

**Supporting document 1**

Regulation of Infant Formula Products in the *Australia New Zealand Food Standards Code*

**Composition comparison tables**

Table 3.1 Compositional requirements for infant formula and follow-on formula as prescribed in the *Australia New Zealand Food Standards Code* and Codex infant formula standard and Codex follow-up formula standard: Energy and macronutrients

| **Requirement** | **Units** | **Infant formula** | **Follow-on formula** |
| --- | --- | --- | --- |
| **Food Standards Code****(Standard 2.9.1)** | **Codex\*****(STAN 72-1981)** | **Food Standards Code****(Standard 2.9.1)** | **Codex^****(STAN 156-1987)** |
| **Minimum** | **Maximum** | **Minimum** | **Maximum** | **Minimum** | **Maximum** | **Minimum** | **Maximum** |
| **ENERGY** | kJ/L | 2500 | 3150 | 2500 | 2950 | 2500 | 3550 | 2500 | 3550 |
| **PROTEIN** | g/100 kJ | 0.45 | 0.7 | 0.45 | 0.7 | 0.45 | 1.3 | 0.7 | 1.3 |
| **Nitrogen conversion factor:** |  |
| Milk proteins and their partial protein hydrolysates |  | 6.38 | 6.25 | 6.38 | 6.25 |
| In any other cases |  | 6.25 | 6.25 | 6.25 | 6.25 |
| **L-amino acids:** |  |
| Histidine | mg/100 kJ | 12 | Protein quality regulated by minimum amino acid levels  | 10 | * Protein quality regulated by amino acid levels (based on breast milk reference).
* Can only be added in amounts necessary to improve protein quality
 | 12 | Can only be added in amounts necessary to improve protein quality | * Protein quality shall not be less than 85% of that of casein.
* Protein quality determined provisionally using the PER method
* Essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose.
 |
| Isoleucine | mg/100 kJ | 21 | 22 | 21 |
| Leucine | mg/100 kJ | 42 | 40 | 42 |
| Lysine | mg/100 kJ | 30 | 27 | 30 |
| Cysteine and cystine | mg/100 kJ | * 19 total
* no less than 6 mg/100kJ of cysteine, cystine or combined cysteine, cystine
 | 9 | •19 total •no less than 6 mg/100kJ of cysteine, cystine or combined cysteine, cystine |
| Methionine | mg/100 kJ | 6methionine and cysteine concentration may be added together if the ratio is less than 2:1 |
| Phenylalanine | mg/100 kJ | * 32 total
* no less than 17 mg/100kJ phenylalanine
 | 19 | * 32 total
* no less than 17 mg/100kJ phenylalanine
 |
| Tyrosine | mg/100 kJ | 18concentrations of tyrosine and phenylalanine may be added together |
| Threonine | mg/100 kJ | 19 | 18 | 19 |
| Tryptophan | mg/100 kJ | 7 | 8 | 7 |
| Valine | mg/100 kJ | 25 | 22 | 25 |
| **Potential renal solute load** | mOsm/100 kJ | NS | NS |  | 8 | NS |
| **FAT** | g/100 kJ | 1.05 | 1.5 | 1.05 | 1.4 | 1.05 | 1.5 | 0.7 | 1.4 |
| **Essential fatty acids** |
| Linoleic acid (18:2) | % total FAs | 9 | 26 | - | - | 9 | 26 | - | - |
| mg/100 kJ | - | - | 70 | 330 (GUL) | - | - | 72 | NS |
| α-Linolenic acid (18:3) | % total FAs | 1.1 | 4 | - | - | 1.1 | 4 | - | - |
| mg/100 kJ | - | - | 12 | NS | - | - | NS | NS |
| Ratio 18:2 to 18:3 |  | 5:1 | 15:1 | 5:1 | 15:1 | 5:1 | 15:1 | - | - |
| **Other fatty acids:** |
| Long chain ω-6 series fatty acids (C≥20) | % total FAs | NS | 2 | At least 1:1 DAH:AA | - | NS | 2 | NS |
| Arachidonic acid (20:4) | % total FAs | NS | 1 | - | - | NS | 1 | NS |
| Long chain ω-3 series fatty acids (C≥20) | % total FAs | NS | 1 | - | - | NS | 1 | NS |
| Ratio long chain ω-6 to ω-3 fatty acids (C≥20) |  | 1:1 | NS | - | - | 1:1 | NS | NS |
| EPA and DHA |  | EPA≤DHA | - | EPA≤DHA | - | EPA≤DHA | - | NS |
| Total trans fatty acids | % total FAs | NS | 4 | NS | 3 | NS | 4 | NS |
| Erucic acid (22:1) | % total FAs | NS | 1 | NS | 1 | NS | 1 | NS |
| Lauric (12:0) and myristic acids (14:0) | % total FAs | NS | NS | 20 | NS | NS |
| **Phospholipids** | mg/100 kJ | NS | NS | 72 | NS | NS |
| **Medium chain triglycerides** (which contain predominantly the saturated fatty acids designated by 8:0 and 10:0) |  | Must not contain except where present as the result of being: (a) a natural constituent of a milk-based ingredient of that particular formula; or (b) a processing aid used in preparations of permitted fat soluble vitamins. | - | Must not contain except where present as the result of being:(a) a natural constituent of a milk-based ingredient of that particular formula; or (b) a processing aid used in preparations of permitted fat soluble vitamins. | - |
| **Commercially hydrogenated oils and fats** |  | NS | Must not be added | NS |  |
| **CARBOHYDRATE** | g/100 kJ | NS | 2.2 | 3.3 | NS | NS |
| **Conditions for carbohydrates** |  | NS | * Lactose; and glucose polymers are the preferred carbohydrate in formula based on cow’s milk protein and hydrolysed protein.
* Only precooked and/or gelatinised starches gluten-free by nature may be added: up to 30% of total carbohydrates and up to 2 g/100 mL.
* sucrose and fructose should be avoided.
 | NS |  |

Notes:

Shaded cells in this table indicate that the substance is listed as part of the essential composition

\*STAN 72-1981 (Revision 2007; Amendment 2011)

^STAN 156-1987 (Amendment 1989, 2011)

NS = none specified

GUL = guidance upper level

FAs = fatty acids

EPA = eicosapentaenoic acid (20:5 n-3)

DHA = docosahexaenoic acid (22:6 n-3)

RE = retinol equivalents

α-TE = alpha-tocopherol

PUFAs = polyunsaturated fatty acids

NATD = National authorities may need to be determined levels

Table 3.2 Compositional requirements for infant formula and follow-on formula as prescribed in the *Australia New Zealand Food Standards Code* and Codex infant formula standard and Codex follow-up formula standard: Vitamins and Minerals

| **Substance** | **Units** | **Infant formula** | **Follow-on formula** |
| --- | --- | --- | --- |
| **Food Standards Code****(Standard 2.9.1)** | **Codex\*****(STAN 72-1981)** | **Food Standards Code****(Standard 2.9.1)** | **Codex^****(STAN 156-1987)** |
| **Minimum** | **Maximum** | **Minimum** | **Maximum** | **Minimum** | **Maximum** | **Minimum** | **Maximum** |
| **Vitamins** |  |
| Vitamin A (RE)  | µg/100 kJ | 14 | 43 | 14 | 43 | 14 | 43 | 18 | 54 |
| Vitamin D | µg/100 kJ | 0.25 | 0.63 | 0.25 | 0.6 | 0.25 | 0.63 | 0.25 | 0.75 |
| Vitamin E (α-TE) | mg/100 kJ | 0.11 | 1.1 | 0.12 | 1.2 (GUL) | 0.11 | 1.1 | NS | NS |
| mg/g PUFAs | 0.5 | NS | - | - | 0.5 | NS | - | - |
| IU/g linoleic | - | - | - | - | - | - | 0.7 | NS |
| IU/100 kJ | - | - | - | - | - | - | 0.15 | NS |
| Vitamin K | µg/100 kJ | 1 | 5.0 (GUL) | 1 | 6.5 (GUL) | 1 | 5.0 (GUL) | 1 | NS |
| Thiamin | µg/100 kJ | 10 | 48 (GUL) | 14 | 72 (GUL) | 10 | 48 (GUL) | 10 | NS |
| Riboflavin | µg/100 kJ | 14 | 86 (GUL) | 19 | 119 (GUL) | 14 | 86 (GUL) | 14 | NS |
| Niacin | µg NE/100 kJ | 130 | 480 (GUL) | 70 | 360 (GUL) | 130 | 480 (GUL) | 60 | NS |
| Vitamin B6 | µg/100 kJ | 9 | 36 | 8.5 | 45 (GUL) | 9 | 36 | 11 | NS |
| Vitamin B12 | µg/100 kJ | 0.025 | 0.17 (GUL) | 0.025 | 0.36 (GUL) | 0.025 | 0.17 (GUL) | 0.04 | NS |
| Pantothenic Acid | µg/100 kJ | 70 | 360 (GUL) | 96 | 478 (GUL) | 70 | 360 (GUL) | 70 | NS |
| Folate/folic acid | µg/100 kJ | 2 | 8 (GUL) | 2.5 | 12 (GUL) | 2 | 8 (GUL) | 1 | NS |
| Vitamin C  | mg/100 kJ | 1.7 | 5.4 (GUL) | 2.5 | 17 (GUL) | 1.7 | 5.4 (GUL) | 1.9 | NS |
| Biotin | µg/100 kJ | 0.36 | 2.7 (GUL) | 0.4 | 2.4 (GUL) | 0.36 | 2.7 (GUL) | 0.4 | NS |
| **Minerals** |  |
| Iron | mg/100 kJ | 0.2 | 0.5 | 0.1 | TBD | 0.2 | 0.5 | 0.25 | 0.5 |
| Calcium | mg/100 kJ | 12 | 33 (GUL) | 12 | 35 (GUL) | 12 | 33 (GUL) | 22 | NS |
| Phosphorus | mg/100 kJ | 6 | 25 | 6 | 24 (GUL) | 6 | 25 | 14 | NS |
| Magnesium | mg/100 kJ | 1.2 | 4.0 | 1.2 | 3.6 (GUL) | 1.2 | 4.0 | 1.4 | NS |
| Sodium | mg/100 kJ | 5 | 15 | 5 | 14 | 5 | 15 | 5 | 21 |
| Chloride | mg/100 kJ | 12 | 35 | 12 | 38 | 12 | 35 | 14 | NS |
| Potassium | mg/100 kJ | 20 | 50 | 14 | 43 | 20 | 50 | 20 | NS |
| Manganese | µg/100 kJ | 0.24 | 24 | 0.25 | 24 (GUL) | 0.24 | 24 | NS | NS |
| Iodine | µg/100 kJ | 1.2 | 10 | 2.5 | 14 (GUL) | 1.2 | 10 | 1.2 | NS |
| Selenium | µg/100 kJ | 0.25 | 1.19 | 0.24 | 2.2 (GUL) | 0.25 | 1.19 | NS | NS |
| Copper | µg/100 kJ | 14 | 43 | 8.5 | 29 (GUL) | 14 | 43 | NS | NS |
| Zinc | mg/100 kJ | 0.12 | 0.43 | 0.12 | 0.36 (GUL) | 0.12 | 0.43 | 0.12 | NS |
| **Ratios** |  |
| Calcium to phosphorus |  | 1.2:1 | 2:1 | 1:1 | 2:1 | 1.2:1 | 2:1 |  |  |
| Zinc to copper |  | NS | 15:1 |  |  | NS | 20:1 |  |  |

Notes: Shaded cells in this table indicate that the substance is listed as part of the essential composition,\*STAN 72-1981 (Revision 2007; Amendment 2011), ^STAN 156-1987 (Amendment 1989, 2011), NS = none specified, GUL = guidance upper level, RE = retinol equivalents, α-TE = alpha-tocopherol equivalents

Table 3.3 Compositional requirements for infant formula and follow-on formula as prescribed in the *Australia New Zealand Food Standards Code* and Codex infant formula standard and Codex follow-up formula standard: other substances

| **Substance** | **Units** | **Infant formula** | **Follow-on formula** |
| --- | --- | --- | --- |
| **Food Standards Code****(Standard 2.9.1)** | **Codex****(STAN 72-1981)** | **Food Standards Code****(Standard 2.9.1)** | **Codex****(STAN 156-1987)** |
| **Minimum** | **Maximum** | **Minimum** | **Maximum** | **Minimum** | **Maximum** | **Minimum** | **Maximum** |
| **OTHER NUTRITIVE SUBSTANCES** |
| Choline | mg/100 kJ | 1.7 | 7.1 | 1.7 | 12 (GUL) | 1.7 | 7.1 | NS | NS |
| Inositol | mg/100 kJ | 1 | 9.5 | 1 | 9.5 (GUL) | 1 | 9.5 | NS | NS |
| L-carnitine | mg/100 kJ | 0.21 | 0.8 | 0.3 | NS | 0.21 | 0.8 | NS | NS |
| Adenosine 5’-monophosphate | mg/100 kJ | 0.14 | 0.38 | NATD | NATD | 0.14 | 0.38 | NS | NS |
| Cytidine 5’-monophosphate | mg/100 kJ | 0.22 | 0.6 | NATD | NATD | 0.22 | 0.6 | NS | NS |
| Guanosine 5’monophophate | mg/100 kJ | 0.04 | 0.12 | NATD | NATD | 0.04 | 0.12 | NS | NS |
| Inosine 5’monophosphate | mg/100 kJ | 0.08 | 0.24 | NATD | NATD | 0.08 | 0.24 | NS | NS |
| Lutein | µg/100 kJ | 1.5 | 5 | - | - | 1.5 | 5 | NS | NS |
| Taurine | mg/100 kJ | 0.8 | 3 | NS | 3 | 0.8 | 3 | NS | NS |
| Uridine 5’monophosphate | mg/100 kJ | 0.13 | 0.42 | NATD | NATD | 0.13 | 0.42 | NS | NS |
| Limit on nucleotide 5’monophosphates | mg/100 kJ | NS | 3.8 | NATD | NATD | NS | 3.8 | NS | NS |
| **OTHER SUBSTANCES** |  |
| L(+) lactic acid cultures |  | May be added | May be added | May be added | NS | NS |
| Inulin-derived substances and galacto-oligosaccharides: |  |
| Inulin-derived substances | mg/100 kJ | NS | 110 | NS | NS | NS | 110 | NS | NS |
| Galacto-oligosaccharides | mg/100 kJ | NS | 290 | NS | NS | NS | 290 | NS | NS |
| Combined (maximum inulin-derived) | mg/100 kJ | NS | 290 (110) | NS | NS | NS | 290 (110) | NS | NS |
| Fluoride | µg/100 kJ | * No maximum specified
* Statement on dental fluorosis required if product contains:

(a) more than 17 µg/100 kJ prior to reconstitution, powdered or concentrated infant formula product; or (b) more than 0.15 mg/100mL in ‘ready to drink’ formula. | * Should not be added.
* Level should not exceed 24 µg/100 kJ in formula prepared ready for consumption as recommended by the manufacturer.
 | * No maximum specified
* Statement on dental fluorosis required if product contains:

(a) more than 17 µg/100 kJ prior to reconstitution, powdered or concentrated infant formula product; or (b) more than 0.15 mg/100mL in ‘ready to drink’ formula. |  |  |

Notes: Shaded cells in this table indicate that the substance is listed as part of the essential composition, \*STAN 72-1981 (Revision 2007; Amendment 2011), ^STAN 156-1987 (Amendment 1989, 2011), NS = none specified, NATD = National authorities may need to be determined levels.

**Table 3.4: Forms of nutrients permitted for use in infant formula products under Codex guideline CAC/GL 10-1979 compared to permissions in the Code**

| **Nutrient** | **Infant formula and follow-up formula: forms listed by Codex1 not listed in Standard 2.9.1** | **IFSDU: forms listed by Codex2 not listed in Standard 2.9.1** | **Forms listed in Standard 2.9.1 not identified for use by Codex3** |
| --- | --- | --- | --- |
| **Chromium** |  |  | chromium sulphate |
| **Copper** | cupric carbonate | cupric carbonate |  |
| **Folate** | calcium–L-methyl-folate | calcium–L-methyl-folate |  |
| **Iodine** |  | sodium iodate |  |
| **Iron** | ferric citrateferrous bisglycinate | ferrous carbonateferric citratehydrogen reduced ironelectrolyte ironcarbonyl ironferric saccharatesodium ferric diphosphateferrous bisglycinate |  |
| **Magnesium** | magnesium hydroxidemagnesium hydroxide carbonatemagnesium salts of citric acid | magnesium glycerolphosphatemagnesium lactatemagnesium acetatemagnesium hydroxidemagnesium hydroxide carbonatemagnesium salts of citric acid |  |
| **Manganese** |  | manganese glycerophosphate II |  |
| **Niacin** | nicotinic acid | nicotinic acid |  |
| **Pantothenic acid** | sodium D-pantothenateDL-pantathenol | sodium D-pantothenateDL-pantathenol |  |
| **Potassium** | potassium L-lactate | potassium L-lactate |  |
| **Selenium** |  | sodium hydrogen selenite | seleno methionine |
| **Vitamin A** |  |  | retinyl propionate |
| **Vitamin D** |  |  | vitamin D (cholecalciferol-cholesterol) |
| **Vitamin E** | d-α-tocopherol  | d-α-tocopherol dl-α-tocopherol-polyethylene glycol 1000 succinate | d-α-tocopherol acid succinatedl-α-tocopherol succinated-α-tocopherol tocopherols concentrate, mixed |
| **Vitamin K** |  |  | phytylmenoquinone |
| **Zinc** | zinc lactate | zinc lactatezinc carbonate |  |

Notes:

1 - Refers to STAN 72-1981 (Revision 2007; Amendment 2011) and STAN 156-1987 (Amendment 1989, 2011)

2 - Refers to STAN 72-1981 (Revision 2007; Amendment 2011)

3 - Refers STAN 72-1981 (Revision 2007; Amendment 2011) and STAN 156-1987 (Amendment 1989, 2011

**Table 3.5. Differences in food additive permissions for infant formula in the Code compared to Codex infant formula standard**

| Food additive | INS | Standard 1.3.1mg/l | CodexSTAN 72-1981 mg/l |
| --- | --- | --- | --- |
| **Infant formula products** |
| Lecithin | 322 | 5000 | 50002 |
| Guar gum | 412 | 1000 | 10003 |
| Calcium hydroxide | 526 | GMP | 2004 |
| Sodium hydroxide | 524 |  | 2004 |
| Sodium hydrogen carbonate | 500ii |  | 2004 |
| Sodium carbonate | 500i |  | 2004 |
| Potassium hydroxide | 525 |  | 2004 |
| Potassium hydrogen carbonate | 501ii |  | 2004 |
| Potassium carbonate | 501i |  | 2004 |
| **Soy-based infant formula** |
| Distarch phosphate | 1412 | 5000 | 50005 |
| Phosphated distarch phosphate | 1413 | 50001 | 50005 |
| Acetylated distarch phosphate | 1414 | 50001 | 50005 |
| Hydroxylpropyl starch | 1440 | 250001 | 50005 |
| Carrageenan |  |  | 3006 |
| **Liquid infant formula products** |
| Carrageenan | 407 | 300 | 3006 |
| **Liquid formula products for specific dietary use based on protein substitutes** |
| Mono- and diglycerides of fatty acids | 471 | 5000 | - |
| Citric and fatty acid esters of glycerol | 472c | 9000 | - |
| Diacetyltartaric and fatty acid esters of glycerol | 472e | 400 | - |
| Distarch phosphate | 1412 | 25000 | 250007 |
| Phosphated distarch phosphate | 1413 | 250001 | 250007 |
| Acetylated distarch phosphate | 1414 | 250001 | 250007 |
| Hydroxylpropyl starch | 1440 | 250001 | 250007 |

**Notes:**

1. Clause 6 (1) of Standard 1.3.1 applies, meaning can be used singling or in combination but the sum of the proportion of these additives in the food must not be greater than 1. .
2. From Codex STAN 72-1981: If more than one of the substances INS 322, 471 are added the maximum level for each of those substances is lowered with the relative part as present of the other substances (comparable to clause 6 of Standard 1.3.1 of the Code)
3. For liquid formulas containing hydrolysed protein
4. Singly or in combination and within the limits for sodium, potassium and calcium in section 3.1.3 (e) of the Standard (STAN 72-1981) in all types of infant formula
5. Singly or in combination in soy-based infant formula only
6. Regular milk and soy-based liquid infant formula only. JECFA evaluation pending; was not endorsed at 39th session of CCFA (2007)
7. Singly or in combination in hydrolyzed protein- and/or amino acid based infant formula only