

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

C. Jeenhuis

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 | Maximum amount | Guidance upper level |
| | per 100 kJ | per 100 kJ | 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 B₅ | 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 | |
| lodine | 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 subst | ances | | |
| 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 |
|----------|----------|----------|----------|
| Columni | 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 | |
| lodine | 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

| 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 lacto-N-tetraose permitted for use by Standard 1.5.2 | | 40 mg 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 lacto-N-tetraose permitted for use by Standard 1.5.2 | | 40 mg 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 lacto-N-tetraose use by Standard 1.5.2 Lutein Lutein from Tagetes erecta L. Inositol Myo-inositol Taurine Taurine

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

Uridine-5'-monophosphate sodium salt

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

The table for this section is as follows:

Uridine-5'-monophosphate

Conditions of use for permitted nutritive substances

| Column 1 | Column 2 | Column 3 |
|-------------|--------------------|--|
| Substance | Permitted Form | Conditions of use |
| Lactoferrin | Bovine lactoferrin | During the exclusive use period, may only be sold under the brand Synlait for *use as a nutritive substance in an infant formula product. For the purposes of condition 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* | |
| — Docosahex (DHA)* | aenoic acid mg |
| — Eicosapent (EPA)* | aenoic acid mg |
| — Arachidonio (ARA)* | c acid 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 (B₁) | μg |
| Minerals | |
| Calcium | mg |
| Copper | μg |
| lodine | 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 | |
| 1 | 1 |

| (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 | μд | μg |
| Vitamin B ₁₂ | μg | μg |
| Vitamin C | mg | mg |
| Vitamin D | μg | μg |
| Vitamin E | mg | mg |

| Vitamin K | μд | μg |
|--|-----------|-----------|
| Biotin | μg | μg |
| Niacin (B ₃) | μg | μg |
| Folate | μg | μg |
| Pantothenic acid (B ₅) | μg | μg |
| Riboflavin (B ₂) | . • | |
| Thiamin (B ₁) | μд | μg |
| Minerals | μg | μg |
| Calcium | ma | ma |
| | mg | mg |
| Copper | μg | μg |
| lodine | μg | μg |
| Iron | mg | mg |
| Magnesium | mg | mg |
| Manganese | μд | μд |
| Phosphorus | mg | mg |
| Selenium | μg | μд |
| 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 D₂ (ergocalciferol)

vitamin D₃ (cholecalciferol)

vitamin D (cholecalciferol-cholesterol)

Thiamin thiamin hydrochloride

thiamin mononitrate

Riboflavin riboflavin

riboflavin-5'-phosphate, sodium

 $\begin{tabular}{lll} Niacin & niacinamide (nicotinamide) \\ Vitamin B_{ϵ} & pyridoxine hydrochloride \\ \end{tabular}$

pyridoxine-5'-phosphate

Folate Folic acid

Pantothenic acid calcium pantothenate

dexpanthenol

D-panthenol

calcium D-pantothenate sodium D-pantothenate

Vitamin B₁₂ 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 K₁ as phylloquinone (phytonadione)

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

lodine

cupric sulphate cupric citrate cupric carbonate 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:
 - (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.
- [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;
- (I) 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-tocopherol307cPotassium hydroxide525Sodium hydroxide524

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

Insert in numerical order:

307c dl-Alpha-tocopherol524 Sodium hydroxide525 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 75 mg/L | See Note 1, below. 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 0.5

medical purpose product for infants (other than special medical purpose product for infants

formulated for pre-term infants)

Soy-based infant formula products 1

Special medical purpose product for infants formulated for pre-term infants

[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 microalgae *Schizochytrium* sp. (American Type Culture Collection (ATCC) PTA-9695) May only be added to infant formula products in accordance with Standard 2.9.1.

0.2

Oil derived from marine microalgae (*Schizochytrium* sp.) rich in docosahexaenoic acid (DHA)

Oil derived from marine microalgae (*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 microalgae *Schizochytrium* sp. (American Type Culture Collection (ATCC) PTA-9695) Only permitted for use in infant formula products in accordance with Standard 2.9.1

Oil derived from marine microalgae (*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 microalgae (*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.