paragraph 2.9.1—24(7)(b)).

That optional method of expressing the information included in the statement is *additional to* the mandatory method of expressing the information in accordance with subsection 2.9.1—24(6) (see above),

Subsection 2.9.1—24(8) requires that unless expressly provided elsewhere in this Code, the statement must not contain any other information.

Section 2.9.1—25: This section sets out the requirements for the form for the declaration of nutrition information required by section 2.9.1—24 (see above).

Subsection 2.9.1—25(1) provides that a reference to the table in subsections 2.9.1—25(2) to (6) is a reference to the table to section S29—10.

Subsection 2.9.1—25(2) sets out the following requirements for the nutrition information statement.

- The statement must be in the same format as specified in the table to section S29—10 (paragraph 2.9.1—25(2)(a)).
- The statement must state the nutrition information in the order specified in the table to section S29—10 (paragraph 2.9.1—25(2)(b)).
- The statement must be titled ‘Nutrition Information’ in bold font (paragraph 2.9.1—25(2)(c)).
- The statement must have the following subheadings - ‘Vitamins’, ‘Minerals’ and ‘Additional’. Infant formula must also have the subheading ‘Other nutrients’. Each subheading must be printed in a size of type that is the same or larger than the nutrient names stated in the statement (paragraph 2.9.1—25(2)(d)). The term ‘size of type’ is defined by subsection 1.1.2—2(3) of the Code.

- The statement must state nutrients and subgroup nutrients using the names and units of measurement that are specified in the table to section S29—10 for that nutrient and subgroup (paragraph 2.9.1—25(2)(e)).
- The statement must not express an amount or quantity other than in accordance with section 2.9.1—24 (paragraph 2.9.1—25(2)(f)).

The intent of subsection 2.9.1—25(2) is to ensure the format and grouping of nutrients and substances in the nutrition information statement is presented in a consistent manner.

Subsection 2.9.1—25(3) applies if the average quantity of a permitted nutritive substance, an inulin-type fructan or a galacto-oligosaccharide is included in the nutrition information statement. In this case, the subsection requires that that average quantity must be included in the nutrition information statement under the subheading ‘Additional’ and in the same format as specified in the table for that substance.

Subsection 2.9.1—25(4) applies if the average quantity of choline, inositol or L-carnitine is included in the nutrition information statement. Paragraph 2.9.1—25(4)(a) provides that, for infant formula, the average quantity must be included in the statement under the subheading ‘Other Nutrients’. Paragraph 2.9.1—25(4)(b) provides that, for follow-on formula, the average quantity must be in the statement under the subheading ‘Additional’. Paragraph 2.9.1—25(4)(c) requires that, in each case, the average quantity must be included in the nutrition information statement in the same format that is specified in the table for the relevant substance.

Subsection 2.9.1—25(5) applies if the nutrition information statement includes the average quantity of a substance listed in subsection 2.9.1—24(4). In that case, the subsection requires that the average quantity must be included in the nutrition information statement in the same format that is specified for that substance in the table to section S29—10.

Subsection 2.9.1—25(6) applies if the nutrition information statement includes the average quantity of a substance listed in subsection 2.9.1—24(5). In that case –

Paragraph 2.9.1—25(6)(a) provides that the nutrition information statement must include the subheading ‘Long chain polyunsaturated fatty acids’ and that subheading must be printed in a size of type that is the same or larger than the nutrient names in the statement. The term ‘size of type’ is defined by subsection 1.1.2—2(3) of the Code.

Paragraph 2.9.1—25(6)(b) provides that the nutrition information statement must include that average quantity under the subheading ‘Long chain polyunsaturated fatty acids’ and in the same format as specified for those substances by the table to section S29—10.

Paragraph 2.9.1—25(6)(c) provides that the nutrition information statement must use the name for each substance that is specified by the table to section S29—10 for that substance.

Paragraph 2.9.1—25(6)(d) provides that the nutrition information statement may use the acronym specified in the table to section S29—10 for the following substances in addition to the name required by paragraph 2.9.1—25(6)(c). These substances are: docosahexaenoic acid, eicosapentaenoic acid and arachidonic acid. An example is provided to assist readers: if the average quantity of docosahexaenoic acid is included in the nutrition information statement, the statement may state that average quantity using either ‘Docosahexaenoic acid (DHA)’ or ‘Docosahexaenoic acid’, but not ‘DHA’.

Subsection 2.9.1—25(7) provides that if the nutrition information statement includes information expressed in accordance with subsection 2.9.1—24(7) (see above), that

information must be in an additional column at the right hand side of Column 2 shown in the table to section S29—10A.

Subsection 2.9.1—25(8) provides that information included in the additional column required by subsection 2.9.1—25(7) must be in the form required by this section.

The Note to subsection 2.9.1—25(8) refers the reader to section S29—10A for an example of a nutrition information statement including information expressed in accordance with subsection 2.9.1—24(7).

The term 'average quantity' is defined in subsection 1.1.2—2(3) of the Code.

Section 2.9.1—26: This section provides that the method listed in paragraph 1.1.1—6(3)(c) of the Code must not be used to calculate the average quantity of a substance in infant formula or follow-on formula. This is an exception to section 1.1.1—6 which lists the methods for how average quantity is to be calculated for Code purposes.

Section 2.9.1—27: This section sets out the requirements for the use of stage numbers on a package of infant formula or follow-on formula.

Paragraph 2.9.1—27(1)(a) provides that the number '1' may be used on the label on a package of infant formula in order to identify for consumers that that product is infant formula.

Paragraph 2.9.1—27(1)(b) provides that the number '2' may be used on the label on a package of follow-on formula in order to identify for consumers that that product is follow-on formula.

Subsection 2.9.1—27(2) sets out where a number used in accordance with subsection 2.9.1—27(1) must appear on the package of the product. For infant formula, the number must appear on the front of the package of the product, immediately adjacent to the statement required by paragraph 2.9.1—21(2)(a) (see above). For follow-on formula, the number must appear on the front of the package of the product, immediately adjacent to the statement required by paragraph 2.9.1—21(2)(b) (see above).

Subsection 2.9.1—27(3) provides that subsection (2) does not prevent a number used in accordance with subsection (1) from also appearing elsewhere on the label.

Section 2.9.1—28: This section sets out representations that the label on a package of infant formula or follow-on formula must not contain.

Subsection 2.9.1—28(1) provides that the label on a package of infant formula or follow-on formula must not contain any of the following:

- A picture of an infant (paragraph 2.9.1—28(1)(a)).
- A picture that idealises the use of infant formula or follow-on formula (paragraph 2.9.1—28(1)(b)).
- For infant formula—information relating to follow-on formula, a special medical purpose product for infants, a formulated supplementary food or a formulated supplementary food for young children (subparagraph 2.9.1—28(1)(c)(i))
- For follow-on formula— information relating to infant formula, a special medical purpose product for infants, a formulated supplementary food or a formulated supplementary food for young children (subparagraph 2.9.1—28(1)(c)(ii))
- The word 'humanised' or 'maternalised' or any word or words having the same or similar effect (paragraph 2.9.1—28(1)(d)).

- The words ‘human milk oligosaccharide’, ‘human identical milk oligosaccharide’ or any word or words having the same or similar effect (paragraph 2.9.1—28(1)(e)).
- The abbreviations ‘HMO’ or ‘HiMO’ or any abbreviation having the same or similar effect (paragraph 2.9.1—28(1)(f)).
- Words claiming that the formula is suitable for all infants (paragraph 2.9.1—28(1)(g)).
- Information relating to the nutritional content of human milk (paragraph 2.9.1—28(1)(h)).
- Information relating to the presence of a substance listed in subsection 2.9.1—28(2) (paragraph 2.9.1—28(1)(i)). The paragraph provides that this prohibition does not apply to a reference in a statement of ingredients or in a declaration or statement expressly permitted or required by the Code.
- Information relating to ingredients (paragraph 2.9.1—28(1)(j)). The paragraph provides that this prohibition does not apply to: the use of the word ‘milk’; a reference in a statement of ingredients; or a reference in a declaration or statement expressly permitted or required by the Code.
- Information relating to the animal or plant source or sources of protein in the formula (paragraph 2.9.1—28(1)(k)). The paragraph provides that this prohibition does not apply to a reference in a statement of ingredients or where the information is required by subsection 2.9.1—20(1).
- The words ‘partially hydrolysed’ or any word or words having the same or similar effect (paragraph 2.9.1—28(1)(l)). The paragraph provides that this prohibition does not apply to the use of these words in a statement of ingredients or where required by subsection 2.9.1—20(2) of the Code.

Subsection 2.9.1—28(2) lists the substances to which the prohibition imposed by paragraph 2.9.1—28(1)(i) applies. The listed substances are: an inulin-type fructan; a galacto-oligosaccharide; a nutrient; and a substance used as a nutritive substance.

The terms ‘inulin-type fructans’ and ‘galacto-oligosaccharides’ are defined in subsection 1.1.2—2(3) of the Code. The phrase ‘used as a nutritive substance’ in relation to a food is defined in section 1.1.2—12 of the Code.

The Note to subsection 2.9.1—28(2) explains that section 2.9.1—24 expressly requires or permits these substances to be declared or stated in the nutrition information statement required by that section.

Division 4: Division 4 contains the sale, compositional, labelling and packaging requirements for special medical purpose products for infants. Division 4 comprises sections 2.9.1—30 to 2.9.1—55.

Section 2.9.1—30: This section provides that, unless the contrary intention appears, Part 1.2 of Chapter 1 of the Code and Division 3 of Standard 2.9.1 do not apply to special medical purpose products for infants. Part 1.2 of Chapter 1 deals with labelling and other information requirements. Division 3 of Standard 2.9.1 contains the labelling and packaging requirements for infant and follow-on formula (see above).

Section 2.9.1—31: This section imposes restrictions on the sale of special medical purpose products for infants.

Subsection 2.9.1—31(1) provides that a special medical purpose product for infants must not be sold to a consumer, other than from or by: a medical practitioner or dietitian; a medical practice, pharmacy or responsible institution; or a majority seller of that special medical purpose product for infants.

Subsection 2.9.1—31(2) defines who is a majority seller and a medical practitioner for the

purposes of section 2.9.1—31.

A majority seller of a special medical purpose product for infants is defined to mean a person who: during any 24 month period, sold that special medical purpose product for infants to any of the following: a medical practitioner; a dietitian; a medical practice; a pharmacy; a responsible institution, provided that these sales represented more than half of the total amount of that product sold by the person during that 24 month period.

A medical practitioner is defined to mean a person registered or licensed as a medical practitioner under legislation in Australia or New Zealand, as the case requires, for the registration or licensing of medical practitioners.

The term “responsible institution” is defined in subsection 1.1.2—2(3) of the Code.

Section 2.9.1—32 This section sets general compositional requirements for special medical purpose products for infants.

Subsection 2.9.1—32(1) provides that a special medical purpose product for infants must have an energy content of no less than 2510 kJ/L and no more than 2930 kJ/L.

Subsection 2.9.1—32(2) provides that, subject to subsections 2.9.1—32(3) and (4) (see below), a special medical purpose product for infants must not contain added fructose and/or added sucrose.

Subsection 2.9.1—32(3) provides an exception to the prohibition imposed by subsection 2.9.1—32(2). This exception applies only to special medical purpose products for infants manufactured from partially hydrolysed protein. The subsection provides that these types of special medical purpose product for infants may contain added fructose and/or added sucrose provided that the fructose and/or sucrose is added to the product to provide a source of carbohydrate; and the sum of the added fructose and/or sucrose to in the product does not exceed 20% of available carbohydrates in that product.

Paragraph 2.9.1—32(4) also provides an exception to the prohibition imposed by subsection 2.9.1—32(2). Section 2.9.1—32(4) provides that that prohibition does not apply to added fructose and/or added sucrose that is present in a special medical purpose product for infants as a result of: the addition of inulin-type fructans to the special medical purpose product for infants in accordance with Standard 2.9.1 (paragraph 2.9.1—32(4)(a)); and/or the use of a substance as a processing aid in accordance with the Code in the manufacture of the special medical purpose products for infants (paragraph 2.9.1—32(4)(b)).

The term ‘inulin-type fructans’ is defined in subsection 1.1.2—2(3) of the Code. The phrase ‘used as a processing aid’ in relation to a food is defined in section 1.1.2—13 of the Code.

Subsection 2.9.1—32(5) provides that the fluoride content of a special medical purpose product for infants must not exceed 17 µg/100 kJ if the product is in a powdered or concentrated form; and 24 µg/100 kJ if the product is in a ready-to-drink form.

Subsection 2.9.1—32(6) provides that the amounts set by subsection 2.9.1—32(5) apply to the special medical purpose product for infants as sold.

Section 2.9.1—33: This section sets out the protein requirements for special medical purpose products for infants.

Subsection 2.9.1—33(1) provides that special medical purpose product for infants must be only derived from one or more of the following proteins listed in that subsection:

- cow milk;
- goat milk;
- sheep milk;
- soy protein isolate;
- a partially hydrolysed protein of one or more of the above.

Subsection 2.9.1—33(2) provides mandatory protein content requirements for special medical purpose products for infants. A special medical purpose product for infants that is a milk-based product must have a protein content of no less than 0.43 g/100 kJ and no more than 0.72 g/100 kJ. A special medical purpose product for infants that is not a milk-based product must have a protein content of no less than 0.54 g/100 kJ and no more than 0.72 g/100 kJ.

Subsection 2.9.1—33(3) defines what is a milk-based product for the purposes of subsection 2.9.1—33(2). A **milk-based product** is defined mean a special medical purpose product for infants that is derived only from one or more of the following proteins: cow milk; goat milk; sheep milk; a partially hydrolysed protein of one or more of cow milk, goat milk and sheep milk.

Subsection 2.9.1—33(4) requires that the L-amino acids listed in the table to section S29—3 must be present in a special medical purpose product for infants at or above the corresponding minimum level specified in that table.

Subsection 2.9.1—33(5) provides an exception to the requirement imposed by subsection 2.9.1—33(4). This exception applies only to the minimum levels specified in the table to section S29—3 for cysteine and for methionine. Subsection 2.9.1—33(5) provides that these minimum levels do not apply to a special medical purpose product for infants when both the following conditions are met: the minimum amount of combined cysteine and methionine in the special medical purpose product for infants is not less than 15 mg per 100 kJ; and the ratio of methionine to cysteine in the special medical purpose product for infants is less than 2 to 1.

Subsection 2.9.1—33(6) provides another exception to the requirement imposed by subsection 2.9.1—33(4). This exception applies only to the minimum levels specified in the table to section S29—3 for phenylalanine and for tyrosine. Subsection 2.9.1—33(6) provides that these minimum levels do not apply to a special medical purpose product for infants when both following conditions are met: the minimum amount of combined phenylalanine and tyrosine in the special medical purpose product for infants is not less than 37 mg per 100 kJ; and the ratio of tyrosine to phenylalanine in the special medical purpose product for infants is less than 2 to 1.

Subsection 2.9.1—33(7) provides that, despite the above-mentioned requirements in subsections 2.9.1—33(4), (5) and (6)), relating to the levels of L-amino acids listed in the table to section S29—3 in special medical purpose products for infants, those L-amino acids must only be added to special medical purpose product for infants in an amount necessary to improve protein quality.

Section 2.9.1—34: This section sets out the fat requirements for special medical purpose products for infants.

Paragraph 2.9.1—34(1)(a) requires that a special medical purpose product for infants must have a fat content of no less than 1.1 g/100 kJ and no more than 1.4 g/100 kJ.

Paragraph 2.9.1—34(1)(b) requires that a special medical purpose product for infants must have a ratio of linoleic acid to α -linolenic acid of no less than 5 to 1 and no more than 15 to 1.

Paragraph 2.9.1—34(1)(c) requires that a special medical purpose product for infants must contain no less than 90 mg/100 kJ of linoleic acid and no less than 12 mg/100 kJ of α -linolenic acid.

The Note to paragraph 2.9.1—34(1)(c) identifies and explains that it is recommended that a special medical purpose product for infants contain not more than 335 mg of linoleic acid. This is not a mandatory or binding maximum limit. This amount or Guidance Upper Level is provided as guidance only and a recommended upper level for this nutrient which poses no significant risks on the basis of current scientific knowledge. The level is a value derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. It is recommended that the amount specified not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formula and follow-on formula or due to technological reasons.

Paragraph 2.9.1—34(1)(d) requires that a special medical purpose product for infants must have an arachidonic acid (20 to 4 n-6) content of equal to or more than docosahexaenoic acid (22 to 6 n-3) content.

Paragraph 2.9.1—34(1)(e) requires that a special medical purpose product for infants must contain no less than 0.5 mg of vitamin E per gram of polyunsaturated fatty acids.

Paragraph 2.9.1—34(1)(f) requires that any long chain polyunsaturated fatty acids that are present in a special medical purpose product for infants must have an eicosapentaenoic acid (20 to 5 n-3) content that is not more than the docosahexaenoic acid (22 to 6 n-3) content. The term 'polyunsaturated fatty acid' is defined in subsection 1.1.2—2(3) of the Code.

Paragraph 2.9.1—34(1)(g) lists requirements for certain fatty acids present in a special medical purpose product for infants. The paragraph provides that, if a fatty acid listed in Column 1 of the table to section S29—4 is present in a special medical purpose product for infants, that product must contain not more than the maximum (if any) amount of that fatty acid that is specified in Column 2 of that table.

Subsection 2.9.1—34(2) provides that a special medical purpose product for infants may only contain medium chain triglycerides that are either: a natural constituent of a milk-based ingredient of that product; or for a fat soluble vitamin that is specified in the table to section S29—5, a substance that was used as a processing aid in the preparation of that permitted fat soluble vitamin for use in the special medical purpose product for infants. The phrase 'used as a processing aid' in relation to a food is defined in section 1.1.2—13 of the Code.

Subsection 2.9.1—34(3) provides that a special medical purpose product for infants must not have a phospholipid content of more than 72 mg/100 kJ.

Section 2.9.1—35: This provision provides a qualified permission for a special medical purpose product to contain a novel food. The section provides that, despite any other provision in the Code, a special medical purpose product for infants for retail sale may have, as an ingredient or a component, a novel food, but only if the presence of that novel food in that product is necessary to achieve that product's intended medical purpose. The terms 'component' of a food and 'novel food' are defined in subsection 1.1.2—2(3) and section 1.1.2—8 of the Code respectively.

Section 2.9.1—36: This section provides that special medical purpose products for infants must contain certain nutritive substances.

Subsection 2.9.1—36(1) provides that a special medical purpose product for infants must contain each substance listed in Column 1 of the table to section S29—5 and in an amount (including any naturally-occurring amount) that is no less than the minimum amount specified in Column 2 of the table (paragraph 2.9.1—36(1)(a)); and no more than the maximum amount (if any) specified in Column 3 of the table (paragraph 2.9.1—36(1)(b)).

The Note to subsection 2.9.1—36(1) identifies and explains the operation of Column 4 of the table to section S29—5. This Note explains that it is recommended that a special medical purpose product for infants contain a substance listed in Column 1 of the table to section S29—5 in an amount that is not more than the amount (if any) specified for that substance in Column 4. This is not a mandatory or binding maximum limit. The amounts or Guidance Upper Levels are provided as guidance only and are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. It is recommended that the amounts specified in Column 4 not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of a special medical purpose product for infants or due to technological reasons. Guidance Upper Levels are listed for substances where no maximum limit is set.

Subsection 2.9.1—36(2) provides that the ratio of calcium to phosphorus in a special medical purpose product for infants must be no less than 1 to 1 and no more than 2 to 1.

Section 2.9.1—37: This section provides that certain substances may be used as a nutritive substance in a special medical purpose product for infants. The phrase ‘used as a nutritive substance’ in relation to a food is defined in section 1.1.2—12 of the Code.

The section provides that a substance listed in Column 1 of the table to S29—7 may be used as a nutritive substance in a special medical purpose product for infants, provided that the amount of the substance in the product (including any naturally-occurring amount) is: no less than the minimum amount (if any) specified in Column 2 of the table; and no more than the maximum amount specified in Column 3 of the table.

Section 2.9.1—38: This section requires that any substance used in a special medical purpose product for infants in accordance with section 2.9.1—36 or 2.9.1—37 must be in the permitted form listed in either the table to section S29—23 (for vitamin, mineral or electrolytes) or the table to section S29—9 (in all other cases).

Section 2.9.1—39: This section permits the addition of L(+) lactic producing microorganisms to special medical purpose products for infants.

Section 2.9.1—40: This section restricts the addition of inulin-type fructans and galacto-oligosaccharides to special medical purpose products for infants. The terms ‘inulin-type fructans’ and ‘galacto-oligosaccharides’ are defined in subsection 1.1.2—2(3) of the Code.

The section lists the requirements that must be met if an inulin-type fructan or a galacto-oligosaccharide is added to a special medical purpose product for infants. The requirements are that the product must contain (taking into account both the naturally-occurring and added substances) no more than:

- if only inulin-type fructans are added—110 mg/100 kJ of inulin-type fructans; or
- if only galacto-oligosaccharides are added—290 mg/100 kJ of galacto-oligosaccharides; or
- if both inulin-type fructans and galacto-oligosaccharides are added:
 - no more than 110 mg/100 kJ of inulin-type fructans; and

- no more than 290 mg/100 kJ of combined inulin-type fructans and galacto-oligosaccharides.

Section 2.9.1—41: This section provides that a special medical purpose product for infants must not contain any of the following: detectable gluten; or more than 3.8 mg/100 kJ of free nucleotide-5'-monophosphates.

There are two Notes to this section.

Note 1 refers readers to section S19—4 that contains the maximum levels of contaminants in infant formula products.

Note 2 refers readers to Standard 1.3.1 and Schedule 15, which together permit the use of certain substances as food additives in infant formula products including a special medical purpose product for infants.

Section 2.9.1—42: This section provides an exception to certain compositional requirements imposed by the Code.

Subsection 2.9.1—42(1) provides that special medical purpose product for infants need not comply with a compositional requirement (as defined by subsection 2.9.1—42(2)) to the extent that a variation from that requirement: is needed to achieve the product's intended medical purpose; or would otherwise prevent the sale of the product.

The intent of subsection 2.9.1—42(1) is to allow special medical purpose products for infants to vary their specialised formulation based on the nutrient requirements of the specified medical disease, disorder or condition. This can include deviation from multiple composition parameters. An example is a special medical purpose product for infants formulated in accordance with an international regulation that has a lower prescribed substance level than that required by the Code. The existence of that lower substance level in line with the intentional regulation would not stop the sale of the food.

Subsection 2.9.1—42(2) defines 'a compositional requirement' for the purposes of subsection 2.9.1—42(1) as meaning a requirement imposed in relation to a special medical purpose product for infants by any of the following provisions of the Code:

- any of sections 2.9.1—32 to 2.9.1—41, but not section 2.9.1—35 (paragraph 2.9.1—42(2)(a));
- paragraph 1.1.1—10(6)(a) (this paragraph imposes a requirement that, unless expressly permitted by this Code, a food for sale must not have, as an ingredient or a component, a substance that was used as a food additive) (paragraph 2.9.1—42(2)(b));
- paragraph 1.1.1—10(6)(b) (this paragraph imposes a requirement that, unless expressly permitted by this Code, a food for sale must not have, as an ingredient or a component, a substance that was used as a nutritive substance) (paragraph 2.9.1—42(2)(c));
- paragraph 1.1.1—10(6)(c) (this paragraph imposes a requirement that, unless expressly permitted by this Code, a food for sale must not have, as an ingredient or a component, a substance that was used as a processing aid) (paragraph 2.9.1—42(2)(d)).

The term 'component' of a food is defined in subsection 1.1.2—2(3) of the Code. The phrases 'used as a food additive', 'used as a nutritive substance' and 'used as a processing aid' in relation to a food are defined in sections 1.1.2—11, 1.1.2—12 and 1.1.2—13 of the Code respectively.

Sections 2.9.1—43 to 2.9.1—55 set out the labelling and packaging requirements for special medical purpose products for infants.

Section 2.9.1—43: This section provides that a food may only be represented as a special medical purpose product for infants if it complies with Division 4 of Standard 2.9.1.

Section 2.9.1—44: This section requires that the label on a package of a special medical purpose product for infants must differentiate that product from other foods by the use of text, pictures and/or colours.

An example is provided: the text, pictures and/or colours used on a label on a package of a special medical purpose product for infants must differentiate that product from, among other things, infant formula, follow-on formula or a formulated supplementary food for young children.

Section 2.9.1—45: This section sets out the representations that the label on a package of a special medical purpose product for infants must not contain. The section provides that the label on a package of a special medical purpose product for infants must not contain any of the following:

- A picture of an infant (paragraph 2.9.1—45(a)).
- A picture or text that idealises the use of special medical purpose product for infants (paragraph 2.9.1—45(b)).
- The words ‘human milk oligosaccharide’, ‘human identical milk oligosaccharide’ or any word or words having the same or similar effect (paragraph 2.9.1—45(c)).
- The abbreviations ‘HMO’ or HiMO’ or any abbreviation having the same or similar effect (paragraph 2.9.1—45(d)).

Section 2.9.1—46: This section sets out a claim must not be made in relation to a special medical purpose product for infants.

Subsection 1.1.2—2(3) defines the term ‘claim’ to mean ‘an express or implied statement, representation, design or information in relation to a food or a property of food which is not mandatory in this Code’.

Subsections 2.9.1—46(1) and (2) provide the following claims are prohibited:

- A claim that refers to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition (paragraph 2.9.1—46(1)(a)).
- A claim that compares the special medical purpose product for infants to a good that is represented in any way to be for therapeutic use (subparagraph 2.9.1—46(1)(b)(i)).
- A claim that compares the special medical purpose product for infants to a good that is likely to be taken to be for therapeutic use, whether because of the way in which the good is presented or for any other reason (subparagraph 2.9.1—46(1)(b)(ii)).
- A nutrition content claim or health claim (subsection 2.9.1—46(2)). The term ‘health claim’ is defined in subsection 1.1.2—2(3) of the Code.

Subsection 2.9.1—46(3) provides exemptions to the prohibitions imposed by subsections 2.9.1—46(1) or (2). Subsection 2.9.1—46(3) provides that section 2.9.1—46 does not apply to: a claim that is expressly permitted by the Code; or a declaration that is required by an application Act.

Section 2.9.1—47: This section provides that a claim that a special medical purpose product for infants is lactose free may only be made if that special medical purpose product for infants contain no detectable lactose.

Section 2.9.1—48: This section sets out the general labelling and related requirements for special medical purpose product for infants for sale.

Subsection 2.9.1—48(1) provides that the requirements listed in section 2.9.1—48 apply to a food for sale that is a special medical purpose product for infants.

Subsection 2.9.1—48(2) requires the special medical purpose product for infants that is in a package to bear a label that complies with section 2.9.1—49 (see below). The phrase 'bear a label' is defined in subsection 1.1.2—2(3) of the Code.

Subsection 2.9.1—48(3) only applies to a special medical purpose product for infants for sale that is in an inner package. The term 'inner package' is defined in subsection 1.1.2—2(3) of the Code. Paragraph 2.9.1—48(3)(a) requires the inner package to bear a label that complies with section 2.9.1—54 (see below). Paragraph 2.9.1—48(3)(b) also requires that there is no other labelling requirement in the Code for any other packaging associated with that product.

Subsection 2.9.1—48(4) applies to a special medical purpose product for infants for sale that is in a transportation outer. 'Transportation outer' is defined in subsection 1.1.2—2(3) of the Code. Paragraph 2.9.1—48(4)(a) requires that the transportation outer or package containing that special medical purpose product for infants to bear a label that complies with section 2.9.1—55 (see below). Paragraph 2.9.1—48(4)(b) also requires that there is no other labelling requirement in the Code for any other packaging associated with that product.

Section 2.9.1—49: This section sets out the information that must be stated on the label required for a special medical purpose product for infants.

Subsection 2.9.1—49(1) requires the following information to be stated on the label.

- A name or description sufficient to indicate the true nature of the food, in accordance with section 1.2.2—2 (paragraph 2.9.1—49(1)(a)).
- Lot identification, in accordance with section 1.2.2—3 (paragraph 2.9.1—49(1)(b)).
- Information relating to foods produced using gene technology, in accordance with section 1.5.2—4, provided that the sale of that product is a sale to which Division 2 or Division 3 of Standard 1.2.1 applies (subparagraph 2.9.1—49(1)(c)(i)). The phrase 'food produced using gene technology' is defined in subsection 1.1.2—2(3) of the Code.
- Information relating to irradiated food, in accordance with section 1.5.3—9, provided that the sale of that product is a sale to which Division 2 or Division 3 of Standard 1.2.1 applies (subparagraph 2.9.1—49(1)(c)(ii)).
- Any mandatory statements and declarations, in accordance with section 2.9.1—50 (paragraph 2.9.1—49(1)(d)).
- Information relating to ingredients, in accordance with section 2.9.1—51 (paragraph 2.9.1—49(1)(e)).
- Date marking information, in accordance with section 2.9.1—52 (paragraph 2.9.1—49(1)(f)).
- Directions for the preparation, use or storage of the food, if the food is of such a nature to require such directions for health or safety reasons (paragraph 2.9.1—49(1)(g)).
- Nutrition information, in accordance with section 2.9.1—53 (paragraph 2.9.1—49(1)(h)).

Subsection 2.9.1—49(2) requires the label for a special medical purpose product for infants to comply with section 1.2.1—24 of the Code. Section 1.2.1—24 sets out general legibility requirements for food for sale.

Section 2.9.1—50: This section sets out the mandatory statements and declarations required for special medical purpose products for infants.

Paragraph 2.9.1—50(a) provides that the following statements are required for the purposes of paragraph 2.9.1—49(1)(d).

- A statement to the effect that the product must be used under medical supervision (paragraph 2.9.1—50(a)).
- A statement indicating, if applicable, any precautions and contraindications associated with consumption of the product (paragraph 2.9.1—50(b)).
- A statement indicating the medical purpose of the product, which may include a disease, disorder or medical condition for which the product has been formulated (paragraph 2.9.1—50(c)).
- A statement describing the properties or characteristics which make the product appropriate for the medical purpose indicated in paragraph 2.9.1—50(c) (paragraph 2.9.1—50(d)).
- if the product has been formulated for a specific age group—a statement to the effect that the product is intended for persons within the specified age group (paragraph 2.9.1—50(e)).
- A statement indicating whether or not the product is suitable for use as a sole source of nutrition (paragraph 2.9.1—50(f)).
- If the product is represented as being suitable for use as a sole source of nutrition, a statement to the effect that the product is not for parenteral use (subparagraph 2.9.1—50(g)(i)).
- If the product has been modified to vary from the compositional requirement of Division 4 such that the content of one or more nutrients falls short of the prescribed minimum, or exceeds the prescribed maximum (if applicable) (see section 2.9.1—42 above), then both the following statements are required for that product (in addition to the statement required by subparagraph 2.9.1—50(g)(i)):
 - a statement indicating the nutrient or nutrients which have been modified (sub-subparagraph 2.9.1—50(g)(ii)(A)); and
 - a statement indicating whether each modified nutrient has been increased, decreased, or eliminated from the product, as appropriate (sub-subparagraph 2.9.1—50(g)(ii)(B))

The statements in sub-subparagraphs 2.9.1—50(g)(ii)(A) and (B) are not required to be on the label required for a special medical purpose product for infants if they are provided in other documentation about the product.

- The declarations required by section 1.2.3—4 (paragraph 2.9.1—50(h)). Section 1.2.3—4 relates to mandatory declarations of certain foods e.g. allergens.

Section 2.9.1—51: This section sets out the information relating to ingredients that must be stated on the label required for a special medical purpose product for infants in accordance with paragraph 2.9.1—49(1)(e). That information is:

- a statement of ingredients; or
- information that complies with Articles 18, 19 and 20 of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers; or
- information that complies with 21 CFR § 101.4. That is, section 101.4 of Title 21 of the

United States Code of Federal Regulations.

Section 2.9.1—52: This section sets out the date marking information that must be stated on the label required for a special medical purpose product for infants in accordance with paragraph 2.9.1—49(1)(f).

Subsection 2.9.1—52(1) provides that the required date marking information is date marking information in accordance with Standard 1.2.5.

Subsection 2.9.1—52(2) provides that, for the purposes of subparagraph 1.2.5—5(2)(a)(ii), the words ‘Expiry Date’, or similar words, may be used on the label.

Section 2.9.1—53: This section sets out the nutrition information that must be stated on the label required for a special medical purpose product for infants in accordance with paragraph 2.9.1—49(1)(h).

Subsection 2.9.1—53(1) requires the following nutrition information about the product, expressed per given amount of the food:

- The minimum or average energy content (paragraph 2.9.1—53(1)(a)).
- The minimum amount or average quantity of: protein, fat and carbohydrate (subparagraph 2.9.1—53(1)(b)(i)).
- The minimum amount or average quantity of any vitamin, mineral or electrolyte that has been used as a nutritive substance in the food (subparagraph 2.9.1—53(1)(b)(ii)).
- A substance - other than a substance listed in paragraph 2.9.1—53(1)(b) - used as a nutritive substance in the special medical purpose product for infants and added to that product to achieve that product’s intended medical purpose (paragraph 2.9.1—53(1)(c)).
- Information on sub-group nutrients of protein, fat and/or carbohydrate (subparagraph 2.9.1—53(1)(d)(i)).
- Osmolality and osmolarity (subparagraph 2.9.1—53(1)(d)(ii)).
- Acid-base balance (subparagraph 2.9.1—53(1)(d)(iii)).

The information referred to in subparagraphs 2.9.1—53(1)(d)(i) – (iii) is only required if declaration of that information is necessary for use of the special medical purpose product for infants for its intended medical purpose.

The terms ‘average energy content’ and ‘average quantity’ are defined in subsection 1.1.2—2(3) of the Code.

The phrase ‘used as a nutritive substance’ in relation to a food is defined in section 1.1.2—12 of the Code.

For clarity, subsection 2.9.1—53(2) provides that, a reference to ‘the intended medical purpose’ in subsection 2.9.1—53(1) is to the intended medical purpose as described in the statement required by paragraph 2.9.1—50(c) (see above).

Subsection 2.9.1—53(3) provides that the label that is required for a special medical purpose product for infants may state information relating to the source or sources of protein in that product. The provision of this information is optional.

Section 2.9.1—54: This section sets out the information that must be stated on the label on an inner package that contains a special medical purpose product for infants.

Subsection 2.9.1—54(1) requires the following information to be stated:

- A name or description sufficient to indicate the true nature of the food, in accordance with

section 1.2.2—2 (paragraph 2.9.1—54(1)(a)).

- Lot identification, in accordance with section 1.2.2—3 (paragraph 2.9.1—54(1)(b)).
- Any declaration that is required by section 1.2.3—4 (paragraph 2.9.1—54(1)(c)).
- Date marking information, in accordance with section 2.9.1—52 (paragraph 2.9.1—54(1)(d)).

Subsection 2.9.1—54(2) requires the label on an inner package that contains a special medical purpose product for infants to comply with section 1.2.1—24 of Standard 1.2.1. Section 1.2.1—24 sets out general legibility requirements for food for sale.

To avoid doubt, subsection 2.9.1—54(3) provides that section 2.9.1—54 continues to apply to the label on the inner package if a responsible institution subsequently supplies the inner package to a patient or resident of the responsible institution.

The terms 'inner package' and 'responsible institution' are defined in subsection 1.1.2—2(3) of the Code.

Section 2.9.1—55: This section sets out the labelling requirements for a special medical purpose product for infants contained in a transportation outer.

Subsection 2.9.1—55(1) provides that, if packages of a special medical purpose product for infants are contained in a transportation outer, the information in accordance with the provision indicated as specified in subsection 2.9.1—55(2) must be: contained in a label on the transportation outer; or contained in a label on a package of the food for sale, and clearly discernible through the transportation outer.

Subsection 2.9.1—55(2) specifies the following information for the purposes of subsection 2.9.1—55(1):

- A name or description sufficient to indicate the true nature of the food, in accordance with section 1.2.2—2 (paragraph 2.9.1—55(2)(a)).
- Lot identification, in accordance with section 1.2.2—3 (paragraph 2.9.1—55(2)(b)).
- The name and address of the supplier, in accordance with section 1.2.2—4 (paragraph 2.9.1—55(2)(c)). This information is not required to be contained in the label if it is provided in accompanying documentation. The term 'supplier' is defined in subsection 1.1.2—2(3) of the Code.