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

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

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

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

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

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

2. Variation is a legislative instrument

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

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

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

administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority approved the draft variation to amend Schedule 29 and other Standards in the Code as a consequence of the Authority's approval of the amendments to Standard 2.9.1 of the Code in the *Food Standards (Proposal P1028 – Infant Formula) Variation*. The purpose of all of the approved amendments are to revise and clarify the Code as it relates to infant formula products comprising category definitions, composition, labelling and representation of products.

4. Documents incorporated by reference

The approved draft variation does not incorporate any documents by reference.

5. Consultation

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

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

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

6. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

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

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

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

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

Clause 4 provides a transitional arrangement.

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

Instead, subclauses 4(2) and (3) provide a transitional arrangement where during a five year transition period commencing on the date of gazettal of the *Food Standards (Proposal P1028*

– *Infant Formula) Variation*, an infant formula product may be sold if the product complies with either: the Code as in force without the amendments made by the variation and *Food Standards (Proposal P1028 – Infant Formula) Variation*; or the Code as amended by those two instruments.

The variations made by the instrument include variations to Schedule 29 of the Code. Schedule 29, among other things, prescribes certain matters in relation to infant formula products for the purposes of Standard 2.9.1 of the Code. 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 of the Code.

Schedule 1 of the Variation

Schedule 1 of the variation amends Schedule 29 of the Code.

Item [1] of Schedule 1 repeals sections S29—2 to S29—10; and substitutes them with new sections S29—2 to S29—10.

New section S29—2: This section prescribes how the energy content of infant formula products must be calculated for the purposes of paragraph 2.9.1—4(2)(a).

Paragraph 2.9.1—4(2)(a) requires that, for the purposes of Standard 2.9.1, energy must be calculated in accordance with section S29—2.

New subsection S29—2(1) provides that the energy content of an infant formula product must be calculated using all of the following:

(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.

The term ‘component’ of a food is defined in subsection 1.1.2—2(3) of the Code.

New subsection S29—2(2) provides that the energy content of an infant formula product must be expressed in kilojoules.

New section S29—2A: This section prescribes how the protein content of infant formula products must be calculated for the purposes of paragraph 2.9.1—4(2)(b).

Paragraph 2.9.1—4(2)(b) requires that, for the purposes of Standard 2.9.1, protein content must be calculated in accordance with section S29—2A.

New section S29—2A provides that the protein content of an infant formula product must be calculated by multiplying the nitrogen content of the product by a nitrogen to protein conversion factor of 6.25.

New section S29—2B: This section prescribes how the vitamin A content of infant formula and follow-on formula must be calculated for the purposes of paragraph 2.9.1—4(2)(c).

Paragraph 2.9.1—4(2)(c) requires that, for the purposes of Standard 2.9.1, vitamin A content must be calculated in accordance with section S29—2B.

New section S29—2B provides that the vitamin A content of infant formula products must be calculated using only the retinol forms of vitamin A prescribed in Column 1 of the table to S29—23 (see **item 2** below).

New section S29—3: This section prescribes the L-amino acids that must be present in: infant formula and follow-on formula for the purposes of subsection 2.9.1—6(5); and special medical purpose products for infants for the purposes of section 2.9.1—33.

Subsection 2.9.1—6(5) provides that 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 no less than the corresponding minimum level specified in that table.

Subsection 2.9.1—33(4) provides that the L-amino acids listed in the table to section S29—3 must be present in a special medical purpose product for infants at a level no less than the corresponding minimum level specified in that table.

However, subsections 2.9.1—33(5) and (6) provide certain exemptions from that requirement for cysteine, methionine, phenylalanine and tyrosine if specific conditions related to each of those L-amino acids are met.

Also, subsection 2.9.1—33(7) provides that despite subsections 2.9.1—33(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.

The table to section S29—3 lists the L-amino acids that must be present in infant formula products and special medical purpose products for infants; and their corresponding minimum amounts per 100 kJ of the respective products.

New section S29—4: This section prescribes the limits on fatty acids that may be present in: infant formula and follow-on formula for the purposes of paragraph 2.9.1—7(1)(g); and special medical purpose product for infants for the purposes of paragraph 2.9.1—34(1)(g).

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

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

The table to new section S29—4 sets out the fatty acids that may be present in infant formula products; and their corresponding limits. The table has two Columns. Column 1 lists the fatty acids; and Column 2 sets out the maximum amount per 100 kJ for each fatty acid.

In summary:

- it is optional (i.e. not mandatory) for an infant formula product to contain a fatty acid listed in Column 1 of the table to section S29—4; and
- if an infant formula product contains a fatty acid listed in Column 1 of the table, the

infant formula product must comply with the corresponding maximum limits for that fatty acid which are set out in the table.

New section S29—5: This section prescribes the vitamins, minerals, electrolytes and other substances which infant formula and special medical purpose products for infants must contain for the purposes of subparagraph 2.9.1—7(2)(b)(i), subsection 2.9.1—8(1), paragraph 2.9.1—34(2)(b) and subsection 2.9.1—36(1).

Subparagraph 2.9.1—7(2)(b)(ii) states that (among other things) infant formula may only contain medium chain triglycerides that are, 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 infant formula. The phrase 'used as a processing aid' in relation to a food is defined in section 1.1.2—13 of the Code.

Subsection 2.9.1—8(1) prescribes the nutritive substances that infant formula must contain. This provision requires infant formula to contain each substance listed in Column 1 of the table to section S29—5 in an amount (including any naturally-occurring amount) that is:

- no less than the minimum amount specified in Column 2 of the table; and
- no more than the maximum amount (if any) specified in Column 3 of the table.

Paragraph 2.9.1—34(2)(b) states that a special medical purpose product for infants may only contain medium chain triglycerides that are, 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. The phrase 'used as a processing aid' in relation to a food is defined in section 1.1.2—13 of the Code.

Section 2.9.1—36 prescribes the nutritive substances that a special medical purpose product for infants must contain. Subsection 2.9.1—36(1) requires that, subject to subsection 2.9.1—36(2), 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:

- no less than the minimum amount specified in Column 2 of the table; and
- no more than the maximum amount (if any) specified in Column 3 of the table.

The table to new section S29—5 sets out the vitamins, minerals, electrolytes and other substances that infant formula and special medical purpose product for infants must contain; and their corresponding limits. The table has four Columns. Column 1 lists the vitamins, minerals, electrolytes, and other substances; and for each substance:

- Column 2 sets out the minimum amount per 100 kJ;
- Column 3 sets out *any* maximum amount per 100 kJ;
- Column 4 sets out *any* 'Guidance upper level per 100 kJ' (this term is explained in the Note to new section S29—5 below).

The Note to section S29—5 identifies and explains for readers the operation of Column 4 of the table to that section. This Note explains that it is recommended that infant formula and special medical purpose product for infants contain a substance listed in Column 1 of the table to section S29—5 in an amount that is not more than the amount (if any) specified for that substance in Column 4. This is not a mandatory or binding maximum limit. The amounts in Column 4 (Guidance Upper) Levels are provided as guidance only and are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. These levels are values derived on the basis of meeting nutritional requirements

of infants and an established history of apparent safe use. It is recommended that the amounts specified in Column 4 not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formula and special medical purpose products for infants or due to technological reasons. Guidance Upper Levels are listed for substances where no maximum limit is set.

The table to new section S29—5 also prescribes medium chain triglycerides that may be contained in infant formula and in special medical purpose product for infants for the purposes of subparagraph 2.9.1—7(2)(b)(ii) and paragraph 2.9.1—34(2)(b) (see above).

New section S29—6: This section prescribes the vitamins, minerals and electrolytes which follow-on formula must contain, and their corresponding limits, for the purposes of subparagraph 2.9.1—7(2)(b)(ii) and subsection 2.9.1—8(2).

Subparagraph 2.9.1—7(2)(b)(ii) states that follow-on formula may only contain medium chain triglycerides that are (among other things), for a fat soluble vitamin that is specified in the table to section S29—6, a substance that was used as a processing aid in the preparation of that permitted fat soluble vitamin for use in the follow-on formula. The phrase “used as a processing aid” in relation to a food is defined in section 1.1.2—13 of the Code.

Subsection 2.9.1—8(2) requires follow-on formula to contain each substance listed in Column 1 of the table to section S29—6 in an amount (including any naturally-occurring amount) that is:

- no less than the minimum amount specified in Column 2 of the table; and
- no more than the maximum amount (if any) specified in Column 3 of the table.

The table to new section S29—6 sets out the vitamins, minerals and electrolytes that follow-on formula must contain; and their corresponding limits. The table has four Columns. Column 1 lists the vitamins, minerals and electrolytes; and for each substance:

- Column 2 sets out the minimum amount per 100 kJ;
- Column 3 sets out *any* maximum amount per 100 kJ;
- Column 4 sets out *any* ‘Guidance upper level per 100 kJ’.

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

The table to section S29—6 also prescribes medium chain triglycerides that may be contained in follow-on formula for the purposes of subparagraph 2.9.1—7(2)(b)(ii) (see above).

New section S29—7: This section prescribes the nutritive substances which infant formula may contain for the purposes of subsection 2.9.1—9(1) and which special medical purpose

product for infants may contain for the purposes of section 2.9.1—37. That is, the addition of these substances in infant formula and in special medical purpose product for infants is optional. The table to this section also sets out the corresponding limits for each substance.

Subsection 2.9.1—9(1) provides that a substance listed in Column 1 of the table to section S29—7 may be used as a nutritive substance in infant formula provided that the amount of the substance in the formula (including any naturally-occurring amount) complies with their corresponding limits in the table.

Section 2.9.1—37 provides that 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) complies with their corresponding limits in the table.

The table to new section S29—7 sets out the substances that may be used as a nutritive substance in infant formula and special medical purpose product for infants; and the corresponding limits for each substance (this includes any naturally-occurring amount of the substance). The table has three Columns. Column 1 lists the nutritive substances; and for each substance:

- Column 2 sets out *any* minimum amount per 100 kJ;
- Column 3 sets out the maximum amount per 100 kJ

In summary:

- it is optional (i.e. not mandatory) for infant formula and special medical purpose product for infants to contain a nutritive substance listed in Column 1 of the table to section S29—7;
- if an infant formula or special medical purpose product for infants contains a nutritive substance listed in Column 1 of the table, the infant formula or special medical purpose product for infants must comply with corresponding minimum and / or maximum limits for that substance which are set out in the table;
- the amount of the nutritive substance in the infant formula or special medical purpose product for infants includes any naturally-occurring amount of the substance.

New section S29—8: this provision prescribes the nutritive substances which follow-on formula may contain for the purposes of subsection 2.9.1—9(2) i.e. the addition of these substances in follow-on formula is optional. The table to this section also sets out the corresponding limits for each substance.

Subsection 2.9.1—9(2) provides that a substance listed in Column 1 of the table to section S29—8 may be used as a nutritive substance in follow-on formula provided that the amount of the substance in the formula (including any naturally-occurring amount) complies with the corresponding limits in the table.

The Note to subsection 2.9.1—9(2) explains that, among other things, 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 table to new section S29—8 sets out the substances that may be used as a nutritive substance in follow-on formula; and the corresponding limits for each substance. The table has four Columns. Column 1 lists the nutritive substances; and for each substance:

- Column 2 sets out *any* minimum amount per 100 kJ;
- Column 3 sets out *any* maximum amount per 100 kJ;
- Column 4 sets out *any* 'Guidance upper level per 100 kJ' (this term is explained in the Note to section S29—8 below).

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

In summary:

- it is optional (i.e. not mandatory) for follow-on formula to contain a nutritive substance listed in Column 1 of the table to section S29—8;
- if a follow-on formula contains a nutritive substance listed in Column 1 of the table, the follow-on formula must comply with any corresponding minimum and / or maximum limits for that substance which are set out in the table;
- the amount of the nutritive substance in the follow-on formula includes any naturally-occurring amount of the substance.

New section S29—9: This section prescribes the permitted forms of nutritive substances in infant formula and follow-on formula for the purposes of paragraph 2.9.1—10(b) and in special medical purpose product for infants for the purposes of paragraph 2.9.1—38(b).

Paragraph 2.9.1—10(b) provides that a substance used in infant formula or follow-on formula in accordance with section 2.9.1—8 or 2.9.1—9 and which is not a vitamin, mineral or electrolyte, must be in the permitted form listed in the table to section S29—9.

Paragraph 2.9.1—38(b) provides that a substance used in special medical purpose product for infants in accordance with section 2.9.1—36 or 2.9.1—37 and, which is not a vitamin, mineral or electrolyte, must be in the permitted form listed in the table to section S29—9.

The table to new section S29—9 sets out the substances and their permitted forms for infant formula products. The table has two Columns. Column 1 lists the substances and Column 2 lists the corresponding permitted form or forms for each substance.

The Note to section S29—9 explains that new section S29—23 lists the permitted forms of vitamins, minerals and electrolytes in infant formula products (for the purposes of paragraphs 2.9.1—10(a) and 2.9.1—38(b)).

New section S29—9A: This section prescribes for the purposes of section 2.9.1—10A conditions of use for certain substances used as a nutritive substance in infant formula products. The phrase 'used as a nutritive substance' in relation to a food is defined in section 1.1.2—12 of the Code.

The section sets out a table headed ‘Conditions of use for permitted nutritive substances’. The table has three Columns listing the substance, the permitted form of the substance, and conditions of use for the permitted form of the substance respectively.

‘Lactoferrin’ is listed as a substance in Column 1.

‘Bovine lactoferrin’ is listed as permitted form of that substance in Column 2.

The following two conditions are listed in Column 3:

1. During the exclusive use period, *Lactoferrin* in the permitted form may only be sold under the brand Synlait for use as a nutritive substance in 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.

New section S29—10: This section prescribes the required format for a nutrition information statement required for infant formula and follow-on formula for the purposes of section 2.9.1—25 as follows.

Section 2.9.1—25 provides that the *statement of nutrition information* required by section 2.9.1—24 for infant formula and follow-on formula (the statement) must (among other things) be in the same format specified in the table to section S29—10, and state the nutrition information in the order specified in that table. Also, specific information contained in the statement must be in the format specified in the table to section S29—10.

The table to section S29—10 sets out the required format for the statement.

The table has two Columns. Column 1 lists the nutrients and/or subgroup nutrients for the purposes of requirements in section 2.9.1—24. Column 2 sets out the corresponding average quantity per 100 mL of prepared formula for each nutrient/subgroup nutrient.

The Note to section S29—10 explains that:

- Where an asterisk (*) is placed next to a nutrient or subgroup nutrient in the table, it refers the reader to the related explanation provided in this Note.

- Entries and amounts for the following only need to be included when stated in accordance with subsections 2.9.1—24(3), 2.9.1—24(4) and paragraph 2.9.1—25(6)(d):
  - whey;
  - casein;
  - docosahexaenoic acid (DHA);
  - eicosapentaenoic acid (EPA);
  - arachidonic acid (ARA).

- The heading ‘Other nutrients’ only need 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 and 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).

New section S29—10A: sets out an example of a nutrition information statement, including quantities expressed as sold, for the purposes of subsection 2.9.1—25(7).

Subsection 2.9.1—24(1) provides that a statement of nutrition information is required for infant formula and follow-on formula. Subsections 2.9.1—24(2) to 8) prescribe what information that statement must or may contain or must not contain.

Subsection 2.9.1—24(7) provides that the statement of nutrition information may, in addition to stating each prescribed average quantity per 100 mL of prepared formula reconstituted according to directions, also state in another column that average quantity per 100 g of formula as sold in powdered form or 100 mL of formula as sold in liquid form.

Subsection 2.9.1—25(7) provides that that additional information must be in an additional column at the right hand side of Column 2 shown in the table to section S29—10A.

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

7.2 Item [2] of Schedule 1 of the approved draft variation inserts new section S29—23 after existing section S29—22.

New section S29—23: This section prescribes the 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 the purposes of the following provisions in the Code:

paragraph 2.9.1—10(a)	This provision requires that a substance used in infant formula or follow-on formula in accordance with section 2.9.1—8 or 2.9.1—9 and which is a vitamin, mineral or electrolyte, must be used or added in the permitted form listed in the table to section S29—23.
paragraph 2.9.1—38(a)	This provision requires that a substance used in a special medical purpose product for infants in accordance with section 2.9.1—36 or 2.9.1—37 and which is a vitamin, mineral or electrolyte, must be used or added in the permitted form listed in the table to new section S29—23.
section 2.9.2—4	This provision deals with additional compositional requirements for certain cereals for infants (from the age of 6 months) and permits such food to contain (among other things) added iron; as well as thiamin, niacin, vitamin B6, vitamin C, folate, magnesium; in forms permitted in the table to section S29—23.
section 2.9.2—5	This provision deals with additional compositional requirements for certain cereal-based food for infants from the age of 4 months and permits such food to contain added iron; and vitamin C to a maximum amount of 90 mg/100 g on a moisture free basis, both in forms permitted in the table to section S29—23.

section 2.9.2—6	This provision deals with additional compositional requirements for non-cereal-based food for infants and permits fruit-based food to contain vitamin C or folate or both in the permitted forms set out in the table to section S29—23.
subparagraph 2.9.3—3(2)(c)(iii)	This provision deals with compositional requirements for formulated meal replacements and permits vitamin K to be used as a nutritive substance in a formulated meal replacement if all of the following conditions are satisfied: the vitamin K is listed in Column 1 of the table to new section S29—13; the total of the naturally occurring and added vitamin K in a serving is not greater than the amount, if any, specified in relation to that vitamin in Column 2 of the table to section S29—13; and the vitamin K is in a permitted form specified in the table to section S29—23.
section 2.9.5—6	This provision deals with substances that may be added to food for special medical purposes; and permits (among other things) substances that are both listed in Column 1 of the table to section S29—23; and in a corresponding form listed in Column 2 of that table.

The table to section S29—23 sets out the relevant vitamins, minerals and electrolytes; and their permitted form(s), in infant formula products, food for infants, formulated meal replacements (vitamin K) and food for special medical purposes. The phrase ‘used as a nutritive substance’ in relation to a food is defined in section 1.1.2—12 of the Code.

Schedule 2 of the Variation

Schedule 2 of the variation amends Standards 1.1.2, 1.2.3, 1.3.1, 1.5.1, 2.9.2, 2.9.3, 2.9.5; and Schedules 8, 15, 19 and 25 of the Code.

Item [1] amends subsection 1.1.2—2(3) by inserting a definition of ‘inner package’ in relation to special medical purpose products for infants. The definition provides that ‘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.

The term ‘responsible institution’ is defined in subsection 1.1.2—2(3) as 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.

An example of an inner package is included at the end of the definition. The example 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.

Item [2] amends subsection 1.1.2—2(3) by repealing the definition of ‘medium chain triglycerides’

Item [2A] amends subsection 1.1.2—2(3) by repealing the definition of 'protein substitute'.

Item [3] amends subsection 1.1.2—2(3) by repealing and replacing paragraph (c) of the definition of 'warning statement' . The new paragraph refers to 'subsection 2.9.1—21(1) (warning statements for infant formula product)'.

Item [4] amends subsection 1.1.2—3(2) by inserting a definition of 'special medical purpose product for infants'. The definition provides that 'special medical purpose product for infants' is a food that meets all of the following criteria.

- It is an infant formula product (as defined by subsection 1.1.2—3(2)).
- It is represented as being 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).
- It is represented as being suitable to constitute either the sole or principal liquid source of nourishment where dietary management cannot medically be achieved without use of the product.
- It is represented as being for the dietary management of a medically diagnosed disease, disorder or condition of an infant.
- It is intended to be used under medical supervision.
- It is not suitable for general use.

Item [5] amends subsection 1.1.2—3(2) by repealing the definition of 'follow-on formula' and substituting a new definition. The new definition provides that 'follow-on formula' is a food that meets all of the following criteria:

- It is an infant formula product (as defined by subsection 1.1.2—3(2)).
- It is represented as either a breast milk substitute or replacement for infant formula,
- It is represented as being suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of 6 months.

Item [6] amends subsection 1.1.2—3(2) by repealing the definition of 'infant formula' and substituting a new definition. The new definition provides that 'infant formula' is a food that meets all of the following criteria:

- It is an infant formula product (as defined by subsection 1.1.2—3(2)).
- It is represented as being a breast milk substitute for infants.
- It is represented as satisfying by itself the nutritional requirements of infants under the age of 6 months.

Item [7] amends subsection 1.1.2—3(2) by repealing the definition of 'infant formula product' and substituting a new definition. The new definition provides that 'infant formula product' means a food that meets all of the following criteria.

- It is a product based on milk or other edible food constituents of animal or plant origin.
- It is represented as being 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.

Item [8] amends subsection 1.1.2—3(2) by repealing the definition of 'pre-term formula'.

Item [8A] repeals and replaces subsection 1.1.2—8(2), which relates to the definition of novel food. Section 1.1.2—8 defines 'novel food'. Current subsection 1.1.2—8(2) sets out

what does not constitute a history of human consumption in Australia or New Zealand in relation to that food for the purposes of that section and definition. New subsection 1.1.2—8(2) restates the current subsection 1.1.2—8(2) with the following changes - the new subsection now also provides that, for the purposes of the definition of novel food in section 1.1.2—8, the presence and/or use of a food in 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.

Item [9] repeals and replaces paragraph 1.2.3—6(4)(b).

Section 1.2.3—6 set out what a mandatory declaration must state. Subsection 1.2.3—6(4) sets out how a declaration in relation to a food for special medical purposes and certain types of infant formula products must be made. Current paragraph 1.2.3—6(4)(b) refers to an infant formula product that is:

- specifically formulated for premature or low birthweight infants;
- specifically formulated to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions;
- represented as lactose free formula or low lactose formula; or
- based on a protein substitute.

The new paragraph 1.2.3—6(4)(b) refers only to ‘a special medical purpose product for infants’ (as defined in subsection 1.1.2—3(2) (see item 4 above).

Item [10] repeals and replaces Note 2 to subsection 1.2.3—6(4).

Current Note 2 states that Division 4 of Standard 2.9.1 applies to infant formula products for special dietary use and sets out compositional and labelling requirements for such food.

The new Note 2 states that 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.

Item [11] amends subsection 1.3.1—3(2) by inserting ‘(other than an infant formula product)’ after ‘any food’ in that subsection. The change is to ensure that the carry-over of food additives noted in the subsection does not apply to infant formula products.

Item [12] repeals and replaces paragraph 1.3.1—4(6)(k) with new paragraphs 1.3.1—4(6)(k) and 1.3.1—4(6)(l). Paragraph 1.3.1—4(6)(k) remains unchanged and states that ‘rosemary extract is calculated as the sum of carnosic acid and carnosol’. That paragraph is currently the last paragraph listed in subsection 1.3.1—4(6) and is being repealed and replaced for grammatical purposes i.e. to change the full stop at the end of the paragraph to a semi-colon as a new last paragraph is being added to this list. Paragraph 1.3.1—4(6)(l) is the new provision and provides that ‘phosphoric acid and phosphates are calculated as phosphorus’.

Item [13] amends the Note to section 1.5.1—2. This Note sets out a copy of the definition of (among other things) novel food in subsection 1.1.2—2(3) of the Code. This item repeals and replaces subsection (2) of the definition of novel food as set out in that Note. This amendment is required as a result of the amendment made to the definition of novel food by item [8A] above.

Item [13A] repeals and replaces section 1.5.1—3, including the Note to that section.

The current section 1.5.1—3 permits a food for retail sale to consist of, or contain as an ingredient, any novel food listed in the table to section S25—2, provided that any conditions of use specified in that table for that novel food are complied with. The term ‘novel food’ is defined in section 1.1.2—8 of the Code.

The new section 1.5.1—3 comprises subsections 1.5.1—3(1) and (2) and a Note to subsection 1.5.1—3(1).

The new subsection 1.5.1—3(1) restates the current section 1.5.1—3 with one change. The change is that the subsection states that this subsection and the permission that this subsection provides do not apply to an infant formula product.

The Note to subsection 1.5.1—3(1) restates the current Note to section 1.5.1—3.

Also, a new provision is added - subsection 1.5.1—3(2), which sets out when an infant formula product for retail sale may consist of, or have as an ingredient or a component, a novel food. The subsection provides that this shall be permitted only when and if each of the following criteria is met.

- The novel food is listed in the table to section S25—2.
- The table to section S25—2 expressly permits the presence of that novel food in that infant formula product (i.e., the table contains an express permission).
- Any conditions of use specified for that novel food in the table to section S25—2 are complied with.

The term ‘component’ of a food is defined in subsection 1.1.2—2(3) of the Code.

Item [14] amends section 2.9.2—4 by omitting ‘section S29—7’ wherever occurring in section 2.9.2—4, and substituting with ‘section S29—23’.

Item [15] amends section 2.9.2—5 by omitting ‘section S29—7’ wherever occurring in section 2.9.2—5, and substituting with ‘section S29—23’.

Item [16] amends subsection 2.9.2—6(3) by omitting ‘section S29—7’ and substituting with ‘section S29—23’.

Item [17] amends subparagraph 2.9.3—3(2)(c)(iii) by omitting ‘section S29—7’ and substituting with ‘section S29—23’.

Item [18] amends paragraph 2.9.5—6(1)(b) by omitting ‘section S29—7’ and substituting with ‘section S29—23’.

Item [19] amends the table to section S8—2 (food additive names—alphabetical listing) by inserting three new entries into that table. The three new entries are:

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

Item [20] amends the table to section S8—2 (food additive names—numerical listing) by inserting three new entries into that table. The three new entries are:

307c dl-Alpha-tocopherol

524 Sodium hydroxide

525 Potassium hydroxide

Item [21] amends the table to section S15—5 by:

- repealing the food classes 13.1 (Infant formula products), 13.1.1 (Soy-based infant formula), 13.1.2 (Liquid infant formula products), and 13.1.3 (Infant formula products for specific dietary use based on a protein substitute); and
- replacing these with new food classes 13.1 (Infant formula products) and 13.1.1 (Special medical purpose product for infants).

The result of this amendment is that the table of food additive permissions for infant formula products now only has two food classes (categories): 'infant formula products' as the higher class and which includes follow-on formula; and 'special medical purpose product for infants' as subclass of 'infant formula products'.

The amended table also includes new food additive permissions, particularly for special medical purpose product for infants. Detailed condition statements have also been added for some food additives.

Item [22] inserts a new entry into the table to section S19—4 (Maximum levels of metal contaminants). The entry is:

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

This amendment adds contaminant limits for aluminium to the contaminants schedule - Schedule 19 - with other metals. These limits were previously located in section 2.9.1—8 (see item 1 of the *Food Standards (Proposal P1028 – Infant Formula) Variation*). The new entry in the table to section S19—4 continues to set the maximum level for soy-based infant formula products at twice that of other products to take account of the higher natural levels in soy ingredients.

Item [23] repeals and replaces an entry in the table to section S19—4 (entry dealing with the food "infant formula products" and its associated maximum level for the table item dealing with 'Lead'). The new entry is:

Infant formula products	0.01

The new entry reduced the permitted contaminant level for lead in infant formula products from 0.02 to 0.01 mg/kg for public health and safety reasons.

Item [24] amends the table to subsection S25—2 by repealing and replacing the permission and condition of use for four permitted novel foods derived from 'marine micro-algae Schizochytrium sp.' and 'marine micro-algae Ulkenia sp'.

The amendment changes the condition of use for:

- dried marine micro-algae (Schizochytrium sp.) rich in docosahexaenoic acid (DHA);
- oil derived from marine micro-algae (*Schizochytrium* sp.) rich in docosahexaenoic acid (DHA); and

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

Each of the above permitted novel foods will now have a condition of use that states expressly that the novel food 'may be added to infant formula products in accordance with Standard 2.9.1'.

The amendment also revises the condition of use for oil derived from marine micro-algae Schizochytrium sp. (American Type Culture Collection (ATCC) PTA-9695). The revised condition of use for this permitted novel food will now state 'Only permitted for use in infant formula products in accordance with Standard 2.9.1'. This revision makes clear that this novel food is permitted for use only in infant formula products.

This amendment is a consequence of the amendment made item 13A above to section 1.5.1—3 of the Code. The Code generally prohibits food for retail sale from being, or containing as an ingredient or component, a novel food unless the latter is expressly permitted by the Code. New subsection 1.5.1—3 will provide that an infant formula products for retail sale may consist of, or have as an ingredient or a component, a novel food *only* where each of the following criteria are met

- the novel food is listed in the table to section S25—2; and
- the presence of that novel food in the infant formula product is expressly permitted by that table; and
- any conditions of use specified in the corresponding row of that table are complied with

The requirement that the presence of the novel food in the infant formula product be expressly permitted by the table to section S25—2 required the above-mentioned amendments to that table.

Item [25] amends the table to subsection S25—2 by repealing and replacing the table item for the novel food 'Isomalto-oligosaccharide'.

The amendment changes the conditions of use for this permitted novel food by removing the condition prohibiting the addition of isomalto-oligosaccharide to infant formula products. The current conditions prohibiting the addition of isomalto-oligosaccharide to foods for infants and to formulated supplementary food for young children are retained.

This amendment is a consequence of the amendment made item 13A above to section 1.5.1—3 of the Code. The Code generally prohibits food for retail sale from being, or containing as an ingredient or component, a novel food unless the latter is expressly permitted by the Code. New subsection 1.5.1—3 will provide that an infant formula products for retail sale may consist of, or have as an ingredient or a component, a novel food *only* where each of the following criteria are met

- the novel food is listed in the table to section S25—2; and
- the presence of that novel food in the infant formula product is expressly permitted by that table; and
- any conditions of use specified in the corresponding row of that table are complied with

The requirement that the presence of the novel food in the infant formula product be expressly permitted by the table to section S25—2 required the above-mentioned amendment to that table. The table will not expressly permit the presence of isomalto-oligosaccharide in an infant formula product.

Item [26] amends the table to subsection S25—2 by repealing and replacing condition 2 of the conditions of use for the novel food ‘Rapeseed protein isolate’.

The amendment changes the conditions of use for this permitted novel food by removing the condition prohibiting the addition of rapeseed protein isolate to infant formula products. The current condition prohibiting the addition of rapeseed protein isolate to foods for infants is retained

This amendment is a consequence of the amendment made item 13A above to section 1.5.1—3 of the Code. The Code generally prohibits food for retail sale from being, or containing as an ingredient or component, a novel food unless the latter is expressly permitted by the Code. New subsection 1.5.1—3 will provide that an infant formula products for retail sale may consist of, or have as an ingredient or a component, a novel food *only* where each of the following criteria are met

- the novel food is listed in the table to section S25—2; and
- the presence of that novel food in the infant formula product is expressly permitted by that table; and
- any conditions of use specified in the corresponding row of that table are complied with

The requirement that the presence of the novel food in the infant formula product be expressly permitted by the table to section S25—2 required the above-mentioned amendment to that table. The table will not expressly permit the presence of rapeseed protein isolate in an infant formula product.

Item [27] amends the table to subsection S25—2 by repealing and replacing the table item dealing with the novel food ‘trehalose’.

The table to subsection S25—2 does not current impose a conditions of use for trehalose’ as a permitted novel food.

The amendment will impose a condition of use that permits trehalose to be added to infant formula products but only as a cryo-preservative for L(+) lactic acid producing microorganisms.