

## 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
<b>ENERGY</b>	kJ/L	2500	3150	2500	2950	2500	3550	2500	3550
<b>PROTEIN</b>	g/100 kJ	0.45	0.7	0.45	0.7	0.45	1.3	0.7	1.3
<b>Nitrogen conversion factor:</b>									
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	
<b>L-amino acids:</b>									
Histidine	mg/100 kJ	12	Protein quality regulated by minimum amino acid levels	10	<ul style="list-style-type: none"> <li>Protein quality regulated by amino acid levels (based on breast milk reference).</li> <li>Can only be added in amounts necessary to improve protein quality</li> </ul>	12	Can only be added in amounts necessary to improve protein quality	<ul style="list-style-type: none"> <li>Protein quality shall not be less than 85% of that of casein.</li> <li>Protein quality determined provisionally using the PER method</li> <li>Essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose</li> </ul>	
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	<ul style="list-style-type: none"> <li>19 total</li> <li>no less than 6 mg/100kJ of cysteine, cystine or combined cysteine, cystine</li> </ul>		9		<ul style="list-style-type: none"> <li>19 total</li> <li>no less than 6 mg/100kJ of cysteine, cystine or combined cysteine, cystine</li> </ul>			
Methionine	mg/100 kJ			6					6

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	
Phenylalanine	mg/100 kJ	<ul style="list-style-type: none"> <li>• 32 total</li> <li>• no less than 17 mg/100kJ phenylalanine</li> </ul>		19		<ul style="list-style-type: none"> <li>• 32 total</li> <li>• no less than 17 mg/100kJ phenylalanine</li> </ul>				
Tyrosine	mg/100 kJ			18						concentrations of tyrosine and phenylalanine may be added together
Threonine	mg/100 kJ			19						18
Tryptophan	mg/100 kJ			7						8
Valine	mg/100 kJ			25						22
<b>Potential renal solute load</b>	mOsm/100 kJ	NS		NS		8		NS		
<b>FAT</b>	g/100 kJ	1.05	1.5	1.05	1.4	1.05	1.5	0.7	1.4	
<b>Essential fatty acids</b>										
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	-	-	
<b>Other fatty acids:</b>										
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		
<b>Phospholipids</b>	mg/100 kJ	NS		NS	72	NS		NS		

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
<b>Medium chain triglycerides</b> (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.		-	
<b>Commercially hydrogenated oils and fats</b>		NS		Must not be added		NS			
<b>CARBOHYDRATE</b>	g/100 kJ	NS		2.2	3.3	NS		NS	
<b>Conditions for carbohydrates</b>		NS		<ul style="list-style-type: none"> <li>Lactose; and glucose polymers are the preferred carbohydrate in formula based on cow's milk protein and hydrolysed protein.</li> <li>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.</li> <li>sucrose and fructose should be avoided.</li> </ul>		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
<b>Vitamins</b>									
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 B <sub>6</sub>	µg/100 kJ	9	36	8.5	45 (GUL)	9	36	11	NS
Vitamin B <sub>12</sub>	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
<b>Minerals</b>									
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
<b>Ratios</b>									
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
<b>OTHER NUTRITIVE SUBSTANCES</b>									
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'-monophosphate	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
<b>OTHER SUBSTANCES</b>									
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	<ul style="list-style-type: none"> <li>No maximum specified</li> <li>Statement on dental fluorosis required if product contains:                             <ul style="list-style-type: none"> <li>(a) more than 17 µg/100 kJ prior to reconstitution, powdered or concentrated infant formula product; or</li> <li>(b) more than 0.15 mg/100mL in 'ready to drink' formula.</li> </ul> </li> </ul>		<ul style="list-style-type: none"> <li>Should not be added.</li> <li>Level should not exceed 24 µg/100 kJ in formula prepared ready for consumption as recommended by the manufacturer.</li> </ul>		<ul style="list-style-type: none"> <li>No maximum specified</li> <li>Statement on dental fluorosis required if product contains:                             <ul style="list-style-type: none"> <li>(a) more than 17 µg/100 kJ prior to reconstitution, powdered or concentrated infant formula product; or</li> <li>(b) more than 0.15 mg/100mL in 'ready to drink' formula.</li> </ul> </li> </ul>			

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 Codex <sup>1</sup> <u>not</u> listed in Standard 2.9.1	IFSDU: forms listed by Codex <sup>2</sup> <u>not</u> listed in Standard 2.9.1	Forms listed in Standard 2.9.1 <u>not</u> identified for use by Codex <sup>3</sup>
<b>Chromium</b>			chromium sulphate
<b>Copper</b>	cupric carbonate	cupric carbonate	
<b>Folate</b>	calcium–L-methyl-folate	calcium–L-methyl-folate	
<b>Iodine</b>		sodium iodate	
<b>Iron</b>	ferric citrate ferrous bisglycinate	ferrous carbonate ferric citrate hydrogen reduced iron electrolyte iron carbonyl iron ferric saccharate sodium ferric diphosphate ferrous bisglycinate	
<b>Magnesium</b>	magnesium hydroxide magnesium hydroxide carbonate magnesium salts of citric acid	magnesium glycerolphosphate magnesium lactate magnesium acetate magnesium hydroxide magnesium hydroxide carbonate magnesium salts of citric acid	
<b>Manganese</b>		manganese glycerophosphate II	
<b>Niacin</b>	nicotinic acid	nicotinic acid	
<b>Pantothenic acid</b>	sodium D-pantothenate DL-pantathenol	sodium D-pantothenate DL-pantathenol	
<b>Potassium</b>	potassium L-lactate	potassium L-lactate	
<b>Selenium</b>		sodium hydrogen selenite	seleno methionine
<b>Vitamin A</b>			retinyl propionate
<b>Vitamin D</b>			vitamin D (cholecalciferol-cholesterol)
<b>Vitamin E</b>	d-α-tocopherol	d-α-tocopherol dl-α-tocopherol-polyethylene glycol 1000 succinate	d-α-tocopherol acid succinate dl-α-tocopherol succinate d-α-tocopherol tocopherols concentrate, mixed
<b>Vitamin K</b>			phytylmenoaquinone
<b>Zinc</b>	zinc lactate	zinc lactate zinc 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 1.3.1 mg/l	Codex STAN 72-1981 mg/l
<b>Infant formula products</b>			
Lecithin	322	5000	5000 <sup>2</sup>
Guar gum	412	1000	1000 <sup>3</sup>
Calcium hydroxide	526	GMP	200 <sup>4</sup>
Sodium hydroxide	524		200 <sup>4</sup>
Sodium hydrogen carbonate	500ii		200 <sup>4</sup>
Sodium carbonate	500i		200 <sup>4</sup>
Potassium hydroxide	525		200 <sup>4</sup>
Potassium hydrogen carbonate	501ii		200 <sup>4</sup>
Potassium carbonate	501i		200 <sup>4</sup>
<b>Soy-based infant formula</b>			
Distarch phosphate	1412	5000	5000 <sup>5</sup>
Phosphated distarch phosphate	1413	5000 <sup>1</sup>	5000 <sup>5</sup>
Acetylated distarch phosphate	1414	5000 <sup>1</sup>	5000 <sup>5</sup>
Hydroxypropyl starch	1440	25000 <sup>1</sup>	5000 <sup>5</sup>
Carrageenan			300 <sup>6</sup>
<b>Liquid infant formula products</b>			
Carrageenan	407	300	300 <sup>6</sup>
<b>Liquid formula products for specific dietary use based on protein substitutes</b>			
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	25000 <sup>7</sup>
Phosphated distarch phosphate	1413	25000 <sup>1</sup>	25000 <sup>7</sup>
Acetylated distarch phosphate	1414	25000 <sup>1</sup>	25000 <sup>7</sup>
Hydroxypropyl starch	1440	25000 <sup>1</sup>	25000 <sup>7</sup>

**Notes:**

1. Clause 6 (1) of Standard 1.3.1 applies, meaning can be used singly 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 39<sup>th</sup> session of CCFA (2007)
7. Singly or in combination in hydrolyzed protein- and/or amino acid based infant formula only