**L.N. 249 of 1998**

# FOOD, DRUGS AND DRINKING WATER ACT (CAP. 231)

## Infant Formulae and Follow-on Formulae Regulations, 1998

IN exercise of the powers conferred by section 12 of the Food, Drugs and Drinking Water Act, the Minister of Health, on the advice of the Malta Standardisation Authority, has made the following regulations:

Citation and commencement.

**1.** (1) These regulations may be cited as the Infant Formulae and Follow-on Formulae Regulations, 1998.

(2) These regulations shall come into force on the 1st January, 1999.

Applicability of these regulations.

**2.** These regulations concern compositional and labelling requirements for infant formulae and follow-on formulae intended for use by infants in good health.

Interpretation.

**3.** In these regulations, unless the context otherwise requires:

(a) "infants" means children under the age of twelve months;

(b) "young children" means children aged between one and three years;

(c) "infant formulae" means foodstuffs intended for particular nutritional use by infants during the first four to six months of life and satisfying by themselves the nutritional requirements of this category of persons;

(d) "follow-on formulae" means foodstuffs intended for particular nutritional use by infants aged over four months and constituting the principal liquid element in a progressively diversified diet of this category of persons.

Sale of infant formulae and follow-on formulae.

**4.** (1) No person may import, keep, manufacture, sell or otherwise distribute any infant formula or follow-on formula which does not comply with the requirements of these regulations.

(2) No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first four to six months of life.

Manufacture of infant formulae and follow-on formulae.

**5.** (1) Infant formulae shall be manufactured from protein sources defined in the Schedules to these regulations and other food ingredients, as the case may be, whose suitability for particular nutritional use by infants from birth has been established by generally accepted scientific data.

(2) Follow-on formulae shall be manufactured from protein sources defined in the Schedules to these regulations and other food ingredients, as the case may be, whose suitability for particular nutritional use by infants aged over four months has been established by generally accepted scientific data.

(3) The prohibitions and limitations on the use of food ingredients laid down in the First and Second Schedules shall be observed.

Compositional criteria.

**6.** (1) Infant formulae must comply with the compositional criteria specified in the First Schedule.

(2) Follow-on formulae must comply with the compositional criteria specified in the Second Schedule.

(3) In order to make infant formulae and follow-on formulae ready for use, nothing more shall be required, as the case may be, than the addition of water.

(4) Only the substances listed in the Third Schedule may be used in the manufacture of infant formulae and follow-on formulae in order to satisfy the requirements on:

* mineral substances,
* vitamins,
* amino acids and other nitrogen compounds,
* other substances having a particular nutritional purpose.

(5) Infant formulae and follow-on formulae shall not contain any substance or microbiological agent in such quantity as to endanger the health of infants and young children.

Labelling and presentation of infant formulae and follow-on formulae.

7. (1) The name under which the products covered by subparagraphs (c) and (d) of paragraph (1) of regulation 3 are sold shall be, respectively:

* "infant formula" and "follow-on formula".

However, the name of products manufactured entirely from cows' milk proteins, shall be respectively:

* "infant milk" and "follow-on milk".

(2) The labelling shall bear, in addition to those provided for in the Labelling and Presentation of Foodstuffs Regulations, 1992 the following mandatory particulars in Maltese and, or English:

L.N. 65 of 1992.

(a) in the case of infant formulae, a statement to the effect that the product is suitable for particular nutritional use by infants from birth when they are not breastfed;

(b) in the case of infant formulae that do not contain added iron, a statement to the effect that, when the product is given to infants over the age of four months, their total iron requirements must be met from other additional sources;

(c) in the case of follow-on formulae, a statement to the effect that the product is suitable only for particular nutritional use by infants over the age of four months, that it should form only part of a diversified diet and that it is not to be used as a substitute for breast milk during the first four months of life;

(d) in the case of infant formulae and follow-on formulae, the available energy value, expressed in kJ and kcal, and the content of proteins, carbohydrates and lipids, expressed in numerical form, per 100 ml of the product ready for use;

(e) in the case of infant formulae and follow-on formulae, the average quantity of each mineral substance and of each vitamin mentioned in the First and Second Schedules respectively, and where applicable, of choline, inositol, carnitine and taurine, expressed in numerical form, per 100 ml of the product ready for use;

(f) in the case of infant formulae and follow-on formulae, instructions for appropriate preparation of the product and a warning against the health hazards of inappropriate preparation.

(3) The labelling may bear:

(a) the average quantity of nutrients mentioned in the Third Schedule when such declaration is not covered by the provisions of subparagraph (e) of paragraph (2) of regulation 7, expressed in numerical form, per 100 ml of the product ready for use;

(b) for follow-on formulae in addition to numerical information, information on vitamins and minerals included in the Eighth Schedule, expressed as a percentage of the reference values given therein, per 100 ml of the product ready for use, provided that the quantities present are at least equal to 15 per cent of the reference values.

(4) The labelling of infant formulae and follow-on formulae shall be designed to provide the necessary information about the appropriate use of the products so as not to discourage breast-feeding. The use of the terms "humanised", "maternalised", or similar terms is prohibited. The term "adapted" may only be used in conformity with paragraph (7) of this regulation and with point 1 of the Fourth Schedule.

(5) The labelling of infant formulae shall in addition bear the following mandatory particulars, preceded by the words "Important Notice" or their equivalent:

(a) a statement concerning the superiority of breast-feeding;

(b) a statement recommending that the product be used only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care.

(6) The labelling of infant formulae shall not include pictures of infants, nor shall it include other pictures or text which may idealise the use of the product. It may, however, have graphic representations for easy identification of the product and for illustrating methods of preparation.

(7) The labelling may bear claims concerning the special composition of an infant formula only in the cases listed in the Fourth Schedule and in accordance with the conditions laid down therein.

(8) The requirements, prohibitions and restrictions referred to in paragraphs (4), (5), (6) and (7) of regulation 7 shall also apply to:

(a) the presentation of the products concerned, in particular their shape, appearance or packaging, the packaging materials used, the way in which they are arranged and the setting in which they are displayed;

(b) advertising.

## FIRST SCHEDULE

**Essential Composition of Infant Formulae when reconstituted as instructed by the manufacturer**

NB: The values refer to the product ready for use.

**1. Energy**

| Minimum | Maximum |
|---|---|
| 250 kJ/100 ml | 315 kJ/100 ml |
| (60 kcal/100 ml) | (75 kcal/100 ml) |

**2. Proteins**

(Protein content = nitrogen content x 6.38) for cows' milk proteins.
(Protein content = nitrogen content x 6.25) for Soya protein isolates and protein partial hydrolysates.

The "chemical index" shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein and the quantity of each corresponding amino acid of the reference protein.

2.1 *Formulae manufactured from cows' milk proteins*

| Minimum | Maximum |
|---|---|
| 0.45 g/100 kJ | 0.7 g/100 kJ |
| (1.8g/100 kcal) | (3 g/100 kcal) |

For an equal energy value, the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast milk, as defined in the Fifth Schedule); nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together.

2.2 *Formulae manufactured from protein partial hydrolysates*

| Minimum | Maximum |
|---|---|
| 0.56 g/100 kJ | 0.7 g/100 kJ |
| (2.25 g/100 kcal) | (3 g/100 kcal) |

For an equal energy value, the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast milk, as defined in the Fifth

Schedule); nevertheless, for calculation purposes, the concentrations of methionine and cystine may be added together.

The protein efficiency ratio (PER) and the net protein utilisation (NPU) must be at least equal to those of casein.

The taurine content shall be equal to at least 10 µmoles/100 kJ (42 µmoles/100 kcal) and the L-carnitine content shall be equal to at least 1.8 µmoles/100 kJ (7.5 µmoles/100 kcal).

2.3 *Formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins*

| Minimum | Maximum |
|---|---|
| 0.56 g/100 kJ | 0.7 g/100 kJ |
| (2.56 g/100 kcal) | (3 g/100 kcal) |

Only soya protein isolates must be used in manufacturing these formulae.

The chemical index shall be equal to at least 80% of that of the reference protein (breast milk, as defined in the Sixth Schedule).

For an equal energy value, the formula must contain an available quantity of methionine at least equal to that contained in the reference protein (breast milk, as defined in the Fifth Schedule).

The L-carnitine content shall be at least equal to 1.8 µmoles/100 kJ (7.5 µmoles/100 kcal).

2.4 In all cases, the addition of amino acids is permitted solely for the purpose of improving the nutritional value of the proteins, and only in the proportions necessary for that purpose.

**3. Lipids**

| Minimum | Maximum |
|---|---|
| 1.05g/100 kJ | 1.5 g/100 kJ |
| (4.4g/100 kcal) | (6.5 g/100 kcal) |

3.1 The use of the following substances is prohibited:

- sesame seed oil,
- cotton seed oil.

3.2 *Lauric acid*

| Minimum | Maximum |
|---|---|
| - | 15 % of the total fat content |

3.3 *Myristic acid*

| Minimum | Maximum |
|---|---|
| - | 15% of the total fat content |

3.4 *Linoleic acid (in the form of glycerides = linoleates)*

| Minimum | Maximum |
|---|---|
| 70 mg/100 kJ (300 mg/100 kcal) | 285 mg/100 kJ (1200 mg/100 kcal) |

3.5 The alpha-linoleic acid content shall not be less than 12 mg/100 kJ (50 mg/100 kcal). The linoleic/alpha-linoleic acid ratio shall not be less than 5 nor greater than 15.

3.6 The trans fatty acid content shall not exceed 4% of the total fat content.

3.7 The erucic acid content shall not exceed 1% of the total fat content.

3.8 Long-chain (20 and 22 carbon atoms) polyunsaturated fatty acids (LCP) may be added. In that case their content shall not exceed:

- 1% of the total fat content for n-3 LCP and
- 2% of the total fat content for n-6 LCP (1% of the total fat content for arachidonic acid)
- The eicosapentaenoic acid (20:5 n-3) content shall not exceed that of docosahexaenoic (22:6 n-3) acid content.

**4. Carbohydrates**

| Minimum | Maximum |
|---|---|
| 1.7 g/100 kJ (7 g/100 kcal) | 3.4 g/100 kJ (14 g/100 kcal) |

4.1 Only the following carbohydrates may be used:

- lactose,
- maltose,
- sucrose,
- maltodextrins,

- glucose syrup or dried glucose syrup,
- pre-cooked starch (naturally free of gluten),
- gelatinised starch (naturally free of gluten).

4.2 *Lactose*

| Minimum | Maximum |
|---|---|
| 0.85 g/100 kJ | - |
| (3.5 g/100 kcal) | - |

This provision does not apply to formulae in which soya proteins represent more than 50% of the total protein content.

4.3 *Sucrose*

| Minimum | Maximum |
|---|---|
| - | 20% of the total carbohydrate content |

4.4 *Pre-cooked starch and/or gelatinised starch*

| Minimum | Maximum |
|---|---|
| - | 2 g/100 ml, and 30% of the total carbohydrate content |

**5. Mineral substances**

5.1 *Formulae manufactured from cows' milk proteins*

| | per 100 kJ | | per 100 kcal | |
|---|---|---|---|---|
| | Minimum | Maximum | Minimum | Maximum |
| Sodium (mg) | 5 | 14 | 20 | 60 |
| Potassium (mg) | 15 | 35 | 60 | 145 |
| Chloride (mg) | 12 | 29 | 50 | 125 |
| Calcium (mg) | 12 | - | 50 | - |
| Phosphorus (mg) | 6 | 22 | 25 | 90 |
| Magnesium (mg) | 1.2 | 3.6 | 5 | 15 |
| Iron (mg)[1] | 0.12 | 0.36 | 0.5 | 1.5 |
| Zinc (mg) | 0.12 | 0.36 | 0.5 | 1.5 |
| Copper (µg) | 4.8 | 19 | 20 | 80 |
| Iodine (µg) | 1.2 | - | 5 | - |
| Selenium (µg)[2] | - | 0.7 | - | 3 |

[1] Limit applicable to formulae with added iron.

[2] Limit applicable to formulae with added selenium.

The calcium/phosphorus ratio shall not be less than 1.2 nor greater than 2.0.

5.2 *Formulae manufactured from soya proteins, alone or in a mixture with cows' milk proteins*

All requirements of paragraph 5.1 are applicable except those concerning iron and zinc, which are as follows:

| | per 100 kJ | | per 100 kcal | |
|---|---|---|---|---|
| | Minimum | Maximum | Minimum | Maximum |
| Iron (mg) | 0.25 | 0.5 | 1 | 2 |
| Zinc (mg) | 0.18 | 0.6 | 0.75 | 2.4 |

## 6. Vitamins

| | per 100 kJ | | per 100 kcal | |
|---|---|---|---|---|
| | Minimum | Maximum | Minimum | Maximum |
| Vitamin A (µg-RE)[3] | 14 | 43 | 60 | 180 |
| Vitamin D (µg)[4] | 0.25 | 0.65 | 1 | 2.5 |
| Thiamine (µg) | 10 | - | 40 | - |
| Riboflavin (µg) | 14 | - | 60 | - |
| Niacin (mg-NE)[5] | 0.2 | - | 0.8 | - |
| Pantothenic acid (µg) | 70 | - | 300 | - |
| Vitamin B6 (µg) | 9 | - | 35 | - |
| Biotin (µg) | 0.4 | - | 1.5 | - |
| Folic acid (µg) | 1 | - | 4 | - |
| Vitamin B12 (µg) | 0.025 | - | 0.1 | - |
| Vitamin C (µg) | 1.9 | - | 8 | - |
| Vitamin K (µg) | 1 | - | 4 | - |

[3] RE = all trans retinol equivalent.

[4] In the form of cholecalciferol, of which 10 µg = 400 i.u. of vitamin D.

[5] NE = niacin equivalent = mg nicotinic acid + mg tryptophan/60.

| | per 100 kJ | | per 100 kcal | |
|---|---|---|---|---|
| | Minimum | Maximum | Minimum | Maximum |
| Vitamin E (mg α-TE)[6] | 0.5/g of poly-unsaturated fatty acids expressed as linoleic acid but in no case less than 0.1 mg per 100 available kJ | | 0.5/g of poly-unsaturated fatty acids expressed as linoleic acid but in no case less than 0.1 mg per 100 available kJ | |

7. The following nucleotides may be added:

| | Maximum[7] | |
|---|---|---|
| | (mg/100 kJ) | (mg/100 kcal) |
| Cytidine 5'-monophosphate | 0.60 | 2.50 |
| Uridine 5'-monophosphate | 0.42 | 1.75 |
| Adenosine 5'-monophosphate | 0.36 | 1.50 |
| Guanosine 5'-monophosphate | 0.12 | 0.50 |
| Inosine 5'-monophosphate | 0.24 | 1.00 |

[6] α-TE = d-α-tocopherol equivalent.

[7] The total concentration of nucleotides shall not exceed 1.2 mg/100 kJ (5 mg/100 kcal).

## SECOND SCHEDULE

**Essential Composition of Follow-on Formulae when reconstituted as instructed by the manufacturer**

NB: The values refer to the product ready for use.

**1. Energy**

| Minimum | Maximum |
|---|---|
| 250 kJ/100 ml | 335 kJ/100 ml |
| (60 kcal/100 ml) | (80 kcal/100 ml) |

**2. Proteins**

(Protein content = nitrogen content x 6.38) for cows' milk proteins.
(Protein content = nitrogen content x 6.25) for soya protein isolates.

| Minimum | Maximum |
|---|---|
| 0.5 g/100 kJ | 1 g/100 kJ |
| (2.25 g/100 kcal) | (4.5 g/100 kcal) |

The chemical index of the proteins present shall be at least equal to 80% of that of the reference protein (casein or breast milk as defined in Schedule Six).

The "chemical index" shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein and the quantity of each corresponding amino acid of the reference protein.

For follow-on formulae manufactured from soya proteins, alone or in a mixture with cows' milk proteins, only protein isolates from soya may be used.

Amino acids may be added to follow-on formulae for the purpose of improving the nutritional value of the proteins, in the proportions necessary for that purpose.

For an equal energy value, these formulae must contain an available quantity of methionine at least equal to that contained in breast milk as defined in the Fifth Schedule.

**3. Lipids**

| Minimum | Maximum |
|---|---|
| 0.8 g/100 kJ | 1.5 g/100 kJ |
| (3.3g/100 kcal) | (6.5 g/100 kcal) |

3.1 The use of the following substances is prohibited:

- sesame seed oil,
- cotton seed oil.

3.2 *Lauric acid*

| Minimum | Maximum |
|---|---|
| - | 15% of the total fat content |

3.3 *Myristic acid*

| Minimum | Maximum |
|---|---|
| - | 15% of the total fat content |

3.4 *Linoleic acid (in the form of glycerides = linoleates)*

| Minimum | Maximum |
|---|---|
| 70 mg/100 kJ (300 mg/100 kcal) this limit applies only to follow-on formulae containing vegetable oils | - |

3.5 The trans fatty acid content shall not exceed 4% of the total fat content.

3.6 The erucic acid content shall not exceed 1% of the total fat content.

**4. Carbohydrates**

| Minimum | Maximum |
|---|---|
| 1.7 g/100 kJ (7 g/100 kcal) | 3.4 g/100 kJ (14 g/100 kcal) |

4.1 The use of ingredients containing gluten is prohibited.

4.2 *Lactose*

| Minimum | Maximum |
|---|---|
| 0.45 g/100 kJ | - |
| (1.8 g/100 kcal) | - |

This provision does not apply to follow-on formulae in which soya proteins represent more than 50% of the total protein content.

4.3 *Sucrose, fructose, honey*

| Minimum | Maximum |
|---|---|
| - | separately or as a whole:<br>20% of the total carbohydrate content |

**5. Mineral substances**

| | per 100 kJ | | per 100 kcal | |
|---|---|---|---|---|
| | Minimum | Maximum | Minimum | Maximum |
| Iron (mg) | 0.25 | 0.5 | 1 | 2 |
| Iodine (µg) | 1.2 | - | 5 | - |

**5.2 Zinc**

5.2.1 *Follow-on formulae manufactured entirely from cows' milk*

| Minimum | Maximum |
|---|---|
| 0.12 mg/100 kJ<br>(0.5 mg/100 kcal) | - |

5.2.2 *Follow-on formulae containing soya protein isolates, or mixed with cows' milk*

| Minimum | Maximum |
|---|---|
| 0.18 mg/100 kJ<br>(0.75 mg/100 kcal) | - |

5.3 *Other mineral substances*

The concentrations are at least equal to those normally found in cows' milk, reduced, where appropriate, in the same ratio as the protein concentration of the follow-on formulae to that of cows' milk. The typical composition of cows' milk is given, for guidance, in the Eighth Schedule.

5.4 The calcium/phosphorus ratio shall not exceed 2.0.

## 6. Vitamins

| | per 100 kJ | | per 100 kcal | |
|---|---|---|---|---|
| | Minimum | Maximum | Minimum | Maximum |
| Vitamin A (µg-RE)[1] | 14 | 43 | 60 | 180 |
| Vitamin D (µg)[2] | 0.25 | 0.75 | 1 | 3 |
| Vitamin C (µg) | 1.9 | - | 8 | - |
| Vitamin E (mg α-TE)[3] | 0.5/g of poly-unsaturated fatty acids expressed as linoleic acid but in no case less than 0.1 mg per 100 available kJ | - | 0.5/g of poly-unsaturated fatty acids expressed as linoleic acid but in no case less than 0.1 mg per 100 available kJ | - |

7. The following nucleotides may be added:

| | Maximum[4] | |
|---|---|---|
| | (mg/100 kJ) | (mg/100 kcal) |
| Cytidine 5'-monophosphate | 0.60 | 2.50 |
| Uridine 5'-monophosphate | 0.42 | 1.75 |
| Adenosine 5'-monophosphate | 0.36 | 1.50 |
| Guanosine 5'-monophosphate | 0.12 | 0.50 |
| Inosine 5'-monophosphate | 0.24 | 1.00 |

[1] RE = all trans retinol equivalent

[2] In the form of cholecalciferol, of which 10 µg = 400 i.u. of vitamin D.

[3] α-TE = d-α-tocopherol equivalent.

[4] The total concentration of nucleotides shall not exceed 1.2 mg/100 kJ (5 mg/100 kcal).

## THIRD SCHEDULE

### Nutritional Substances

**1. Vitamins**

| Vitamins | Vitamin formulation |
|---|---|
| Vitamin A | Retinyl acetate<br>Retinyl palmitate<br>Beta-carotene<br>Retinol |
| Vitamin D | Vitamin D2 (ergocalciferol)<br>Vitamin D3 (cholecalciferol) |
| Vitamin B1 | Thiamine hydrochloride<br>Thiamine mononitrate |
| Vitamin B2 | Riboflavin<br>Riboflavin-5'-phosphate, sodium |
| Niacin | Nicotinamide<br>Nicotinic acid |
| Vitamin B6 | Pyridoxine hydrochloride<br>Pyridoxine-5'-phosphate |
| Folate | Folic acid |
| Pantothenic acid | D-pantothenate, calcium<br>D-pantothenate, sodium<br>Dexpanthenol |
| Vitamin B12 | Cyanocobalamin<br>Hydroxocobalamin |
| Biotin | D-biotin |
| Vitamin C | L-ascorbic acid<br>Sodium L-ascorbate<br>Calcium L-ascorbate<br>6-palmityl-L-ascorbic acid (ascorbyl palmitate)<br>Potassium ascorbate |

| | |
|---|---|
| Vitamin E | D-alpha tocopherol<br>DL-alpha tocopherol<br>D-alpha tocopherol acetate<br>DL-alpha tocopherol acetate |
| Vitamin K | Phylloquinone (Phytomenadione) |

**2. Mineral substances**

| Mineral substances | Permitted salts |
|---|---|
| Calcium (Ca) | Calcium carbonate<br>Calcium chloride<br>Calcium salts of citric acid<br>Calcium gluconate<br>Calcium glycerophosphate<br>Calcium lactate<br>Calcium salts of orthophosphoric acid<br>Calcium hydroxide |
| Magnesium (Mg) | Magnesium carbonate<br>Magnesium chloride<br>Magnesium oxide<br>Magnesium salts of orthophosphoric acid<br>Magnesium sulphate<br>Magnesium gluconate<br>Magnesium hydroxide<br>Magnesium salts of citric acid |
| Iron (Fe) | Ferrous citrate<br>Ferrous gluconate<br>Ferrous lactate<br>Ferrous sulphate<br>Ferric ammonium citrate<br>Ferrous fumarate<br>Ferric diphosphate (Ferric pyrophosphate) |
| Copper (Cu) | Cupric citrate<br>Cupric gluconate<br>Cupric sulphate<br>Cupric-lysine complex<br>Cupric carbonate |
| Iodine (I) | Potassium iodide<br>Sodium iodide<br>Potassium iodate |

| | |
|---|---|
| Zinc (Zn) | Zinc acetate<br>Zinc chloride<br>Zinc lactate<br>Zinc sulphate<br>Zinc citrate<br>Zinc gluconate<br>Zinc oxide |
| Manganese (Mn) | Manganese carbonate<br>Manganese chloride<br>Manganese citrate<br>Manganese sulphate<br>Manganese gluconate |
| Sodium (Na) | Sodium bicarbonate<br>Sodium chloride<br>Sodium citrate<br>Sodium gluconate<br>Sodium carbonate<br>Sodium lactate<br>Sodium salts of orthophosphoric acid<br>Sodium hydroxide |
| Potassium (K) | Potassium bicarbonate<br>Potassium carbonate<br>Potassium chloride<br>Potassium salts of citric acid<br>Potassium gluconate<br>Potassium lactate<br>Potassium salts of orthophosphoric acid<br>Potassium hydroxide |
| Selenium (Se) | Sodium selenate<br>Sodium selenite |

## 3. Amino acids and other nitrogen compounds

L-arginine and its hydrochloride
L-cystine and its hydrochloride
L-histidine and its hydrochloride
L-isoleucine and its hydrochloride
L-leucine and its hydrochloride
L-cystine and its hydrochloride

L-methionine
L-phenylalanine
L-threonine
L-tryptophan
L-tyrosine
L-valine
L-carnitine and its hydrochloride
Taurine
Cytidine 5'-monophosphate and its sodium salt
Uridine 5'-monophosphate and its sodium salt
Adenosine 5'-monophosphate and its sodium salt
Guanosine 5'-monophosphate and its sodium salt
Inosine 5'-monophosphate and its sodium salt

**4. Others**

Choline
Choline chloride
Choline citrate
Choline bitartrate
Inositol

## FOURTH SCHEDULE

**Compositional Criteria for Infant Formulae, warranting a corresponding claim**

| *Claim related to:–* | *Conditions warranting the claim* |
|---|---|
| 1. Adapted protein | The protein content is lower than 0.6 g/100 kJ (2.5 g/100 kcal) and the whey protein/casein ratio is not less than 1.0. |
| 2. Low sodium | The sodium content is lower than 9 mg/100 kJ (39 mg/100 kcal). |
| 3. Sucrose free | No sucrose is present. |
| 4. Lactose only | Lactose is the only carbohydrate present. |
| 5. Lactose free | No lactose is present. |
| 6. Iron enriched | Iron is added. |
| 7. Reduction of risk to allergy to milk proteins. This claim may include terms referring to reduced allergen or reduced antigen properties. | (a) The formulae shall satisfy the provisions laid down in paragraph 2.2 of the First Schedule and the amount of immunoreactive protein measured with methods generally acceptable as appropriate shall be less than 1% of nitrogen containing substances in the formulae;<br><br>(b) The label shall indicate that the protein must not be consumed by infants allergic to the intact proteins from which it is made unless generally accepted clinical tests provide proof of the formulae's tolerance in more than 90% of infants (confidence interval 95%) hypersensitive to proteins from which the hydrolysate is made;<br><br>(c) The formulae administered orally should not induce sensitisation, in animals, to the intact proteins from which the formulae are derived;<br><br>(d) Objective and scientifically verified data as proof to the claimed properties must be available. |

## FIFTH SCHEDULE

### Essential and Semi-Essential Amino Acids in Breast Milk

For the purpose of this report, the essential and semi-essential amino acids in breast milk, expressed in mg per 100 kJ and 100 kcal, are the following:

| | *Per 100 kJ*[1] | *Per 100 kcal* |
|---|---|---|
| Arginine | 16 | 69 |
| Cystine | 6 | 24 |
| Histidine | 11 | 45 |
| Isoleucine | 17 | 72 |
| Leucine | 37 | 156 |
| Lysine | 29 | 122 |
| Methionine | 7 | 29 |
| Phenylalanine | 15 | 62 |
| Threonine | 19 | 80 |
| Tryptophan | 7 | 30 |
| Tyrosine | 14 | 59 |
| Valine | 19 | 80 |

[1] 1 kJ = 0.239 kcal.

## SIXTH SCHEDULE

### Amino Acid Composition of Casein and Breast Milk Protein

The amino acid composition of casein and breast milk protein (g/100 g of protein):

| | *Casein*[1] | *Breast milk*[1] |
|---|---|---|
| Arginine | 3.7 | 3.8 |
| Cystine | 0.3 | 1.3 |
| Histidine | 2.9 | 2.5 |
| Isoleucine | 5.4 | 4.0 |
| Leucine | 9.5 | 8.5 |
| Lysine | 8.1 | 6.7 |
| Methionine | 2.8 | 1.6 |
| Phenylalanine | 5.2 | 3.4 |
| Threonine | 4.7 | 4.4 |
| Tryptophan | 1.6 | 1.7 |
| Tyrosine | 5.8 | 3.2 |
| Valine | 6.7 | 4.5 |

[1]Amino acid content of foods and biological data on protein. FAO Nutritional Studies, No. 24, Rome 1970, items 375 and 383.

## SEVENTH SCHEDULE

### The Mineral Elements in Cows' Milk

As a reference, the contents of mineral elements in cows' milk expressed per 100 g of solids-non-fat and per g of proteins are the following:

| | *Per 100 g SNF*[1] | *Per g of proteins* |
|---|---|---|
| Sodium (mg) | 550 | 15 |
| Potassium (mg) | 1680 | 43 |
| Chloride (mg) | 1050 | 28 |
| Calcium (mg) | 1350 | 35 |
| Phosphorus (mg) | 1070 | 28 |
| Magnesium (mg) | 135 | 3.5 |
| Copper (µg) | 225 | 6 |
| Iodine | NS[2] | NS |

[1] SNF : 'solids-non-fats'.

[2] NS : non-specified, varies widely according to season and stock farming conditions.

## EIGHTH SCHEDULE

**Reference Values for Nutrition Labelling for Foods intended for Infants and Young Children**

| *Nutrient* | *Labelling Reference Value* |
|---|---|
| Vitamin A | 400 µg |
| Vitamin D | 10 µg |
| Vitamin C | 25 mg |
| Thiamine | 0.5 mg |
| Riboflavin | 0.8 mg |
| Niacin equivalents | 9 mg |
| Vitamin B6 | 0.7 mg |
| Folate | 100 µg |
| Vitamin B12 | 0.7 µg |
| Calcium | 400 mg |
| Iron | 6 mg |
| Zinc | 4 mg |
| Iodine | 70 µg |
| Selenium | 10 µg |
| Copper | 0.4 mg |