ATTACHMENT 4

DRAFT VARIATIONS TO VOLUME 1 AND VOLUME 2 OF THE *FOOD STANDARDS CODE*

To commence: on gazettal

The Food Standards Code *is varied by –*

[1] ***Standard A11*** *of Volume 1 is varied by –*

[1.1] *inserting in the Schedule to A11 into Column 1 and Column 2 respectively, after the entry for* Divinylbenzene copolymer –

Docosahexaenoic acid (DHA) – rich oil derived from the algae *Crypthecodinium cohnii*	Addendum 17

[1.2] *inserting in the Schedule to A11 into Column 1 and Column 2 respectively, after the entry for* Anthocyanins –

Arachidonic acid (ARA) – rich oil derived from the fungus *Mortierella alpina*	Addendum 18

[1.3] *inserting following* ADDENDUM 16 –

ADDENDUM 17

SPECIFICATION FOR DOCOSAHEXAENOIC ACID (DHA) - RICH OIL DERIVED FROM THE ALGAE *CRYPTHECODINIUM COHNII*

Full chemical name for DHA	4,7,10,13,16,19-docosahexaenoic acid (22:6n-3)
Appearance	Free flowing oil
Colour	Yellow to orange
Odour	Characteristic
DHA (%)	min. 40 max. 45
Dodecanoic acid 12:0 (%)	min. 0 max. 6
Tetradecanoic acid 14:0 (%)	min. 10 max. 20
Hexadecanoic acid 16:0 (%)	min. 10 max. 20
Octadecenoic acid 18:1 (%)	min. 10 max. 30
Peroxide value (meq/kg)	max. 5
Moisture and volatiles (%)	max. 0.01
Non-saponifiables (%)	max. 3.5
Trans fatty acids (%)	max. 1.0
Free fatty acid (%)	max. 0.4
Lead (ppm)	max. 0.2
Arsenic (ppm)	max. 0.5
Copper (ppm)	max. 0.1

Iron (ppm)	max. 0.5
Mercury (ppm)	max. 0.2
Hexane (ppm)	max. 0.3

ADDENDUM 18

SPECIFICATIONS FOR ARACHIDONIC ACID (ARA) – RICH OIL DERIVED FROM THE FUNGUS *MORTIERELLA ALPINA*

Full chemical name for ARA	5,8,11,14-eicosatetraenoic acid (20:4n-6)	
Appearance	Free flowing oil	
Colour	Yellow	
Odour	Characteristic	
ARA (%)	min. 38	max. 44
Hexadecanoic acid 16:0 (%)	min. 3	max. 15
Octadecanoic acid 18:0 (%)	min. 5	max. 20
Octadecenoic acid 18:1 (%)	min. 5	max. 38
Octadecadienoic acid 18:2 (%)	min. 4	max. 15
Peroxide value (meq/kg)	max. 5	
Moisture and volatiles (%)	max. 0.05	
Non-saponifiables (%)	max. 3.5	
Trans fatty acids (%)	max. 1.0	
Free fatty acid (%)	max. 0.4	
Lead (ppm)	max. 0.2	
Arsenic (ppm)	max. 0.5	
Copper (ppm)	max. 0.1	
Iron (ppm)	max. 0.5	
Mercury (ppm)	max. 0.2	
Hexane (ppm)	max. 0.3	

[2] ***Standard 1.1.1*** *of Volume 2 is varied by omitting from* clause 2, *in the definition for* warning statement *subclause* (d) –

substituting

(d) subclauses 14(1), 14(3) and 26(1) of Standard 2.9.1; and

[3] ***Standard 1.3.4*** *of Volume 2 is varied by inserting in the Schedule immediately after the* Specification for tall oil phytosterols derived from tall oils *the following* -

Specification for docosahexaenoic acid (DHA) – rich oil derived from the algae *Crypthecodinium cohnii*

Full chemical name for DHA	4,7,10,13,16,19-docosahexaenoic acid (22:6n-3)	
Appearance	Free flowing oil	
Colour	Yellow to orange	
Odour	Characteristic	
DHA (%)	min. 40	max. 45
Dodecanoic acid 12:0 (%)	min. 0	max. 6
Tetradecanoic acid 14:0 (%)	min. 10	max. 20
Hexadecanoic acid 16:0 (%)	min. 10	max. 20

Octadecenoic acid 18:1 (%)	min. 10 max. 30
Peroxide value (meq/kg)	max. 5
Moisture and volatiles (%)	max. 0.01
Non-saponifiables (%)	max. 3.5
Trans fatty acids (%)	max. 1.0
Free fatty acid (%)	max. 0.4
Lead (ppm)	max. 0.2
Arsenic (ppm)	max. 0.5
Copper (ppm)	max. 0.1
Iron (ppm)	max. 0.5
Mercury (ppm)	max. 0.2
Hexane (ppm)	max. 0.3

Specification for arachidonic acid (ARA) – rich oil derived from the fungus *Mortierella alpina*

Full chemical name for ARA	5,8,11,14-eicosatetraenoic acid (20:4n-6)
Appearance	Free flowing oil
Colour	Yellow
Odour	Characteristic
ARA (%)	min. 38 max. 44
Hexadecanoic acid 16:0 (%)	min. 3 max. 15
Octadecanoic acid 18:0 (%)	min. 5 max. 20
Octadecenoic acid 18:1 (%)	min. 5 max. 38
Octadecadienoic acid 18:2 (%)	min. 4 max. 15
Peroxide value (meq/kg)	max. 5
Moisture and volatiles (%)	max. 0.05
Non-saponifiables (%)	max. 3.5
Trans fatty acids (%)	max. 1.0
Free fatty acid (%)	max. 0.4
Lead (ppm)	max. 0.2
Arsenic (ppm)	max. 0.5
Copper (ppm)	max. 0.1
Iron (ppm)	max. 0.5
Mercury (ppm)	max. 0.2
Hexane (ppm)	max. 0.3

[4] ***Standard 2.9.1*** *of Volume 2 is varied by* -

[4.1] *omitting* Standard 2.9.1 *and substituting* -

STANDARD 2.9.1

INFANT FORMULA PRODUCTS

Purpose

This Standard provides for the compositional, and labelling requirements for foods intended or represented for use as a substitute for breast milk, herein referred to as 'infant formula products'. This Standard applies to all infant formula products whether in powder, liquid concentrate or 'ready to drink' forms.

This Standard also provides for infant formula products intended for infants with special nutritional requirements.

Additionally, recommended guidelines regarding vitamins and minerals are contained at the end of this Standard. Standard 1.3.1 contains provisions relating to the food additives permitted in infant formula products. Standard 1.6.1 contains the microbiological limits in relation to infant formula products. Standard 1.3.4 contains specifications for permitted nucleotides and added nutrients. Standard 1.1.1 defines nutritive substances for the purposes of this Code.

Table of Provisions

Clauses

Division 1

Subdivision 1 – Interpretation

1 Definitions

(1) The definitions in clauses 1 and 2 of Standard 1.2.8 apply to this Standard.

(2) In this Code –

follow-on formula means an infant formula product represented as either a breast-milk substitute or replacement for infant formula and which constitutes the principal liquid source of nourishment in a progressively diversified diet for infants aged from six months.

infant means a person under the age of 12 months.

infant formula means an infant formula product represented as a breast milk substitute for infants and which satisfies the nutritional requirements of infants aged up to four to six months.

Editorial note:

A reference to infant formula product may include a reference to infant formula but the converse does not apply.

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

Editorial note:

The intent of this definition is to limit the addition of ingredients to infant formula product to ingredients that would be considered to be foods. The addition of an ingredient that is not considered to be a food is prohibited unless specifically permitted elsewhere in this Standard.

Standard 1.5.1 contains prohibitions and restrictions relating to novel foods and novel food ingredients. Nothing contained in this Standard permits infant formula products to contain novel foods or novel food ingredients that are not permitted in Standard 1.5.1.

lactose free formula and **low lactose formula** means infant formula products which satisfy the needs of lactose intolerant infants.

medium chain triglycerides means triacylglycerols which contain predominantly the saturated fatty acids designated by 8:0 and 10:0.

pre-term formula means an infant formula product specifically formulated to satisfy particular needs of infants born prematurely or of low birthweight.

protein substitute means L-amino acids and/or the hydrolysate of one or more of the proteins on which infant formula product is normally based.

soy-based formula means an infant formula product in which soy protein isolate is the sole source of protein.

2 Interpretation

A reference to any infant formula product in the compositional provisions of this Standard is a reference to –

(a) a powdered or concentrated form of infant formula product which has been reconstituted with water according to directions; or
(b) an infant formula product in 'ready to drink' form.

Subdivision 2 – Calculations

3 Calculation of energy

The energy content of infant formula product, expressed in kilojoules (kJ), must be calculated using –

(a) only the energy value contributions of the fat, protein and carbohydrate ingredients of the infant formula product; and
(b) the relevant energy factors set out in Standard 1.2.8.

4 Calculation of protein

The prescribed formula for the calculation of the protein content of infant formula product for the purposes of this Standard is -

Formula

For milk proteins and their partial protein hydrolysates -

Protein content = nitrogen content x 6.38; or

In any other case -

Protein content = nitrogen content x 6.25.

5 Calculation of potential renal solute load

The prescribed formula for the calculation of the potential renal solute load for the purposes of this Standard is -

Formula

Potential renal solute load in mOsm/100 kJ = [Na (mg/100 kJ) /23] + [Cl (mg/100 kJ) /35] + [K (mg/100 kJ) /39] + [P_{avail} (mg/100 kJ)/ 31] + [N (mg/100 kJ) /28)].

In this formula

P_{avail} = P of milk-based formula + 2/3 of P of soy-based formulas.

Subdivision 3 - General compositional requirements

6 Restrictions and prohibitions

(1) A vitamin, mineral, food additive or nutritive substance must not be added to infant formula product unless -

(a) expressly permitted by this Code; or
(b) it is naturally present in an ingredient of the infant formula product.

(2) Infant formula product must contain no detectable gluten.

7 Permitted nutritive substances

(1) Any nutritive substance listed in column 1 of the Table to this clause may be added to infant formula product provided that -

(a) the nutritive substance is in one or more of the forms specified in column 2 of the Table in relation to that substance; and

(b) the total amount of the nutritive substance in the infant formula product is no more than the amount specified in column 4 of the Table.

(2) The label on a package of infant formula product must not include any words indicating, or any other indication, that the product contains a nutritive substance specified in column 1 or in column 2 of the Table to this clause unless the total amount of the nutritive substance in the food is no less than the amount specified in column 3 of the Table.

Editorial note:

The intent of subclause 7(1) is that the maximum permitted amounts only apply when the substance is added, and in that case, it then applies to the sum of the naturally occurring and added nutritive substances.

This Standard contains guidelines on the use and format of nutrient information tables.

Table to clause 7

Column 1	Column 2	Column 3	Column 4
Nutritive substance	**Permitted forms**	**Minimum amount for claim per 100 kJ**	**Maximum amount per 100 kJ**
Choline	Choline chloride Choline bitartrate	1.7 mg	7.1 mg
Inositol	Inositol	1.0 mg	9.5 mg
Taurine	Taurine	0.8 mg	3 mg
L-carnitine	L-carnitine	0.21 mg	0.8 mg
Cytidine 5’-monophosphate	Cytidine 5’-monophosphate Cytidine 5’-monophosphate sodium salt	0.22 mg	0.6 mg
Uridine 5’-monophosphate	Uridine 5’-monophosphate Uridine 5’-monophosphate sodium salt	0.13 mg	0.42 mg
Adenosine 5’-monophosphate	Adenosine 5’-monophosphate Adenosine 5’-monophosphate sodium salt	0.14 mg	0.38 mg
Guanosine 5’-monophosphate	Guanosine 5’-monophosphate Guanosine 5’-monophosphate sodium salt	0.04 mg	0.12 mg
Inosine 5’-monophosphate	Inosine 5’-monophosphate Inosine 5’-monophosphate sodium salt	0.08 mg	0.24 mg

8 Limit on nucleotide 5’-monophosphates

Infant formula product must contain no more than 3.8 mg/100 kJ of nucleotide 5'-monophosphates.

Editorial note:

Standard 1.3.4 contains specifications for nucleotides.

9 Lactic acid cultures

L(+) producing lactic acid cultures may be added to infant formula product.

10 Limit on aluminium

(1) Infant formula product, other than a pre-term formula or soy-based formula product, must contain no more than 0.05 mg of aluminium per 100 mL.

(2) Pre-term formula must contain no more than 0.02 mg of aluminium per 100 mL.

(3) Soy-based formula must contain no more than 0.1 mg of aluminium per 100 mL.

Editorial note:

Standard 1.4.1 contains the maximum level (ML) of lead contaminant in infant formula products.

Subdivision 4 - General labelling and packaging requirements

11 Representations of food as infant formula product

A food must not be represented as an infant formula product unless it complies with this Standard.

12 Prescribed names

'Infant Formula' and 'Follow-on Formula' are prescribed names.

13 Requirement for a measuring scoop

(1) A package of infant formula product in a powdered form must contain a scoop to enable the use of the infant formula product in accordance with the directions contained in the label on the package.

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

14 Required warnings, directions and statements

(1) The label on a package of infant formula product must include the following warning statement -

(a) in the case of infant formula product in powdered form -

'Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not change proportions of powder except on medical advice. Incorrect preparation can make your baby very ill'; and

(b) in the case of concentrated infant formula product -

'Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not change proportions of concentrate except on medical advice. Incorrect preparation can make your baby very ill'; and

(c) in the case of 'ready to drink' infant formula product -

'Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not dilute or add anything to this 'ready to drink' formula except on medical advice. Incorrect preparation can make your baby very ill'.

(2) The label on a package of infant formula product must include directions for the preparation and use of the infant formula product which include words and pictures instructing -

(a) that each bottle should be prepared individually; and
(b) that if a bottle of made up formula is to be stored prior to use, it must be refrigerated and used within 24 hours; and
(c) that potable, previously boiled water should be used; and
(d) where a package contains a measuring scoop, that only the enclosed scoop should be used; and
(e) that formula left in the bottle after a feed must be discarded.

(3) Subject to subclause (4), the label on a package of infant formula product must contain the following warning statement -

'Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice.';

under a heading that states –

'Important Notice' or any word or words having the same or similar effect.

(4) Subclause (3) does not apply to infant formula products for metabolic, immunological, renal, hepatic or malabsorptive conditions.

(5) The label on a package of an infant formula product must contain statements indicating that -

(a) the infant formula product may be used from birth, in the case of infant formula; and

(b) the infant formula product should not be used for infants aged under 6 months in the case of follow-on formula; and
(c) except in the case of packages of pre-term formula, it is recommended that infants over the age of 6 months should be offered foods in addition to the infant formula product.

15 Print and package size

(1) Where an infant formula product is in a package having a net weight of more than 500g, the statements required by subclauses 14(1), (3) and 26(1) must be in size of type of no less than 3 mm.

(2) Where an infant formula product is in a package having a net weight of 500 g or less the statements required by subclauses 14(1), (3) and 26(1) must be in size of type of no less than 1.5 mm.

16 Declaration of nutrition information

(1) The label on a 'ready to drink' infant formula product must include a statement, which may be in the form of a table, that contains the following information –

(a) the average energy content expressed in kJ per 100 mL; and
(b) the average amount of protein, fat and carbohydrate expressed in g per 100 mL; and
(c) the average amount of each vitamin, mineral and any other nutritive substance permitted by this Standard expressed in weight per 100 mL.

(2) The label on a powdered or concentrated form of infant formula product must include a statement, which may be in the form of a table that contains the following information -

(a) the average energy content expressed in kJ per 100 mL of infant formula product that has been reconstituted according to directions; and
(b) the average amount of protein, fat and carbohydrate expressed in g per 100 mL of infant formula product that has been reconstituted according to directions; and
(c) the average amount of each vitamin, mineral and any other nutritive substance permitted by this Standard expressed in weight per 100 mL of infant formula product that has been reconstituted according to directions; and
(d) a declaration –

(i) of the weight of one scoop in the case of powdered infant formula; and
(ii) of the proportion of powder or concentrate required to reconstitute the formula according to directions.

17 Date marking and storage instructions

(1) Paragraphs 2(1)(c) and (d) of Standard 1.2.5 do not apply to this Standard.

(2) A label on a package of infant formula product must contain storage instructions covering the period after it is opened.

Editorial note:

The appropriate storage instructions should be valid for the full range of climatic conditions that exist in Australia and New Zealand.

18 Statement of protein source

The label on a package of infant formula product must contain a statement of the specific source, or sources, of protein in the infant formula product immediately adjacent to the name of the infant formula product.

Editorial note:

Standard 1.2.2 requires that all food be labelled with its name. The requirement in clause 18 of this Standard applies only to the name on the label on the product in accordance with the requirement in Standard 1.2.2.

19 Statement on dental fluorosis

(1) An infant formula product must comply with subclause (2) where it contains -

(a) more than 17 μg of fluoride per 100 kJ prior to reconstitution, in the case of powdered or concentrated infant formula product; or
(b) more than 0.15 mg of fluoride per 100 mL, in the case of 'ready to drink' formula.

(2) The label on a package of infant formula product referred to in subclause (1) must contain statements -

(a) indicating that consumption of the formula has the potential to cause dental fluorosis; and
(b) recommending that the risk of dental fluorosis should be discussed with a medical practitioner or other health professional.

20 Prohibited representations

The label on a package of infant formula product must not contain -

(a) a picture of an infant; or
(b) a picture that idealises the use of infant formula product; or
(c) the word 'humanised' or 'maternalised' or any word or words having the same or similar effect; or
(d) words claiming that the formula is suitable for all infants; or
(e) information relating to the nutritional content of human milk; or
(f) subject to clause 28, a reference to the presence of any nutrient or nutritive substance, except for a reference to a nutrient or nutritive substance in -

(i) the name of a lactose free formula or a low lactose formula; or
(ii) a statement of ingredients; or
(iii) a nutrition information statement; or

(g) subject to Division 3, a representation that the food is suitable for a particular condition, disease or disorder.

Editorial Note:

Division 3 relates to Infant Formula Products for Special Dietary Use. Clause 28 permits labelling which varies from this clause.

Division 2 – Infant Formula and Follow-on Formula

21 Composition

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

(a) have an energy content of no less than 2500 kJ/L and no more than 3150 kJ/L in the case of infant formula, and no less than 2500 kJ/L and no more than 3550 kJ/L in the case of follow-on formula; and
(b) contain an amount of each nutrient specified in column 1 of the Table to this clause which is no less than the amount specified in column 2 of the Table and no more than the amount specified in column 3 of the Table.

Table to clause 21

Column 1	Column 2	Column 3
Nutrient	**Minimum amount per 100 kJ**	**Maximum amount per 100 kJ**
Protein	0.45 g	0.7 g for infant formula 1.3 g for follow-on formula
Fat	1.05 g	1.5 g

(2) Follow-on formula must have a potential renal solute load value of no more than 8 mOsm/100 kJ.

22 Protein

(1) The L-amino acids listed in column 1 of the Table to this clause must be present in infant formula and follow-on formula at the minimum level specified in column 2 of the Table, subject to subclause 2 and 3.

Table to clause 22

Column 1	Column 2
L-Amino Acid	**Minimum amount per 100 kJ**
Histidine	12 mg
Isoleucine	21 mg
Leucine	42 mg

Lysine	30 mg
Cysteine & Methionine	19 mg
Phenylalanine & Tyrosine	32 mg
Threonine	19 mg
Tryptophan	7 mg
Valine	25 mg

(2) Infant formula or follow-on formula must provide no less than -

(a) 6 mg cysteine per 100 kJ; and
(b) 17 mg phenylalanine per 100 kJ.

(3) L-amino acids listed in the Table to this clause must be added to infant formula or follow-on formula only in an amount necessary to improve protein quality.

23 Fat

The fats in infant formula and follow-on formula must -

(a) not contain medium chain triglycerides except where a medium chain triglyceride is present in a particular infant formula or follow-on formula as the result of being a natural constituent of a milk-based ingredient of that particular infant formula or follow-on formula; 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) if specified in column 1 of the Table to this clause, comply with the limits, if any, specified in columns 2 and 3 of the Table; and
(d) have a ratio of total long chain omega 6 series fatty acids (C>= 20) to total long chain omega 3 series fatty acids (C>= 20) of approximately 2 in an infant formula or follow-on formula which contains those fatty acids; and
(e) where long chain polyunsaturated fatty acids are present in an infant formula or follow-on formula, an eicosapentaenoic acid (20:5 n-3) content of no more than the docosahexaenoic acid (22:6 n-3) content.

Table to clause 23

Column 1	**Column 2**	**Column 3**
Fatty acids	**Minimum % total fatty acids**	**Maximum % total fatty acids**
Essential fatty acids		
Linoleic acid (18:2)	9	26
α-Linolenic acid (18:3)	1.1	4
Long chain polyunsaturated fatty acids		
Long chain omega 6 series fatty acids (C>= 20)		2
Arachidonic acid (20:4)		1
Long chain omega 3 series fatty acids (C>= 20)		1
Total *trans* fatty acids		4
Erucic acid (22:1)		1

Editorial note:

Standard 1.3.4 contains specifications for Docosahexaenoic acid (DHA) rich oil derived from the algae *Crypthecodinium cohnii* and Arachidonic acid (ARA) rich oil derived from the fungus *Mortierella alpina*.

24 Vitamins and minerals

(1) Infant formula and follow-on formula must contain the vitamins and minerals specified in column 1 of the Table to this subclause provided that, in relation to each vitamin or mineral -

(a) the added vitamin or mineral is in a permitted form as listed in Schedule 1; and

(b) the infant formula or follow-on formula contains no less than the amount specified in column 2 of the Table; and

(c) the infant formula or follow-on formula contains no more than the amount specified in column 3 of the Table, if any.

Table to clause 24(1)

Column 1	Column 2	Column 3
Nutrient	**Minimum amount per 100 kJ**	**Maximum amount per 100 kJ**
Vitamins		
Vitamin A	14 µg	43 µg
Vitamin D	0.25 µg	0.63 µg
Vitamin C	1.7 mg	
Thiamin	10 µg	
Riboflavin	14 µg	
Preformed Niacin	130 µg	
Vitamin B_6	9 µg	36 µg
Folate	2.0 µg	
Pantothenic acid	70 µg	
Vitamin B_{12}	0.025 µg	
Biotin	0.36 µg	
Vitamin E	0.11 mg	1.1 mg
Vitamin K	1.0 µg	
Minerals		
Sodium	5 mg	15 mg
Potassium	20 mg	50 mg
Chloride	12 mg	35 mg
Calcium	12 mg	
Phosphorus	6 mg	25 mg
Magnesium	1.2 mg	4.0 mg
Iron	0.2 mg	0.5 mg
Iodine	1.2 µg	10 µg
Copper	14 µg	43 µg
Zinc	0.12 mg	0.43 mg
Manganese	0.24 µg	24.0 µg
Selenium	0.25 µg	1.19 µg

(2) Infant formula and follow-on formula must contain no less than 0.5 mg of Vitamin E per g of polyunsaturated fatty acids.

(3) The ratio of calcium to phosphorus in infant formula and follow-on formula must be no less than 1.2 to 1 and no more than 2 to 1.

(4) The ratio of zinc to copper -

(a) in infant formula must be no more than 15 to 1; and
(b) in follow-on formula must be no more than 20 to 1.

Editorial note:

This Standard contains guidelines setting out the recommended levels of vitamins and minerals that as a matter of good practice should not be exceeded.

Division 3 - Infant Formula Products for Special Dietary Use

Subdivision 1 – Infant formula products formulated for premature or low birthweight infants

25 Composition and labelling

Infant formula products may be specifically formulated for premature or low birthweight infants provided that in all other respects they comply with this Standard.

26 Additional labelling

(1) The label on a package of pre-term formula must include the warning statement -

'Suitable only for pre-term infants under specialist medical supervision'.

(2) The words 'pre-term' must appear as part of the name of a food standardised in this subdivision.

Subdivision 2 - Infant formula products for metabolic, immunological, renal, hepatic and malabsorptive conditions

27 Composition

(1) Subject to subclause (2), infant formula products may be specifically formulated to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions.

(2) The permission in subclause (1) only applies where the infant formula products comply with –

(a) this Division; and
(b) all the other requirements of this Standard that are not inconsistent with this Division.

(3) Other than for the operation of clause 28, subclause (2) takes effect 5 years after the commencement of this Standard.

28 Claims

Where a label contains a claim that the infant formula product is suitable for infants with metabolic, immunological, renal, hepatic or malabsorptive conditions, then the label on the package of infant formula product must include a statement indicating -

(a) that the product is not suitable for general use and should be used under medical supervision; and
(b) the condition, disease or disorder for which the food has been specially formulated; and
(c) the nutritional modifications, if any, which have been made to the infant formula product.

29 Composition of lactose free and low lactose formulas

(1) A lactose free formula or low lactose formula must, except for the lactose content, comply with the compositional and labelling requirements which apply to the infant formula product of which they are a variety.

(2) Lactose free formula must contain no detectable lactose.

(3) Low lactose formula must contain no more than 0.3 g lactose per 100 mL of infant formula product.

30 Claims relating to lactose free and low lactose formulas

Where a label contains a claim that the infant formula product is lactose free, low lactose or words of similar import, the label on a package of lactose free or a low lactose formula product must include -

(a) the words ‘lactose free' as part of the name of lactose free formula; and
(b) the words ‘low lactose' as part of the name of low lactose formula; and
(c) the following statements -

(i) the amount of lactose expressed in g per 100 mL; and
(ii) the amount of galactose expressed in g per 100 mL.

Subdivision 3 - Infant formula products for specific dietary use based upon protein substitutes

31 Composition

An infant formula product for specific dietary use based upon protein substitutes must -

(a) have an energy content of no less than 2500 kJ/L and no more than 3150 kJ/L in the case of infant formula, and no less than 2500 kJ/L and no more than 3550 kJ/L in the case of follow-on formula; and
(b) have a potential renal solute load of no more than 8 mOsm per 100 kJ; and

(c) contain an amount of each nutrient specified in column 1 of the Table to this clause which is no less than the amount specified in column 2 of the Table and no more than the amount specified in column 3 of the Table.

Table to clause 31

Column 1	Column 2	Column 3
Nutrient	**Minimum amount per 100 kJ**	**Maximum amount per 100 kJ**
Protein	0.45 g	1.4 g
Fat	0.93 g	1.5 g

32 Protein

(1) The protein content of an infant formula product for specific dietary use based upon protein substitutes may be in the form of protein substitute.

(2) The L-amino acids listed in column 1 of the Table to this clause must be present in infant formula product for special dietary use at the minimum level specified in column 2 of the Table, subject to subclause 3 and 4.

Table to clause 32

Column 1	Column 2
L-Amino Acid	**Min amount per 100 kJ**
Histidine	12 mg
Isoleucine	21 mg
Leucine	42 mg
Lysine	30 mg
Cysteine & Methionine	19 mg
Phenylalanine & Tyrosine	32 mg
Threonine	19 mg
Tryptophan	7 mg
Valine	25 mg

(3) Infant formula product for specific dietary use based upon protein substitutes must provide no less than -

(a) 6 mg cysteine per 100 kJ; and
(b) 17 mg phenylalanine per 100 kJ.

(4) L-amino acids listed in the Table to this clause must be added to infant formula product for specific dietary use base upon protein substitutes only in an amount necessary to improve protein quality.

33 Vitamins and minerals

An infant formula product for specific dietary use based upon protein substitutes must contain -

(a) chromium in an amount of no less than 0.35 µg per 100 kJ and no more than 2.0 µg per 100 kJ; and

(b) molybdenum in an amount of no less than 0.36 μg per 100 kJ and no more than 3.0 μg per 100 kJ.

Editorial note:

The provisions of clause 24 of this Standard also apply in respect of the vitamins and minerals permitted in an infant formula product for specific dietary use based upon protein substitutes.

34 Additional permitted triglycerides

An infant formula product for specific dietary use based upon protein substitutes may contain added medium chain triglycerides.

SCHEDULE 1

PERMITTED FORMS OF VITAMINS AND MINERALS IN INFANT FORMULA PRODUCTS

Column 1 Vitamins or minerals	Column 2 Permitted Forms
Vitamin A	Retinol Forms vitamin A (retinol) vitamin A acetate (retinyl acetate) vitamin A palmitate (retinyl palmitate) retinyl propionate Carotenoid 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
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) phytylmenoquinone
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
Iodine	potassium iodate potassium iodide sodium iodide
Iron	ferric ammonium citrate ferric pyrophosphate 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
Manganese	manganese chloride manganese gluconate manganese sulphate manganese carbonate manganese citrate
Molybdenum	sodium molybdate VI dehydrate
Phosphorus	calcium glycerophosphate calcium phosphate, dibasic calcium phosphate, monobasic calcium phosphate, tribasic magnesium phosphate, dibasic potassium phosphate, dibasic potassium phosphate, monobasic potassium phosphate, tribasic

Potassium	sodium phosphate, dibasic sodium phosphate, monobasic sodium phosphate, tribasic potassium bicarbonate potassium carbonate potassium chloride potassium citrate potassium glycerophosphate potassium gluconate potassium hydroxide potassium phosphate, dibasic potassium phosphate, monobasic potassium phosphate, tribasic
Selenium	sodium selenite seleno methionine
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 gluconate zinc oxide zinc sulphate

GUIDELINES FOR INFANT FORMULA PRODUCTS
(These guidelines are not part of the legally binding Standard)

Guideline for maximum amount of vitamins and minerals in infant formula products

It is recommended that the quantities specified in the table below be observed as the maximum levels of vitamins and minerals in infant formula product.

Nutrient	Recommended maximum amount per 100 kJ
Vitamins	
Vitamin C	5.4 mg
Thiamin	48 µg
Riboflavin	86 µg
Preformed Niacin	480 µg
Folate	8.0 µg
Pantothenic acid	360 µg
Vitamin B_{12}	0.17 µg
Vitamin K	5.0 µg
Biotin	2.7 µg
Minerals	
Calcium	33 mg
Phosphorus	22 mg
Manganese	7.2 µg for infant formula products regulated by Division 3, Subdivision 2 only
Chromium	2.0 µg
Molybdenum	3 µg

Guideline on advice regarding additional vitamin and mineral supplementation

Manufacturers are recommended to provide an advice in the label on a package of infant formula product to the effect that consumption of vitamin or mineral preparations are not necessary.

Nutrition information table

The nutrition information contained in the label on a package of infant formula product is recommended in the following format -

NUTRITION INFORMATION

	Average amount per 100 mL made up formula *1	**Average amount per 100 g of powder (or per 100 mL for liquid concentrate)** *2
Energy	kJ	kJ
Protein	g	g
Fat	g	g
Carbohydrate	g	g

Vitamin A	µg	µg
Vitamin B_6	µg	µg
Vitamin B_{12}	µg	µg
Vitamin C	mg	mg
Vitamin D	µg	µg
Vitamin E	µg	µg
Vitamin K	µg	µg
Biotin	µg	µg
Niacin	mg	mg
Folate	µg	µg
Pantothenic acid	µg	µg
Riboflavin	µg	µg
Thiamin	µg	µg
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
(insert any other nutritive substance to be declared)	g, mg, µg	g, mg, µg

***1** – Delete the words 'made up formula' in the case of formulas sold in 'ready to drink' form.
***2** – Delete this column in the case of formulas sold in 'ready to drink' form.

Note: The information in column 2 is not mandatory.

[5] *omitting from the* Table of Contents *of Volume 2 the following –*

Standard 2.9.1 Reserved (Infant Formula Products)

substituting –

Standard 2.9.1 Infant Formula Products