Commonwealth of Australia

Gazette

No. FSC 171 13 September 2024
Published by Commonwealth of Australia

Food Standards

Amendment No. 231

The following instruments are separate instruments in the Federal Register of Legislation and are known collectively in the Food Standards Gazette as Amendment No. 231

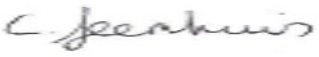
Table of contents

ISSN 1446-9685

Food Standards (Proposal P1028 – Infant Formula) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated 12 September 2024



Christel Leemhuis, General Manager Risk Assessment and Science Branch
Delegate of the Board of Food Standards Australia New Zealand

Note:
This variation will be published in the Commonwealth of Australia Gazette No. FSC 171 on 13 September 2024. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Proposal P1028 – Infant Formula) Variation*.

2 Variation to a standard in the *Australia New Zealand Food Standards Code*

The Schedule varies a Standard in the *Australia New Zealand Food Standards Code*.

3 Commencement

The instrument commences on gazettal.

4 Effect of the variations made by this instrument

Note 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.

(1) Section 1.1.1—9 of Standard 1.1.1 does not apply to the variations made by this instrument.

(2) During the transition period, a food product may be sold if the product complies with one of the following:

(a) the Code as in force without the variations made by the instruments; or

(b) the Code as amended by the variations made by the instruments.

(3) For the purposes of this clause:

(a) the **instruments** means:

(i) this instrument; and

(ii) the *Food Standards (Proposal P1028 – Infant Formula – Consequential Amendments) Variation*;

(b) the **transition period** means the period commencing on this instrument's date of commencement and ending 60 months after the date of commencement.

Schedule

Standard 2.9.1

[1] Sections 2.9.1—2 to 2.9.1—25

Repeal the sections, substitute:

2.9.1—2 Outline of Standard

(1) This Standard regulates various types of infant formula products.

(2) Division 1 deals with preliminary matters.

(3) Division 2 sets out compositional requirements for infant formula and follow-on formula.

(4) Division 3 sets out labelling and packaging requirements for infant formula and follow-on formula.

(5) Division 4 sets out compositional, labelling and restriction on sale requirements for a special medical purpose product for infants.

2.9.1—3 Definitions

Note In this Code (see sections 1.1.2—2 and 1.1.2—3):

follow-on formula means an infant formula product that is represented as:

(a) either a breast milk substitute or replacement for infant formula; and

(b) being suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of 6 months.

infant formula means an infant formula product that is represented as:

(a) a breast milk substitute for infants; and

(b) satisfying by itself the nutritional requirements of infants under the age of 6 months.

infant formula product means a product based on milk or other edible food constituents of animal or plant origin which is represented as nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants, depending on the age of the infant.

inner package, in relation to a special medical purpose product for infants, means an individual package of the food that is:

(a) contained and sold within another package that is labelled in accordance with Division 4 of Standard 2.9.1; and

(b) not designed for individual sale, other than a sale by a *responsible institution to a patient or resident of the responsible institution.

Example An example of an inner package is an individual sachet (or sachets) of a powdered food contained within a box that is fully labelled, being a box available for retail sale.

responsible institution means a hospital, hospice, aged care facility, disability facility, prison, boarding school or similar institution that is responsible for the welfare of its patients or residents and provides food to them.

special medical purpose product for infants means an infant formula product that is:

(a) represented as being:

(i) specially formulated for the dietary management of infants who have medically determined nutrient requirements (such as limited or impaired capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food); and

(ii) suitable to constitute either the sole or principal liquid source of nourishment where dietary management cannot medically be achieved without use of the product; and

(iii) for the dietary management of a medically diagnosed disease, disorder or condition of an infant; and

(b) intended to be used under medical supervision; and

(c) not suitable for general use.

2.9.1—4 Interpretation

Interpretation of compositional requirements

(1) Unless otherwise expressly stated, compositional requirements in this Standard apply to:

(a) a powdered or concentrated form of infant formula product that has been reconstituted with water according to directions; and

(b) an infant formula product in ‘ready to drink’ form.

Calculation of energy, protein and vitamin A

(2) In this Standard:

(a) energy must be calculated in accordance with section S29—2; and

(b) protein content must be calculated in accordance with section S29—2A; and

(c) vitamin A content must be calculated in accordance with section S29—2B.

Division 2 Compositional requirements for infant formula and follow -on formula

Note Subsection 1.5.1—3(2) provides that an infant formula product for retail sale may consist of, or have as an ingredient or a component, a novel food only if each condition specified in that subsection is met.

2.9.1—5 General requirements

(1) 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.

(2) Subject to subsections (3) and (4), infant formula and follow-on formula must not contain added fructose and/or added sucrose.

(3) Infant formula and follow-on formula manufactured from partially hydrolysed protein may contain added fructose and/or added sucrose, provided that:

(a) the fructose and/or sucrose is added to the formula to provide a source of carbohydrate; and

(b) the sum of the fructose and/or sucrose in the formula does not exceed 20% of available carbohydrates in the formula.

(4) Subsection (2) does not apply to added fructose and/or added sucrose that is present in infant formula and follow-on formula as a result of:

(a) the addition of inulin-type fructans to the infant formula or follow-on formula in accordance with this Standard; and/or

(b) the use of a substance as a processing aid in accordance with this Code in the manufacture of the infant formula or follow-on formula.

(5) The fluoride content of infant formula and follow-on formula must not exceed:

(a) if in a powdered or concentrated form—17 µg/100 kJ; and

(b) if in a 'ready-to-drink' form—24 µg/100 kJ.

(6) The amounts in subsection (5) apply to the infant formula or follow-on formula as sold.

2.9.1—6 Protein requirements

(1) Infant formula and follow-on formula must be derived only from one or more of the following proteins:

(a) cow milk;

(b) goat milk;

(c) sheep milk;

(d) soy protein isolate;

(e) a partially hydrolysed protein of one or more of the above.

(2) Infant formula must have a protein content of:

(a) for milk-based infant formula—no less than 0.43 g/100 kJ and no more than 0.72 g/100 kJ; and

(b) for infant formula that is not milk-based infant formula—no less than 0.54 g/100 kJ and no more than 0.72 g/100 kJ.

(3) Follow-on formula must have a protein content of:

(a) for milk-based follow-on formula—no less than 0.38 g/100 kJ and no more than 0.72 g/100 kJ; and

(b) for follow-on formula that is not milk-based follow-on formula—no less than 0.54 g/100 kJ and no more than 0.72 g/100 kJ.

(4) For the purposes of subsections (2) and (3):

(a) ***milk-based infant formula*** means 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; and

(b) ***milk-based follow-on formula*** means 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.

(5) The L-amino acids listed in the table to section S29—3 must be present in infant formula and follow-on formula at a level not less than the corresponding minimum level specified in the table.

(6) The minimum levels specified in the table to section S29—3 for cysteine and for methionine do not apply if:

(a) 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

(b) the ratio of methionine to cysteine in the infant formula and follow-on formula is less than 2 to1.

(7) The minimum levels specified in the table to section S29—3 for phenylalanine and for tyrosine do not apply if:

(a) 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

(b) the ratio of tyrosine to phenylalanine in the infant formula and follow-on formula is less than 2 to 1.

(8) Despite subsections (5), (6) and (7), L-amino acids listed in the table to section S29—3 must only be added to infant formula or follow-on formula in an amount necessary to improve protein quality.

2.9.1—7 Fat requirements

(1) Infant formula and follow-on formula must:

(a) have a fat content of no less than 1.1 g/100 kJ and no more than 1.4 g/100 kJ; and

(b) have a ratio of linoleic acid to α-linolenic acid of no less than 5 to 1 and no more than 15 to 1; and

(c) contain no less than:

(i) 90 mg/100 kJ of linoleic acid; and

(ii) 12 mg/100 kJ of α-linolenic acid; and

Note. It is recommended that infant formula and follow-on formula contain not more than 335 mg/100 kJ of linoleic acid. This amount is a Guidance Upper Level and a recommended upper level for this nutrient which poses 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. This Guidance Upper Level should not be exceeded unless a higher nutrient level cannot be avoided due to high or variable contents in constituents of infant formulas and follow-on formula or due to technological reasons.

(d) have an arachidonic acid (20 to 4 n-6) content of equal to or more than docosahexaenoic acid (22 to 6 n-3) content; and

(e) contain no less than 0.5 mg of vitamin E per gram of polyunsaturated fatty acids; and

(f) for any long chain *polyunsaturated fatty acids that are present—have an eicosapentaenoic acid (20 to 5 n-3) content of no more than the docosahexaenoic acid (22 to 6 n-3) content; and

(g) for a fatty acid listed in Column 1 of the table to section S29—4 and present in the formula—contain not more than the maximum amount (if any) specified in Column 2 of the table for that fatty acid.

(2) Infant formula and follow-on formula may only contain medium chain triglycerides that:

(a) contain predominantly the saturated fatty acids designated by 8 to 0 and 10 to 0; and

(b) are one of the following:

(i) a natural constituent of a milk-based ingredient of that formula; or

(ii) for a fat soluble vitamin that is specified in a following table—a substance that was *used as a processing aid in the preparation of that permitted fat soluble vitamin for use in the formula:

(A) for infant formula—the table to section S29—5; and

(B) for follow-on formula—the table to section S29—6.

(3) Infant formula and follow-on formula must not have a phospholipid content of more than 72 mg/100 kJ.

2.9.1—8 Required nutritive substances

(1) 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) that is:

(a) no less than the minimum amount specified in Column 2 of the table; and

(b) no more than the maximum amount (if any) specified in Column 3 of the table.

Note 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 of that table. The amounts specified in Column 4 are Guidance Upper Levels 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. These Guidance Upper Levels should 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.

(2) Follow-on formula must contain each substance listed in Column 1 of the table to section S29—6 in an amount (including any naturally-occurring amount) that is:

(a) no less than the minimum amount specified in Column 2 of the table; and

(b) no more than the maximum amount (if any) specified in Column 3 of the table.

Note 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 of that table. The amounts specified in Column 4 are Guidance Upper Levels, which 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. The Guidance Upper Levels should 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.

(3) 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.

2.9.1—9 Optional nutritive substances

(1) 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:

(a) no less than the minimum amount (if any) specified in Column 2 of the table; and

(b) no more than the maximum amount (if any) specified in Column 3 of the table.

(2) 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 is the amount of the substance in the formula (including any naturally-occurring amount) is:

(a) no less than the minimum amount (if any) specified in Column 2 of the table; and

(b) no more than the maximum amount (if any) specified in Column 3 of the table.

Note 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 of that table. The amounts specified in Column 4 are Guidance Upper Levels 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. These Guidance Upper Levels should 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.

2.9.1—10 Required forms for nutritive substances

A substance used in infant formula or follow-on formula in accordance with section 2.9.1—8 or 2.9.1—9 must be added in a permitted form listed in:

(a) if a vitamin, mineral or electrolyte—the table to section S29—23; and

(b) in any other case— the table to section S29—9.

2.9.1—10A Infant formula products—conditions on use of permitted nutritive substances

(1) This section applies to a substance that is:

(a) used as a nutritive substance in an infant formula product; and

(b) listed in Column 1 of the table to section S29—9A; and

(c) in a permitted form listed in Column 2 of that table for that substance.

(2) The substance must comply with the conditions (if any) specified in Column 3 of the table to section S29—9A for that substance in that permitted form.

2.9.1—11 Addition of lactic acid producing microorganisms

L(+) lactic acid producing microorganisms may be added to infant formula and follow-on formula.

2.9.1—12 Restriction on addition of inulin-type fructans and galacto-oligosaccharides

If an *inulin-type fructan or a *galacto-oligosaccharide is added to infant formula or follow-on formula, 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 galacto-oligosaccharides.

2.9.1—13 Restriction on levels of other substances

Infant formula and follow-on formula must not contain any of the following:

(a) detectable gluten; or

(b) more than 3.8 mg/100 kJ of free nucleotide-5′-monophosphates.

Note 1 Section S19—4 contains the maximum levels (ML) of contaminants in infant formula products.

Note 2 Standard 1.3.1 and Schedule 15 permit the use of certain substances as food additives in infant formula products.

Division 3 Labelling and packaging requirements for infant formula and follow-on formula

Note Standard 1.2.7 provides that a nutrition content claim or *health claim must not be made about infant formula products. See paragraph 1.2.7—4(b). Paragraph 1.2.7—6(a) provides that this prohibition does not apply to claims that are expressly permitted by the Code, including by this Division.

2.9.1—14 Representations about food as infant formula or follow-on formula

A food may only be represented as infant formula or follow-on formula if the food complies with this Standard.

2.9.1—15 Product differentiation

The label on a package of infant formula or follow-on formula must differentiate that infant formula or follow-on formula from other foods by the use of text, pictures and/or colour.

Example 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.

2.9.1—16 Prescribed names

(1) 'Infant formula' is the *prescribed name for infant formula.

(2) 'Follow-on formula' is the *prescribed name for follow-on formula.

Note Under the labelling provisions in Standard 1.2.1 and section 1.2.2—2, if a food has a prescribed name, that prescribed name must be used in the labelling of the food.

2.9.1—17 Requirement for measuring scoop

(1) 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.

(2) Subsection (1) does not apply to single serve sachets, or packages containing single serve sachets, of formula in a powdered form.

2.9.1—18 Storage instructions

For the labelling provisions, the storage instructions for infant formula and follow-on formula must cover the period after the package is opened.

Note The labelling provisions are set out in Standard 1.2.1.

2.9.1—19 Requirement for the name of the food

For the labelling provisions, the name of the food must be stated on the front of a package of infant formula or follow-on formula.

Note The labelling provisions are set out in Standard 1.2.1.

2.9.1—20 Statement of protein source

(1) For the labelling provisions, the specific animal or plant source or sources of protein in infant formula and follow-on formula must be included in the statement of the name of the food required by section 2.9.1—19.

Examples 'Infant formula based on cow milk'. 'Follow-on formula based on goat milk. 'Infant formula based on soy protein'.

Note 1 Section 2.9.1—6(1) lists the permitted sources of protein for infant formula and follow-on formula.

Note 2 The labelling provisions are set out in Standard 1.2.1.

(2) 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 protein source required by subsection (1).

Example 'Infant formula based on partially hydrolysed cow milk'.

(3) The statement of protein source required by subsection (1) must not use the word 'milk' as the sole descriptor of the protein source.

Example 'Infant formula based on milk' or 'Infant formula sourced from milk' is not permitted.

Note See subparagraph 2.9.1—28(1)(j)(i) in relation to the use of the word 'milk' on the label separately and in addition to in a statement of protein source.

2.9.1—21 Requirement for warning statements and directions

Warning statements

(1) For the labelling provisions, the following *warning statements are required for infant formula and follow-on formula:

(a) 'Warning – follow instructions exactly. Prepare bottles and teats as directed. Incorrect preparation can make your baby very ill.'; and

(b) 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.’.

Note The labelling provisions are set out in Standard 1.2.1.

Required statements on use

(2) For the labelling provisions, the required statements for infant formula and follow-on formula are ones indicating that:

(a) for infant formula—the infant formula may be used from birth; and

(b) for follow-on formula—the follow-on formula should not be used for infants aged under the age of 6 months; and

(c) 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.

Note The labelling provisions are set out in Standard 1.2.1.

Location of required statements

(3) The statements required by paragraphs (2)(a) and (b) must appear on the front of the package of the product.

(4) Subsection (3) does not prevent a statement required by subsection (2) from appearing more than once on the label.

Directions on preparation and use

(5) For the labelling provisions, directions on preparation and use are required for infant formula and follow-on formula which instruct (in words and pictures) that:

(a) each bottle must be prepared individually; and

(b) if a bottle of prepared formula is to be stored prior to use, it must be refrigerated and used within 24 hours; and

(c) previously boiled and cooled potable water must be used; and

(d) if a package contains a measuring scoop—only the enclosed scoop must be used; and

(e) for powdered or concentrated formula—do not change proportions of the powder or concentrate or add other food except on medical advice; and

(f) for ready-to-drink formula—do not dilute or add other food except on medical advice; and

(g) formula left in the bottle after a feed must be discarded within 2 hours.

Note The labelling provisions are set out in Standard 1.2.1.

(6) Paragraphs (5)(a), (b) and (c) do not apply to ready-to-drink formula.

(7) Paragraph (5)(d) does not apply to concentrated formula and ready-to drink formula.

(8) For the labelling provisions, the following must be declared for infant formula and follow-on formula:

(a) for a product in powdered or concentrated form—the proportion of powder or concentrate required to reconstitute the formula according to directions; and

(b) for a product in powdered form—the weight of one scoop.

Note The labelling provisions are set out in Standard 1.2.1.

2.9.1—22 Print size

The warning statements required by subsection 2.9.1—21(1) must be in a *size of type of at least:

(a) if the package of infant formula or follow-on formula has a net weight of more than 500 g—3 mm;

(b) if the package of infant formula or follow-on formula has a net weight of 500 g or less—1.5 mm.

2.9.1—23 Optional format for the statement of ingredients – added vitamins and minerals

(1) Despite section 1.2.4—5, 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 the statement of ingredients:

(a) lists all added vitamins together under the subheading 'Vitamins'; and

(b) lists all added minerals together under the subheading 'Minerals'.

Note See Standard 1.2.4 for other ingredient labelling requirements.

(2) Section 1.2.4—8 does not apply to a statement of ingredients referred to in subsection (1).

2.9.1—24 Declaration of nutrition information

(1) For the labelling provisions, a statement of nutrition information is required for infant formula and follow-on formula.

(2) A reference in this section to 'the statement' is the statement required by subsection (1).

(3) The statement must contain the following information:

(a) the *average energy content expressed in kilojoules per 100 mL of formula; and

(b) the *average quantity of protein, fat and *carbohydrate expressed in grams per 100 mL of formula and as 'protein', 'fat' and 'carbohydrate', respectively; and

(c) the *average quantity of each vitamin or mineral expressed in micrograms or milligrams per 100 mL of formula (including any naturally-occurring amount); and

(d) for infant formula—the *average quantity of choline, inositol and L-carnitine expressed in milligrams per 100 mL of formula (including any naturally-occurring amount); and

(e) if added, the *average quantity of the following, expressed in grams, micrograms or milligrams per 100 mL of formula:

(i) any substance *used as a nutritive substance (including any naturally-occurring amount); or

(ii) *inulin-type fructans; or

(iii) *galacto-oligosaccharides; or

(iv) a combination of inulin-type fructans and galacto-oligosaccharides.

Note The labelling provisions are set out in Standard 1.2.1.

(4) The statement may 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):

(a) whey; and

(b) casein.

(5) The statement may 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):

(a) docosahexaenoic acid; and

(b) eicosapentaenoic acid; and

(c) arachidonic acid.

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

(7) In addition to being expressed in accordance with subsection (6), information included in the statement in accordance with subsection (3), (4) or (5) may also be expressed:

(a) if sold in a concentrated form —per 100 mL of the formula as sold; or

(b) if sold in a powdered form —per 100 g of formula as sold.

(8) Unless expressly provided elsewhere in this Code, the statement must not contain any other information.

2.9.1—25 Required form for the declaration of nutrition information

(1) A reference to 'the table' in this section is a reference to the table to section S29—10.

(2) Subject to this section, the statement required by section 2.9.1—24 must:

(a) be in the same format as specified in the table; and

(b) state the nutrition information in the order specified in the table; and

(c) be titled 'Nutrition Information' in bold font; and

(d) have the following subheadings printed in a size of type that is the same or larger than the nutrient names in the statement:

(i) for infant formula and follow-on formula—'Vitamins', 'Minerals' and 'Additional'; and

(ii) for infant formula only—'Other nutrients'; and

(e) state nutrients and subgroup nutrients using the names and units of measurement specified in the table for that nutrient and subgroup; and

(f) not express an amount or quantity other than in accordance with section 2.9.1—24.

(3) If the statement includes the *average quantity of a permitted nutritive substance, an *inulin-type fructan or a *galacto-oligosaccharide, that average quantity must be included in the statement:

(a) under the subheading 'Additional'; and

(b) in the same format as specified in the table for that substance.

(4) If the statement includes the *average quantity of choline, inositol or L-carnitine, that average quantity must be included in the statement:

(a) for infant formula—under the subheading 'Other nutrients'; and

(b) for follow-on formula—under the subheading 'Additional'; and

(c) in the same format as specified in the table for that substance.

(5) If the statement includes the *average quantity of a substance listed in subsection 2.9.1—24(4), that average quantity must be included in the statement in the same format as specified in the table for that substance.

(6) If the statement includes the *average quantity of the substances listed in subsection 2.9.1—24(5), the statement:

(a) must include the subheading 'Long chain polyunsaturated fatty acids' that is printed in a size of type that is the same or larger than the nutrient names in the statement; and

(b) must include that average quantity:

(i) under the subheading 'Long chain polyunsaturated fatty acids'; and

(ii) in the same format as specified in the table for those substances; and

(c) must use the name for each substance specified in the table for that substance; and

(d) may use the acronym specified in the table for the following substances in addition to the name required for those substances by paragraph (c):

(i) docosahexaenoic acid; and

(ii) eicosapentaenoic acid; and

(iii) arachidonic acid.

Example The statement may use 'Docosahexaenoic acid (DHA)' or 'Docosahexaenoic acid', but not 'DHA'.

(7) If the statement includes information expressed in accordance with subsection 2.9.1—24(7), that information must be in an additional column at the right hand side of the column shown in the table.

(8) Information included in the additional column required by subsection (7) must be in the form required by this section.

Note For an example nutrition information statement including information expressed in accordance with subsection 2.9.1—24(7), see section S29—10A.

2.9.1—26 How average quantity is to be calculated

Despite section 1.1.1—6, the method in paragraph 1.1.1—6(3)(c) must not be used to calculate the *average quantity of a substance in infant formula or follow-on formula.

2.9.1—27 Requirements for use of stage numbers

(1) The following numbers may be used on the label on a package of infant formula or follow-on formula to identify for consumers that the product is infant formula or follow-on formula:

(a) if the product is infant formula—the number '1'; and

(b) if the product is follow-on formula—the number '2'.

(2) A number used in accordance with subsection (1) must appear:

(a) on the front of the package of the product; and

(b) immediately adjacent to:

(i) for infant formula—the statement required by paragraph 2.9.1—21(2)(a); and

(ii) for follow-on formula—the statement required by paragraph 2.9.1—21(2)(b).

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

2.9.1—28 Prohibited representations

(1) The label on a package of infant formula or follow-on formula must not contain:

(a) a picture of an infant; or

(b) a picture that idealises the use of infant formula or follow-on formula; or

(c) information relating to:

(i) for infant formula—follow-on formula, a special medical purpose product for infants, a formulated supplementary food or a formulated supplementary food for young children; or

(ii) for follow-on formula—infant formula, a special medical purpose product for infants,a formulated supplementary food or a formulated supplementary food for young children.

(d) the word 'humanised' or 'maternalised' or any word or words having the same or similar effect; or

(e) the words ‘human milk oligosaccharide’, ‘human identical milk oligosaccharide’ or any word or words having the same or similar effect; or

(f) the abbreviations ‘HMO’ or HiMO’ or any abbreviation having the same or similar effect; or

(g) words claiming that the formula is suitable for all infants; or

(h) information relating to the nutritional content of human milk; or

(i) information relating to the presence of a substance listed in subsection (2), except for a reference in:

(i) a statement of ingredients; or

(ii) a declaration or statement expressly permitted or required by this Code; or

(j) information relating to ingredients, except for:

(i) use of the word ‘milk’; or

(ii) a reference in a statement of ingredients; or

(iii) a reference in a declaration or statement expressly permitted or required by this Code; or

(k) information relating to the animal or plant source or sources of protein except:

(i) in a statement of ingredients; or

(ii) where required by subsection 2.9.1—20(1); or

(l) the words ‘partially hydrolysed’ or any word or words having the same or similar effect, except:

(i) in a statement of ingredients; or

(ii) where required by subsection 2.9.1—20(2).

(2) For the purposes of paragraph (1)(i), the following substances are listed:

(a) an *inulin-type fructan; and

(b) a *galacto-oligosaccharide; and

(c) a nutrient; and

(d) a substance *used as a nutritive substance.

Note 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 Special medical purpose product for infants

2.9.1—30 Application of other Standards

Unless the contrary intention appears, the following provisions do not apply to a special medical purpose product for infants:

(a) Part 1.2 of Chapter 1 (labelling and other information requirements); and

(b) Division 3 of this Standard.

2.9.1—31 Restriction on the sale of special medical purpose products for infants

(1) A special medical purpose product for infants must not be sold to a consumer, other than from or by:

(a) a medical practitioner or dietitian; or

(b) a medical practice, pharmacy or *responsible institution; or

(c) a majority seller of that special medical purpose product for infants.

(2) In this section:

majority seller means, in relation to a special medical purpose product for infants, a person who:

(a) during any 24 month period, sold that special medical purpose product for infants to any of the following:

(i) a medical practitioner;

(ii) a dietitian;

(iii) a medical practice;

(iv) a pharmacy;

(v) a *responsible institution; and

(b) the sales mentioned in paragraph (a) represent more than one half of the total amount of that special medical purpose product for infants sold by the person during that 24 month period.

medical practitioner means 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.

2.9.1—32 General compositional requirements

(1) 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.

(2) Subject to subsections (3) and (4), a special medical purpose product for infants must not contain added fructose and/or added sucrose.

(3) A special medical purpose product for infants manufactured from partially hydrolysed protein may contain added fructose and/or added sucrose, provided that:

(a) the fructose and/or sucrose is added to the product to provide a source of carbohydrate; and

(b) the sum of the fructose and/or sucrose in the product does not exceed 20% of available carbohydrates in the product.

(4) Subsection (2) 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:

(a) the addition of *inulin-type fructans to the product in accordance with this Standard; and/or

(b) the use of a substance as a processing aid in accordance with this Code in the manufacture of the product.

(5) The fluoride content of a special medical purpose product for infants must not exceed:

(a) if in a powdered or concentrated form—17 µg/100 kJ; and

(b) if in a 'ready-to-drink' form—24 µg/100 kJ.

(6) The amounts in subsection (5) apply to the special medical purpose product for infants as sold.

2.9.1—33 Protein requirements

(1) A special medical purpose product for infants must be only derived from one or more of the following proteins:

(a) cow milk;

(b) goat milk;

(c) sheep milk;

(d) soy protein isolate;

(e) a partially hydrolysed protein of one or more of the above.

(2) A special medical purpose product for infants must have a protein content of:

(a) for a milk-based product—no less than 0.43 g/100 kJ and no more than 0.72 g/100 kJ; and

(b) for a product that is not milk-based product—no less than 0.54 g/100 kJ and no more than 0.72 g/100 kJ.

(3) For the purposes of subsection (2), ***milk-based product*** means 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.

(4) The L-amino acids listed in the table to section S29—3 must be present in a special medical purpose product for infants at a level not less than the corresponding minimum level specified in the table.

(5) The minimum levels specified in the table to section S29—3 for cysteine and for methionine do not apply if:

(a) 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

(b) the ratio of methionine to cysteine in the special medical purpose product for infants is less than 2 to 1.

(6) The minimum levels specified in the table to section S29—3 for phenylalanine and for tyrosine do not apply if:

(a) 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

(b) the ratio of tyrosine to phenylalanine in the special medical purpose product for infants is less than 2 to 1.

(7) Despite subsections (4), (5) and (6), L-amino acids listed in the table to section S29—3 must only be added to a special medical purpose product for infants in an amount necessary to improve protein quality.

2.9.1—34 Fat requirements

(1) A special medical purpose product for infants must:

(a) have a fat content of no less than 1.1 g/100 kJ and no more than 1.4 g/100 kJ; and

(b) have a ratio of linoleic acid to α-linolenic acid of no less than 5 to 1 and no more than 15 to 1; and

(c) contain no less than:

(i) 90 mg/100 kJ of linoleic acid; and

(ii) 12 mg/100 kJ of α-linolenic acid; and

Note. It is recommended that a special medical purpose product for infants contain not more than 335 mg/100 kJ of linoleic acid. This amount is a Guidance Upper Level and a recommended upper level for this nutrient which poses 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. This Guidance Upper Level should not be exceeded unless a higher nutrient level cannot be avoided due to high or variable contents in constituents of a special medical purpose product for infants or due to technological reasons.

(d) have an arachidonic acid (20 to 4 n-6) content of equal to or more than docosahexaenoic acid (22 to 6 n-3) content; and

(e) contain no less than 0.5 mg of vitamin E per gram of polyunsaturated fatty acids; and

(f) for any long chain *polyunsaturated fatty acids that are present in the product—have an eicosapentaenoic acid (20 to 5 n-3) content of no more than the docosahexaenoic acid (22 to 6 n-3) content; and

(g) for a fatty acid listed in Column 1 of the table to section S29—4 and present in the product—contain not more than the maximum amount (if any) specified in Column 2 of the table for that fatty acid.

(2) A special medical purpose product for infants may only contain medium chain triglycerides that are:

(a) a natural constituent of a milk-based ingredient of that product; or

(b) 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 product.

(3) A special medical purpose product for infants must not have a phospholipid content of more than 72 mg/100 kJ.

2.9.1—35 Permitted novel foods

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, provided that the presence of that novel food in the product is necessary to achieve that product's intended medical purpose.

2.9.1—36 Required nutritive substances

(1) A special medical purpose product for infants must contain each substance listed in Column 1 of the table to section S29—5 in an amount (including any naturally-occurring amount) that is:

(a) no less than the minimum amount specified in Column 2 of the table; and

(b) no more than the maximum amount (if any) specified in Column 3 of the table.

Note 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 of that table. The amounts specified in Column 4 are Guidance Upper Levels 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. These Guidance Upper Levels should 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.

(2) 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.

2.9.1—37 Optional nutritive substances

A substance listed in Column 1 of the table to section 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:

(a) no less than the minimum amount (if any) specified in Column 2 of the table; and

(b) no more than the maximum amount specified in Column 3 of the table.

2.9.1—38 Required forms for nutritive substances

A 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 a permitted form listed in:

(a) if a vitamin, mineral or electrolyte—the table to section S29—23; and

(b) in any other case— the table to section S29—9.

2.9.1—39 Addition of lactic acid producing microorganisms

L(+) lactic acid producing microorganisms may be added to a special medical purpose product for infants.

2.9.1—40 Restriction on addition of inulin-type fructans and galacto-oligosaccharides

If an *inulin-type fructan or a *galacto-oligosaccharide is added to a special medical purpose product for infants, 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 galacto-oligosaccharides.

2.9.1—41 Restriction on levels of other substances

A special medical purpose product for infants must not contain any of the following:

(a) detectable gluten; or

(b) more than 3.8 mg/100 kJ of free nucleotide-5′-monophosphates.

Note 1 Section S19—4 contains the maximum levels (ML) of contaminants in infant formula products.

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

2.9.1—42 Permitted variation from compositional requirements

(1) A special medical purpose product for infants need not comply with a compositional requirement to the extent that a variation from that requirement:

(a) is necessary to achieve the product's intended medical purpose; or

(b) would otherwise prevent the sale of the product.

(2) For the purposes of subsection (1), ***a compositional requirement*** means a requirement imposed in relation to a special medical purpose product for infants by any of the following:

(a) any of sections 2.9.1—32 to 2.9.1—41, but not section 2.9.1—35;

(b) paragraph 1.1.1—10(6)(a);

(c) paragraph 1.1.1—10(6)(b);

(d) paragraph 1.1.1—10(6)(c).

2.9.1—43 Representations about food as a special medical purpose product for infants

A food may only be represented as a special medical purpose product for infants if it complies with this Division.

2.9.1—44 Product differentiation

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 colour.

Example The text, pictures and/or colours used on a label 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.

2.9.1—45 Prohibited representations

The label on a package of a special medical purpose product for infants must not contain:

(a) a picture of an infant; or

(b) a picture or text that idealises the use of special medical purpose product for infants; or

(c) the words ‘human milk oligosaccharide’, ‘human identical milk oligosaccharide’ or any word or words having the same or similar effect; or

(d) the abbreviations ‘HMO’ or HiMO’ or any abbreviation having the same or similar effect.

2.9.1—46 Prohibited claims

(1) A claim in relation to a special medical purpose product for infants must not:

(a) refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition; or

(b) compare the product with a good that is:

(i) represented in any way to be for therapeutic use; or

(ii) 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.

(2) A nutrition content claim or *health claim must not be made about a special medical purpose product for infants.

(3) This section does not apply to:

(a) a claim that is expressly permitted by this Code; or

(b) a declaration that is required by an application Act.

2.9.1—47 Permitted lactose free claim

A claim that a special medical purpose product for infants is lactose free may be made if that special medical purpose product for infants contains no detectable lactose.

2.9.1—48 Labelling and related requirements

(1) This section applies to a food for sale that is a special medical purpose product for infants.

(2) If the food for sale is in a package, it is required to *bear a label that complies with section 2.9.1—49.

(3) If the food for sale is in an *inner package:

(a) the inner package is required to *bear a label that complies with section 2.9.1—54; and

(b) there is no labelling requirement under this Code for any other packaging associated with the food for sale.

(4) If the food for sale is in a *transportation outer:

(a) the transportation outer or package containing the food for sale is required to *bear a label that complies with section 2.9.1—55; and

(b) there is no labelling requirement under this Code for any other packaging associated with the food for sale.

2.9.1—49 Mandatory labelling information

(1) The label that is required for a special medical purpose product for infants must state the following information in accordance with the provision indicated:

(a) a name or description sufficient to indicate the true nature of the food (see section 1.2.2—2);

(b) lot identification (see section 1.2.2—3);

(c) if the sale of the product for sale is one to which Division 2 or Division 3 of Standard 1.2.1 applies:

(i) information relating to *foods produced using gene technology (see section 1.5.2—4); and

(ii) information relating to irradiated food (see section 1.5.3—9);

(d) any mandatory statements and declarations (see section 2.9.1—50);

(e) information relating to ingredients (see section 2.9.1—51);

(f) date marking information (see section 2.9.1—52);

(g) directions for the preparation, use or storage of the product, if the product is of such a nature to require such directions for health or safety reasons;

(h) nutrition information (see section 2.9.1—53).

(2) The label that is required for a special medical purpose product for infants must comply with section 1.2.1—24 of Standard 1.2.1.

2.9.1—50 Mandatory statements and declarations— special medical purpose product for infants

For paragraph 2.9.1—49(1)(d), the following statements are required:

(a) a statement to the effect that the product must be used under medical supervision;

(b) a statement indicating, if applicable, any precautions and contraindications associated with consumption of the product;

(c) 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;

(d) a statement describing the properties or characteristics which make the product appropriate for the medical purpose indicated in paragraph (c);

(e) 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;

(f) a statement indicating whether or not the product is suitable for use as a sole source of nutrition;

(g) if the product is represented as being suitable for use as a sole source of nutrition:

(i) a statement to the effect that the product is not for parenteral use; and

(ii) if the product has been modified to vary from the compositional requirement of this Division such that the content of one or more nutrients falls short of the prescribed minimum, or exceeds the prescribed maximum (if applicable):

(A) unless provided in other documentation about the product—a statement indicating the nutrient or nutrients which have been modified; and

(B) unless provided in other documentation about the product—a statement indicating whether each modified nutrient has been increased, decreased, or eliminated from the product, as appropriate; and

(h) the declarations required by section 1.2.3—4.

2.9.1—51 Information relating to ingredients—special medical purpose product for infants

For paragraph 2.9.1—49(1)(e), the information relating to ingredients is:

(a) a statement of ingredients; or

(b) 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

(c) information that complies with 21 CFR § 101.4.

2.9.1—52 Date marking information—special medical purpose product for infants

(1) For paragraph 2.9.1—49(1)(f), the required date marking information is date marking information in accordance with Standard 1.2.5.

(2) Despite subsection (1), for subparagraph 1.2.5—5(2)(a)(ii), the words 'Expiry Date', or similar words, may be used on the label.

2.9.1—53 Nutrition information—special medical purpose product for infants

(1) For paragraph 2.9.1—49(1)(h), the nutrition information required for a special medical purpose product for infants is the following, expressed per given amount of the product:

(a) the minimum or *average energy content; and

(b) the minimum amount or *average quantity of:

(i) protein, fat and carbohydrate; and

(ii) any vitamin, mineral or electrolyte that has been *used as a nutritive substance in the product; and

(c) any other substance:

(i) *used as a nutritive substance in that product; and

(ii) added to that product to achieve that product's intended medical purpose; and

(d) any of the following information if declaration of that information is necessary for use of the special medical purpose product for infants for its intended medical purpose:

(i) information on sub-group nutrients of protein, fat and/or carbohydrate;

(ii) osmolality and osmolarity;

(iii) acid-base balance.

(2) A reference in subsection (1) to the intended medical purpose is to the intended medical purpose as described in the statement required by paragraph 2.9.1—50(c).

(3) 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.

2.9.1—54 Labelling requirements—special medical purpose product for infants in inner package

(1) The label on an *inner package that contains a special medical purpose product for infants must state the following information in accordance with the provision indicated:

(a) a name or description sufficient to indicate the true nature of the food (see section 1.2.2—2);

(b) lot identification (see section 1.2.2—3);

(c) any declaration that is required by section 1.2.3—4;

(d) date marking information (see section 2.9.1—52).

(2) The label must comply with section 1.2.1—24 of Standard 1.2.1.

(3) To avoid doubt, this section 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.

2.9.1—55 Labelling requirements—special medical purpose product for infants in transportation outer

(1) If packages of a special medical purpose product for infants are contained in a transportation outer, the information specified in subsection (2) must, in accordance with the provisions indicated, be:

(a) contained in a label on the transportation outer; or

(b) contained in a label on a package of the food for sale, and clearly discernible through the transportation outer.

(2) For subsection (1), the information is:

(a) a name or description sufficient to indicate the true nature of the food (see section 1.2.2—2); and

(b) lot identification (see section 1.2.2—3); and

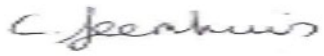
(c) unless it is provided in accompanying documentation—the name and address of the *supplier (see section 1.2.2—4).

Food Standards (Proposal P1028 – Infant Formula Products – Consequential Amendments) Variation

---

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated 12 September 2024



Christel Leemhuis, General Manager Risk Assessment and Science Branch
Delegate of the Board of Food Standards Australia New Zealand

Note:
This variation will be published in the Commonwealth of Australia Gazette No. FSC 171 on 13 September 2024. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Proposal P1028 – Infant Formula – Consequential Amendments) Variation*.

2 Variation to standards in the *Australia New Zealand Food Standards Code*

(1) The Schedules to this instrument vary Standards in the *Australia New Zealand Food Standards Code*.

(2) Each Standard that is specified in a Schedule to this instrument is amended as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

3 Commencement

This instrument commences immediately after the commencement of the *Food Standards (Proposal P1028 – Infant Formula) Variation.*

4 Effect of the variations made by this instrument

(1) Section 1.1.1—9 of Standard 1.1.1 does not apply to the variations made by this instrument.

(2) During the transition period, a food product may be sold if the product complies with one of the following:

(a) the Code as in force without the variations made by the instruments; or

(b) the Code as amended by the variations made by the instruments.

(3) For the purposes of this clause:

(a) the **instruments** means:

(i) this instrument; and

(ii) the *Food Standards (Proposal P1028 – Infant Formula) Variation*;

(b) the **transition period** means the period commencing on the date of commencement of the *Food Standards (Proposal P1028 – Infant Formula) Variation* and ending 60 months after that date of commencement.

Schedule 1

Schedule 29—Special purpose foods

[1] Sections S29—2 to S29—10

Repeal the sections, substitute:

S29—2 Infant formula products—calculation of energy content

(1) For paragraph 2.9.1—4(2)(a), the energy content of infant formula product must be calculated using:

(a) the energy contributions of the following *components only:

(i) fat; and

(ii) protein; and

(iii) carbohydrate; and

(b) the relevant energy factors set out in section S11—2.

(2) The energy content of an infant formula product must be expressed in kilojoules.

S29—2A Infant formula products—calculation of protein content

For paragraph 2.9.1—4(2)(b), the protein content of infant formula product must be calculated by multiplying the nitrogen content of the product by a nitrogen-to-protein conversion factor of 6.25.

S29—2B Infant formula products—calculation of vitamin A content

For paragraph 2.9.1—4(2)(c), the vitamin A content of infant formula products must be calculated using only the retinol forms of vitamin A prescribed in Column 1 of Table S29—23.

S29—3 Infant formula products—L-amino acids that must be present

For subsection 2.9.1—6(5) and section 2.9.1—33, the table is:

L-amino acids that must be present in infant formula products

L-amino acid	*Minimum amount per 100 kJ*
Cysteine	9 mg
Histidine	10 mg
Isoleucine	22 mg
Leucine	40 mg
Lysine	27 mg
Methionine	6 mg
Phenylalanine	19 mg
Threonine	18 mg
Tryptophan	8 mg
Tyrosine	18 mg
Valine	22 mg

S29—4 Infant formula products—limits on fatty acids

For paragraphs 2.9.1—7(1)(g) and 2.9.1—34(1)(g), the table is:

Limits on fatty acids that may be present in infant formula products

Column 1	*Column 2*
Substance	*Maximum amount per 100 kJ*
Docosahexaenoic acid	12 mg
Total *trans* fatty acids	Not more than 4% of the total fatty acids
Erucic acid (22:1)	Not more than 1% of the total fatty acids

S29—5 Vitamins, minerals, electrolytes and other substances required in infant formula and special medical purpose product for infants

For sections 2.9.1—7(2)(b)(i), 2.9.1—8(1), 2.9.1—34(2)(b) and 2.9.1—36(1), the table is:

Vitamins, minerals, electrolytes and other nutritive substances required in infant formula and special medical purpose product for infants

Column 1	*Column 2*	*Column 3*	*Column 4*
Substance	*Minimum amount per 100 kJ*	*Maximum amount per 100 kJ*	*Guidance upper level per 100 kJ (see Note)*
Vitamins			

Vitamin A	14 µg RE	43 µg RE	
Vitamin D	0.24 µg	0.63 µg	
Vitamin C	1.7 mg		17 mg
Thiamin	10 µg		72 µg
Riboflavin	14.3 µg		120 µg
Niacin	72 µg		359 µg
Vitamin B_6	8 µg		42 µg
Folic acid	2.4 µg		12 µg
Pantothenic acid	96 µg		478 µg
Vitamin B_{12}	0.02 µg		0.36 µg
Biotin	0.24 µg		2.4 µg
Vitamin E	0.14 mg α-TE		1.2 mg α-TE
Vitamin K	0.24 µg		6 µg
Minerals			
Calcium	12 mg		35 mg
Phosphorus	6 mg		24 mg
Magnesium	1.2 mg		3.6 mg
Iron	0.14 mg	0.48 mg	
Iodine	2.4 µg		14 µg
Copper	8 µg		29 µg
Zinc	0.12 mg		0.36 mg
Manganese	0.24 µg		24 µg
Selenium	0.48 µg		2.2 µg
Electrolytes			
Chloride	12 mg	38 mg	
Sodium	4.8 mg	14 mg	
Potassium	14 mg	43 mg	
Other essential substances			
Choline	1.7 mg		12 mg
L-carnitine	0.3 mg		0.8 mg
Inositol	1 mg		10 mg

Note It is recommended that infant formula and a special medical purpose product for infants contain a substance listed in Column 1 of the table in an amount that is not more than the amount (if any) specified for that substance in Column 4 of the table. The amounts specified in Column 4 are Guidance Upper Levels 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. These Guidance Upper Levels should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formulas or special medical purpose product for infants; or due to technological reasons.

S29—6 Vitamins, minerals and electrolytes required in follow-on formula

For subparagraph 2.9.1—7(2)(b)(ii) and subsection 2.9.1—8(2), the table is:

Vitamins, minerals and electrolytes required in follow-on formula

Column 1	***Column 2***	***Column 3***	***Column 4***

Vitamin, mineral or electrolyte	*Minimum amount per 100 kJ*	*Maximum amount per 100 kJ*	*Guidance upper level per 100 kJ (see Note)*
Vitamins			
Vitamin A	14 µg RE	43 µg RE	
Vitamin D	0.24 µg	0.72 µg	
Vitamin C	1.7 mg		17 mg
Thiamin	10 µg		72 µg
Riboflavin	14.3 µg		120 µg
Niacin	72 µg		359 µg
Vitamin B_6	8 µg		42 µg
Folic acid	2.4 µg		12 µg
Pantothenic acid	96 µg		478 µg
Vitamin B_{12}	0.02 µg		0.36 µg
Biotin	0.24 µg		2.4 µg
Vitamin E	0.14 mg α-TE		1.2 mg α-TE
Vitamin K	0.24 µg		6 µg
Minerals			
Calcium	12 mg		43 mg
Phosphorus	6 mg		24 mg
Magnesium	1.2 mg		3.6 mg
Iron	0.24 mg	0.48 mg	
Iodine	2.4 µg		14 µg
Copper	8 µg		29 µg
Zinc	0.12 mg		0.36 mg
Manganese	0.24 µg		24 µg
Selenium	0.48 µg		2.2 µg
Electrolytes			
Chloride	12 mg	38 mg	
Sodium	4.8 mg	14 mg	
Potassium	14 mg	43 mg	

Note It is recommended that follow-on formula contain a substance listed in Column 1 of the table in an amount that is not more than the amount (if any) specified for that substance in column 4 of the table. The amounts specified are Guidance Upper Levels 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. The Guidance Upper Levels should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of follow-on formula or due to technological reasons.

S29—7 Optional nutritive substances in infant formula and special medical purpose product for infants

For subsection 2.9.1—9(1) and section 2.9.1—37, the table is set out below.

Optional nutritive substances in infant formula and special medical purpose product for infants

Column 1	***Column 2***	***Column 3***

Substance	*Minimum amount per 100 kJ*	*Maximum amount per 100 kJ*
2′-fucosyllactose permitted for use by Standard 1.5.2		96 mg
3′-sialyllactose sodium salt permitted for use by Standard 1.5.2		8 mg
6′-sialyllactose sodium salt permitted for use by Standard 1.5.2		16 mg
A combination of 2′-fucosyllactose and difucosyllactose, permitted for use by Standard 1.5.2		96 mg
A combination of: 2′-fucosyllactose permitted for use by Standard 1.5.2; and lacto-N-neotetraose permitted for use by Standard 1.5.2		96 mg which contains not more than 24 mg of lacto-N-neotetraose
Adenosine-5′-monophosphate		0.36 mg
Cytidine-5′-monophosphate		0.6 mg
Guanosine-5′monophosphate		0.4 mg
Inosine-5′-monophosphate		0.24 mg
Lactoferrin		40 mg
lacto-N-tetraose permitted for use by Standard 1.5.2		32 mg
Lutein	1.5 µg	5 µg
Taurine		2.9 mg
Uridine-5′-monophosphate		0.42 mg

S29—8 Optional nutritive substances in follow-on formula

For subsection 2.9.1—9(2), the table is set out below.

Optional nutritive substances in follow-on formula

Column 1	***Column 2***	***Column 3***	***Column 4***
Substance	*Minimum amount per 100 kJ*	*Maximum amount per 100 kJ*	*Guidance upper level per 100 kJ (see Note)*
2′-fucosyllactose permitted for use by Standard 1.5.2		96 mg	
3′-sialyllactose sodium salt permitted for use by Standard 1.5.2		8 mg	
6′-sialyllactose sodium salt permitted for use by Standard 1.5.2		16 mg	
A combination of 2′-fucosyllactose and difucosyllactose, permitted for use by Standard 1.5.2		96 mg	
A combination of: 2′-fucosyllactose permitted for use by Standard 1.5.2; and		96 mg which contains not more than 24 mg of lacto-N-neotetraose	

lacto-N-neotetraose permitted for use by Standard 1.5.2			
Adenosine-5′-monophosphate		0.36 mg	
L-carnitine	0.3 mg		
Choline			12 mg
Cytidine-5′-monophosphate		0.6 mg	
Guanosine-5′-monophosphate		0.4 mg	
Inosine-5′-monophosphate		0.24 mg	
Lactoferrin		40 mg	
lacto-N-tetraose permitted for use by Standard 1.5.2		32 mg	
Lutein	1.5 µg	5 µg	
Inositol			10 mg
Taurine		2.9 mg	
Uridine-5′-monophosphate		0.42 mg	

Note It is recommended that follow-on formula contain a substance listed in Column 1 of the table in an amount that is not more than the amount (if any) specified for that substance in Column 4 of the table. The amounts specified in Column 4 are Guidance Upper Levels 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. The Guidance Upper Levels should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of follow-on formula or due to technological reasons.

S29—9 Permitted forms of nutritive substances in infant formula products

For paragraphs 2.9.1—10(b) and 2.9.1—38(b), the table is set out below.

Permitted forms for nutritive substances used in infant formula products

Substance	***Permitted forms***
2′-fucosyllactose permitted for use by Standard 1.5.2	2′-fucosyllactose
3′-sialyllactose sodium salt permitted for use by Standard 1.5.2	3′-sialyllactose sodium salt
6'-sialyllactose sodium salt permitted for use by Standard 1.5.2	6'-sialyllactose sodium salt
A combination of 2′-fucosyllactose and difucosyllactose, permitted for use by Standard 1.5.2	2'-fucosyllactose and difucosyllactose
A combination of: 2′-fucosyllactose permitted for use by Standard 1.5.2; and lacto-N-neotetraose permitted for use by Standard 1.5.2	2′-fucosyllactose and lacto-N-neotetraose
Adenosine-5′-monophosphate	Adenosine-5′- monophosphate
L-carnitine	L-carnitine L-carnitine hydrochloride L-carnitine tartrate
Choline	Choline chloride Choline bitartrate

	Choline
	Choline citrate
	Choline hydrogen tartrate
Cytidine-5′-monophosphate	Cytidine-5′-monophosphate
Guanosine-5′-monophosphate	Guanosine-5′-monophosphate
	Guanosine-5′-monophosphate sodium salt
Inosine-5′-monophosphate	Inosine-5′-monophosphate
	Inosine-5′-monophosphate sodium salt
Lactoferrin	Bovine lactoferrin
lacto-N-tetraose permitted for use by Standard 1.5.2	lacto-N-tetraose
Lutein	Lutein from *Tagetes erecta L.*
Inositol	Myo-inositol
Taurine	Taurine
Uridine-5′-monophosphate	Uridine-5′-monophosphate sodium salt

Note Section S29—23 lists the permitted forms of vitamins, minerals and electrolytes in infant formula products.

S29—9A Infant formula products—conditions on use of permitted nutritive substances

The table for this section is as follows:

Conditions of use for permitted nutritive substances

Column 1	***Column 2***	***Column 3***
Substance	***Permitted Form***	***Conditions of use***
Lactoferrin	Bovine lactoferrin	1. During the exclusive use period, may only be sold under the brand Synlait for *use as a nutritive substance in an infant formula product. 2. For the purposes of condition 1 above, **exclusive use period** means the period commencing on the date of gazettal of the *Food Standards (Application A1253 – Bovine Lactoferrin in Infant Formula Products) Variation* and ending 15 months after that date.

S29—10 Required format for a nutrition information statement

The table to this section is:

NUTRITION INFORMATION	
	Average quantity per 100 mL prepared formula

Energy	kJ
Protein	g
— Whey*	g
— Casein*	g
Fat	g
— Long chain polyunsaturated fatty acids*	
— Docosahexaenoic acid (DHA)*	mg
— Eicosapentaenoic acid (EPA)*	mg
— Arachidonic acid (ARA)*	mg
Carbohydrate	g
Vitamins	
Vitamin A	µg
Vitamin B_6	µg
Vitamin B_{12}	µg
Vitamin C	mg
Vitamin D	µg
Vitamin E	mg
Vitamin K	µg
Biotin	µg
Niacin (B_3)	µg
Folate	µg
Pantothenic acid (B_5)	µg
Riboflavin (B_2)	µg
Thiamin (B_1)	µg
Minerals	
Calcium	mg
Copper	µg
Iodine	µg
Iron	mg
Magnesium	mg
Manganese	µg
Phosphorus	mg
Selenium	µg
Zinc	mg
Chloride	mg
Potassium	mg
Sodium	mg
Other nutrients*	
Choline*	mg
Inositol*	mg
L-carnitine*	mg
Additional	

(insert any other substance used as a nutritive substance; or inulin-type fructans and / or galacto-oligosaccharides, to be declared)	g, mg, µg

Note: *See the following.

Entries and amounts for the following need only be included when stated in accordance with subsection 2.9.1—24(4), 2.9.1—24(5) and paragraph 2.9.1—25(6)(d): whey; casein; docosahexaenoic acid; eicosapentaenoic acid; arachidonic acid.

The heading 'Other nutrients' need only be included when required by subparagraph 2.9.1—25(2)(d)(ii) and paragraph 2.9.1—25(4)(a).

The heading 'Long chain polyunsaturated fatty acids' need only be included when required by paragraph 2.9.1—25(6)(a).

Entries and amounts for choline, inositol, L-carnitine are included under the heading 'Other nutrients' when required by paragraph 2.9.1—25(4)(a) and under the heading 'Additional' when required by paragraph 2.9.1—25(4)(b).

S29—10A Example of a nutrition information statement including quantities expressed as sold

For subsection 2.9.1—25(7), an example nutrition information statement including information expressed in accordance with subsection 2.9.1—24(7) is:

NUTRITION INFORMATION		
	Average quantity per 100 mL prepared formula	Quantity per 100 g powder (or 100 mL liquid concentrate)
Energy	kJ	kJ
Protein	g	g
— Whey	g	g
— Casein	g	g
Fat	g	g
— Long chain polyunsaturated fatty acids		
— Docosahexaenoic acid (DHA)	mg	mg
— Eicosapentaenoic acid (EPA)	mg	mg
— Arachidonic acid (ARA)	mg	mg
Carbohydrate	g	g
Vitamins		
Vitamin A	µg	µg
Vitamin B_6	µg	µg
Vitamin B_{12}	µg	µg
Vitamin C	mg	mg
Vitamin D	µg	µg
Vitamin E	mg	mg

Vitamin K	µg	µg
Biotin	µg	µg
Niacin (B_3)	µg	µg
Folate	µg	µg
Pantothenic acid (B_5)	µg	µg
Riboflavin (B_2)	µg	µg
Thiamin (B_1)	µg	µg
Minerals		
Calcium	mg	mg
Copper	µg	µg
Iodine	µg	µg
Iron	mg	mg
Magnesium	mg	mg
Manganese	µg	µg
Phosphorus	mg	mg
Selenium	µg	µg
Zinc	mg	mg
Chloride	mg	mg
Potassium	mg	mg
Sodium	mg	mg
Other nutrients		
Choline	mg	mg
Inositol	mg	mg
L-carnitine	mg	mg
Additional		
(insert any other substance used as a nutritive substance; or inulin-type fructans and / or galacto-oligosaccharides, to be declared)	g, mg, µg	g, mg, µg

[2] After section S29—22

Insert:

S29—23 Permitted forms of vitamins, minerals and electrolytes in infant formula products, food for infants, formulated meal replacements (vitamin K) and food for special medical purposes

For sections 2.9.1—10(a), 2.9.1—38(a), 2.9.2—4, 2.9.2—5, 2.9.2—6, 2.9.3—3(2)(c)(iii) and 2.9.5—6, the table is:

Permitted forms of vitamins, minerals and electrolytes in infant formula products, food for infants, formulated meal replacements (vitamin K) and food for special medical purposes

Vitamin, mineral or electrolyte	***Permitted forms***
Vitamin A	
Retinol forms	vitamin A (retinol)
	vitamin A acetate (retinyl acetate)

	vitamin A palmitate (retinyl palmitate)
	retinyl propionate
Provitamin A forms	beta-carotene
Vitamin C	L-ascorbic acid
	L-ascorbyl palmitate
	calcium ascorbate
	potassium ascorbate
	sodium ascorbate
Vitamin D	vitamin D_2 (ergocalciferol)
	vitamin D_3 (cholecalciferol)
	vitamin D (cholecalciferol-cholesterol)
Thiamin	thiamin hydrochloride
	thiamin mononitrate
Riboflavin	riboflavin
	riboflavin-5′-phosphate, sodium
Niacin	niacinamide (nicotinamide)
Vitamin B_6	pyridoxine hydrochloride
	pyridoxine-5′-phosphate
Folate	Folic acid
Pantothenic acid	calcium pantothenate
	dexpanthenol
	D-panthenol
	calcium D-pantothenate
	sodium D-pantothenate
Vitamin B_{12}	cyanocobalamin
	hydroxocobalamin
Biotin	d-biotin
Vitamin E	dl-α-tocopherol
	d-α-tocopherol concentrate
	tocopherols concentrate, mixed
	d-α-tocopheryl acetate
	dl-α-tocopheryl acetate
	d-α-tocopheryl acid succinate
	dl-α-tocopheryl succinate
Vitamin K	Vitamin K_1 as phylloquinone (phytonadione)
Calcium	calcium carbonate
	calcium chloride
	calcium citrate
	calcium gluconate
	calcium glycerophosphate
	calcium hydroxide
	calcium lactate

	calcium oxide
	calcium phosphate, dibasic
	calcium phosphate, monobasic
	calcium phosphate, tribasic
	calcium sulphate
Chloride	calcium chloride
	magnesium chloride
	potassium chloride
	sodium chloride
Chromium	chromium sulphate
Copper	copper gluconate
	cupric sulphate
	cupric citrate
	cupric carbonate
Iodine	potassium iodate
	potassium iodide
	sodium iodide
Iron	ferric ammonium citrate
	ferric citrate
	ferric pyrophosphate
	ferrous bisglycinate
	ferrous citrate
	ferrous fumarate
	ferrous gluconate
	ferrous lactate
	ferrous succinate
	ferrous sulphate
Magnesium	magnesium carbonate
	magnesium chloride
	magnesium gluconate
	magnesium oxide
	magnesium phosphate, dibasic
	magnesium phosphate, tribasic
	magnesium sulphate
	magnesium hydroxide carbonate
	magnesium hydroxide
	magnesium salts of citric acid
Manganese	manganese carbonate
	manganese chloride
	manganese citrate
	manganese gluconate
	manganese sulphate
Molybdenum	sodium molybdate VI

Phosphorus	calcium glycerophosphate
	calcium phosphate, dibasic
	calcium phosphate, monobasic
	calcium phosphate, tribasic
	magnesium phosphate, dibasic
	potassium phosphate, dibasic
	potassium phosphate, monobasic
	potassium phosphate, tribasic
	sodium phosphate, dibasic
	sodium phosphate, monobasic
	sodium phosphate, tribasic
Potassium	potassium bicarbonate
	potassium carbonate
	potassium chloride
	potassium citrate
	potassium glycerophosphate
	potassium gluconate
	potassium hydroxide
	potassium phosphate, dibasic
	potassium phosphate, monobasic
	potassium phosphate, tribasic
	potassium L-lactate
Selenium	seleno methionine
	sodium selenate
	sodium selenite
Sodium	sodium bicarbonate
	sodium carbonate
	sodium chloride
	sodium chloride iodised
	sodium citrate
	sodium gluconate
	sodium hydroxide
	sodium iodide
	sodium lactate
	sodium phosphate, dibasic
	sodium phosphate, monobasic
	sodium phosphate, tribasic
	sodium sulphate
	sodium tartrate
Zinc	zinc acetate
	zinc chloride
	zinc citrate (zinc citrate dihydrate or zinc citrate trihydrate)

zinc gluconate
zinc lactate
zinc oxide
zinc sulphate

Schedule 2

Standard 1.1.2—Definitions used throughout the Code

[1] Subsection 1.1.2—2(3)

Insert:

inner package, in relation to a special medical purpose product for infants, means an individual package of the food that is:

(a) contained and sold within another package that is labelled in accordance with Division 4 of Standard 2.9.1; and

(b) not designed for individual sale, other than a sale by a *responsible institution to a patient or resident of the responsible institution.

Example An example of an inner package is an individual sachet (or sachets) of a powdered food contained within a box that is fully labelled, being a box available for retail sale.

[2] Subsection 1.1.2—2(3) (definition of *medium chain triglycerides*)

Repeal the definition.

[2A] Subsection 1.1.2—2(3) (definition of *protein substitute*)

Repeal the definition.

[3] Subsection 1.1.2—2(3) (paragraph (c) of the definition of *warning statement*)

Repeal the paragraph, substitute:

(c) subsection 2.9.1—21(1) (warning statements for infant formula product);

[4] Subsection 1.1.2—3(2) (definitions—particular foods)

Insert:

special medical purpose product for infants means an infant formula product that is:

(a) represented as being:

(j) specially formulated for the dietary management of infants who have medically determined nutrient requirements (such as limited or impaired capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food); and

(iii) suitable to constitute either the sole or principal liquid source of nourishment where dietary management cannot medically be achieved without use of the product; and

(iii) for the dietary management of a medically diagnosed disease, disorder or condition of an infant; and

(b) intended to be used under medical supervision; and

(c) not suitable for general use.

[5] Subsection 1.1.2—3(2) (definition of *follow-on formula*)

Repeal the definition, substitute:

follow-on formula means an infant formula product that is represented as:

(a) either a breast milk substitute or replacement for infant formula; and

(b) being suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of 6 months.

[6] Subsection 1.1.2—3(2) (definition of *infant formula*)

Repeal the definition, substitute:

infant formula means an infant formula product that is represented as:

(a) a breast milk substitute for infants; and

(b) satisfying by itself the nutritional requirements of infants under the age of 6 months.

[7] Subsection 1.1.2—3(2) (definition of *infant formula product*)

Repeal the definition, substitute:

infant formula product means a product based on milk or other edible food constituents of animal or plant origin which is represented as nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants, depending on the age of the infant.

[8] Subsection 1.1.2—3(2) (definition of *pre-term formula*)

Repeal the definition.

[8A] Subsection 1.1.2—8(2) (definition of *novel food*)

Repeal the subsection, substitute:

(2) Any of the following:

(a) the presence of a food in a food for special medical purposes;

(b) the presence of a food in a special medical purpose product for infants;

(c) the use of a food as a food for special medical purpose;

(d) the use of a food as a special medical purpose product for infants;

does not constitute a history of human consumption in Australia or New Zealand in relation to that food for the purposes of this section

Standard 1.2.3—Information requirements – warning statements, advisory statements and declarations

[9] Paragraph 1.2.3—6(4)(b)

Repeal the paragraph, substitute

(b) a special medical purpose product for infants.

[10] Note 2 to subsection 1.2.3—6(4)

Repeal the note, substitute:

Note 2 Division 4 of Standard 2.9.1 applies to a special medical purpose product for infants and sets out compositional and labelling requirements for such food**.**

Standard 1.3.1—Food Additives

[11] Subsection 1.3.1—3(2)

After ‘any food’, insert ‘(other than an infant formula product)’

[12] Paragraph 1.3.1—4(6)(k)

Repeal the paragraph, substitute:

(k) rosemary extract is calculated as the sum of carnosic acid and carnosol;

(l) phosphoric acid and phosphates are calculated as phosphorus.

Standard 1.5.1—Novel Foods

[13] Note to subsection 1.5.1—2(2) (Definition of novel food)

Repeal subsection (2) of the definition, substitute:

(2) Any of the following:

(a) the presence of a food in a food for special medical purposes;

(b) the presence of a food in a special medical purpose product for infants;

(c) the use of a food as a food for special medical purpose;

(d) the use of a food as a special medical purpose product for infants;

do not constitute a history of human consumption in Australia or New Zealand in relation to that food for the purposes of this section.

[13A] Section 1.5.1—3

Repeal the section, substitute:

1.5.1—3 Sale of novel foods

(1) Despite paragraphs 1.1.1—10(5)(b) and (6)(f), a food offered for retail sale (other than an infant formula product) may consist of, or have as an ingredient, a *novel food if:

(a) the novel food is listed in the table to section S25—2; and

(b) any conditions of use specified in the corresponding row of that table are complied with.

Note Novel foods are added to the table to section S25—2 by variations to the Code. When added for the first time, the conditions may include some that apply to the novel food only during the first 15 months after gazettal of the variation. Conditions may also deal with matters such as the following:

- the need for preparation or cooking instructions, warning statements or other advice;
- the need to meet specific requirements of composition or purity;
- the class of food within which the food must be sold;
- during the first 15 months after gazettal, the brand under which the food may be sold.

(2) Despite paragraphs 1.1.1—10(5)(b) and (6)(f), an infant formula product for retail sale may consist of, or have as an ingredient or a *component, a novel food only if:

(a) the novel food is listed in the table to section S25—2; and

(b) the presence of that novel food in the infant formula product is expressly permitted by that table; and

(c) any conditions of use specified in the corresponding row of that table are complied with.

Standard 2.9.2—Food for infants

[14] Section 2.9.2—4

Omit ‘section S29—7’ (wherever occurring), substitute ‘section S29—23’.

[15] Section 2.9.2—5

Omit ‘section S29—7’ (wherever occurring), substitute ‘section S29—23’.

[16] Subsection 2.9.2—6(3)

Omit ‘section S29—7’, substitute ‘section S29—23’.

Standard 2.9.3—Formulated meal replacements and formulated supplementary foods

[17] Subparagraph 2.9.3—3(2)(c)(iii)

Omit ‘section S29—7’, substitute ‘section S29—23’.

Standard 2.9.5—Food for special medical purposes

[18] Paragraph 2.9.5—6(1)(b)

Omit ‘section S29—7’, substitute ‘section S29—23’.

Schedule 8—Food additive names and code numbers (for statement of ingredients)

[19] The table to section S8—2 (food additive names—alphabetical listing)

Insert:

dl-Alpha-tocopherol	307c
Potassium hydroxide	525
Sodium hydroxide	524

[20] The table to section S8—2 (food additive names—numerical listing)

Insert in numerical order:

307c	dl-Alpha-tocopherol
524	Sodium hydroxide
525	Potassium hydroxide

Schedule 15—Substances that may be used as food additives

[21] The table to section S15—5 (food classes 13.1, 13.1.1, 13.1.2 and 13.1.3)

Repeal the food classes, substitute:

13.1	***Infant formula products***		
270	Lactic acid	GMP	
300	Ascorbic acid	50 mg/L	See Note 1, below.
301	Sodium ascorbate	50 mg/L	See Note 1, below.
		75 mg/L	May only be added to polyunsaturated fatty acid preparations
302	Calcium ascorbate	50 mg/L	See Note 1, below.
304	Ascorbyl palmitate	50 mg/L	See Note 1, below.
304	Ascorbyl palmitate	10 mg/L	
307b	Tocopherols concentrate, mixed	10 mg/L	
307b	Tocopherols concentrate, mixed	30 mg/L	See Note 1, below
307c	dl-Alpha-tocopherol	10 mg/L	
307c	dl-Alpha-tocopherol	30 mg/L	See Note 1, below
308	Gamma-tocopherol	10 mg/L	
309	Delta-tocopherol	10 mg/L	
322	Lecithin	5 000 mg/L	
330	Citric acid	GMP	
331	Sodium citrates	GMP	
332	Potassium citrates	GMP	
333	Calcium citrates	0.1 mg/L	As calcium, may only be added as part of a nutrient preparation
338	Phosphoric acid	450 mg/L	
339	Sodium phosphates	450 mg/L	
340	Potassium phosphates	450 mg/L	
407	Carrageenan	300 mg/L	Only in a liquid product
410	Locust bean (carob bean) gum	1 000 mg/L	
412	Guar gum	1 000 mg/L	Only in a liquid product that contains hydrolysed protein

414	Gum arabic (acacia)	10 mg/L	May only be added as part of a nutrient preparation
440	Pectins	10 000 mg/L	See Note 1, below
471	Mono- and diglycerides of fatty acids	4 000 mg/L	
472c	Citric and fatty acid esters of glycerol	7 500 mg/L	Only in a powdered product
		9 000 mg/L	Only in a liquid product
500	Sodium carbonates	2 000 mg/L	
501	Potassium carbonates	2 000 mg/L	
524	Sodium hydroxide	2 000 mg/L	
525	Potassium hydroxide	2 000 mg/L	
526	Calcium hydroxide	2 000 mg/L	
551	Silicon dioxide (amorphous)	10 mg/L	May only be added as part of a nutrient preparation
1412	Distarch phosphate	5 000 mg/L	See Note 2, below.
1413	Phosphated distarch phosphate	5 000 mg/L	See Note 3, below.
1414	Acetylated distarch phosphate	5 000 mg/L	See Note 4, below.
1422	Acetylated distarch adipate	5 000 mg/L	See Note 5, below.
1440	Hydroxypropyl starch	5 000 mg/L	See Note 6, below.
1450	Starch sodium octenylsuccinate	100 mg/L	May only be added as part of a nutrient preparation
		1 000 mg/L	May only be added to polyunsaturated fatty acid preparations

Note 1. For additives 300, 301, 302, 304, 307b, 307c, 440—the additive may only be used in follow-on formula products.

Note 2. Additive 1412 may only be used in:

(a) soy based infant formula product (other than follow-on formula) either singly or in combination with one or more of additives 1413, 1414 and 1440; and

(b) soy based follow-on formula either singly or in combination with one or more of additives 1413, 1414 and 1422.

Note 3. Additive 1413 may only be used in:

(a) soy based infant formula product (other than follow-on formula) either singly or in combination with one or more of additives 1412, 1414 and 1440; and

(b) soy based follow-on formula either singly or in combination with one or more of additives 1412, 1414 and 1422.

Note 4. Additive 1414 may only be used in:

(a) soy based infant formula product (other than follow-on formula) either singly or in combination with one or more of additives 1412, 1413, and 1440; and

(b) soy based follow-on formula either singly or in combination with one or more of additives 1412, 1413, and 1422.

Note 5. Additive 1422 may only be used in soy based follow-on formula, either singly or in combination with one or more of additives 1412, 1413 and 1414.

Note 6. Additive 1440 may only be used in soy based infant formula product (other than follow-on formula), either singly or in combination with one or more of additives 1412, 1413, and 1414.

13.1.1	**Special medical purpose product for infants**		
170	Calcium carbonates	GMP	
304	Ascorbyl palmitate	100 mg/L	
333	Calcium citrates	GMP	
338	Phosphoric acid	450 mg/L	For pH adjustment only
339	Sodium phosphates	450 mg/L	
340	Potassium phosphates	450 mg/L	
341	Calcium phosphates	450 mg/L	

401	Sodium alginate	1 000 mg/L	Only in a product specifically formulated for both the dietary management of metabolic disorders of infants aged 4 months and above and general tube-feeding of infants aged 4 months and above.
407	Carrageenan	1 000 mg/L	Only in a liquid product that contain hydrolysed proteins and/or amino acids
410	Locust bean (carob bean) gum	5 000 mg/L	Only in a product specifically formulated for reduction of gastro-oesophageal reflux
412	Guar gum	10 000 mg/L	See Note 1, below.
415	Xanthan gum	1 200 mg/L	Only in a product that is based on hydrolysed protein, amino acids or peptides
440	Pectins	2 000 mg/L	Only in a liquid product that contain hydrolysed protein
		5 000 mg/L	Only in a product formulated for infants with gastro-intestinal disorders
471	Mono- and diglycerides of fatty acids	5 000 mg/L	Only in product formulated for diets devoid of proteins
472e	Diacyltartaric and fatty acid esters of glycerol	400 mg/L	
1412	Distarch phosphate	25 000 mg/L	See Notes 2 and 7, below.
1413	Phosphated distarch phosphate	25 000 mg/L	See Notes 3 and 7, below.
1414	Acetylated distarch phosphate	25 000 mg/L	See Notes 4 and 7, below.
1422	Acetylated distarch adipate	25 000 mg/L	See Notes 5 and 7, below
1440	Hydroxypropyl starch	25 000 mg/L	Sees Note 6 and 7, below.
1450	Starch sodium octenylsuccinate	20 000 mg/L	See Note 7, below

Note 1. Additive 412 may only be used in a product that contains one or more of the following: hydrolysed proteins; peptides; amino acids.

Note 2. Additive 1412 may only be used in:

(a) a product (other than a product formulated for infants aged 6 to 12 months) either singly or in combination with one or more of additives 1413, 1414 and 1440; and

(b) a product formulated for infants aged 6 to 12 months either singly or in combination with one or more of additives 1413, 1414 and 1422.

Note 3. Additive 1413 may only be used in:

(a) a product (other than a product formulated for infants aged 6 to 12 months) either singly or in combination with one or more of additives 1412, 1414 and 1440; and

(b) a product formulated for infants aged 6 to 12 months either singly or in combination with one or more of additives 1412, 1414 and 1422.

Note 4. Additive 1414 may only be used in:

(a) a product (other than a product formulated for infants aged 6 to 12 months) either singly or in combination with one or more of additives 1412, 1413 and 1440; and

(b) a product formulated for infants aged 6 to 12 months either singly or in combination with one or more of additives 1412, 1413 and 1422.

Note 5. Additive 1422 may only be used in a product formulated for infants aged 6 to 12 months either singly or in combination with one or more of additives 1412, 1413 and 1414.

Note 6. Additive 1440 may only be used in a product (other than a product formulated for infants aged 6 to 12 months) either singly or in combination with one or more of additives 1412, 1413, and 1414.

Note 7. Additives 1412, 1413, 1414, 1422, 1440 and 1450 may only be used in a product that contains hydrolysed proteins, amino acids or both.

Schedule 19—Maximum levels of contaminants and natural toxicants

[22] The table to section S19—4 (Maximum levels of metal contaminants)

Insert:

Aluminium	Infant formula, follow-on formula and special medical purpose product for infants (other than special medical purpose product for infants formulated for pre-term infants)	0.5
	Soy-based infant formula products	1
	Special medical purpose product for infants formulated for pre-term infants	0.2

[23] The table to section S19—4 (table item dealing with "Lead", entry dealing with the food "infant formula products" and its associated maximum level)

Repeal the entry, substitute:

	Infant formula products	0.01

Schedule 25—Permitted novel foods

[24] Subsection S25—2

Repeal

Dried marine micro-algae (*Schizochytrium* sp.) rich in docosahexaenoic acid (DHA)	
Oil derived from marine micro-algae *Schizochytrium* sp. (American Type Culture Collection (ATCC) PTA-9695)	1. May only be added to infant formula products in accordance with Standard 2.9.1.

Oil derived from marine micro-algae (*Schizochytrium* sp.) rich in docosahexaenoic acid (DHA)	
Oil derived from marine micro-algae (*Ulkenia* sp.) rich in docosahexaenoic acid (DHA)	

substitute:

Dried marine micro-algae (*Schizochytrium* sp.) rich in docosahexaenoic acid (DHA)	1. May be added to infant formula products in accordance with Standard 2.9.1.
Oil derived from marine micro-algae *Schizochytrium* sp. (American Type Culture Collection (ATCC) PTA-9695)	1. Only permitted for use in infant formula products in accordance with Standard 2.9.1
Oil derived from marine micro-algae (*Schizochytrium* sp.) rich in docosahexaenoic acid (DHA)	1. May be added to infant formula products in accordance with Standard 2.9.1.
Oil derived from marine micro-algae (*Ulkenia* sp.) rich in docosahexaenoic acid (DHA)	1. May be added to infant formula products in accordance with Standard 2.9.1.

[25] Subsection S25—2 (table item dealing with "Isomalto-oligosaccharide")

Repeal the table item, substitute:

Isomalto-oligosaccharide	1. Must not be added to: (a) food for infants; and (b) formulated supplementary food for young children.

[26] Subsection S25—2 (table item dealing with "Rapeseed protein isolate", column headed "*Conditions of use*", condition 2)

Repeal the condition, substitute:

2. Must not be added to food for infants.

[27] Subsection S25—2 (table item dealing with "Trehalose")

Repeal the table item, substitute:

Trehalose	1. May be added to infant formula products only as a cryo-preservative for L(+) lactic acid producing microorganisms.