

REGULATIONS RELATING TO FOODSTUFFS FOR INFANTS, YOUNG CHILDREN AND CHILDREN

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As amended by:

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The Minister of Health and Welfare, in terms of section 15(1) of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972), has made the regulations contained in the Schedule hereto.

SCHEDULE

Definitions

1. In these regulations "**the Act**" shall mean the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972), and any word to which a meaning has been ascribed in the Act shall bear such meaning and, unless inconsistent with the context—

"canned foodstuff for infants and young children" shall mean a foodstuff, whether in a ready-to-eat form or in a dry form requiring reconstitution with water only, packed in a hermetically sealed package and intended primarily for use during the infant's normal weaning period and for the progressive adaptation of infants and young children to ordinary foodstuffs;

"children" shall mean persons from the age of three years up to the age of 10 years;

"food additive" shall mean any substance not normally consumed as a foodstuff, intentionally added to a foodstuff for a technological (including organoleptic) purpose, but shall not include substances added to foodstuffs for the purpose of enhancing the nutritional value thereof;

"gluten free" shall mean that the total nitrogen content of the gluten-containing cereals used in the product does not exceed 0,05 g/100 g of such cereals on a dry matter basis;

"hermetically sealed package" shall mean an unopened package which cannot be opened without the breaking or damaging of such package or of the seal, adhesive label or other part thereof or attachment thereto which forms an air-tight closure and is impervious to liquid;

"infant" shall mean a person under the age of 12 months;

"infant formula" shall mean a foodstuff based on milk of cows or other animals and/or on other wholesome constituents of animal origin, including fish, or plant origin, in liquid or powdered form intended for use, where necessary, as infant feeding in order to meet the normal nutritional requirements of infants;

“processed cereal-based foodstuff” shall mean a foodstuff prepared primarily from one or more milled cereal products and/or legumes (pulses), including sesame, arachis and soybean, intended to supplement the diet of the infants and young children, and the term shall include—

- (a) dry cereals, that is foodstuffs based on cereals and/or legumes (pulses), processed to low moisture content and so fragmented as to permit dilution with water, milk or some other suitable liquid or, as in the case of preparations such as pasta, used after cooking in boiling water or other liquids;
- (b) simple or composite cooked flours of cereals, that is foodstuffs which have been cooked in a way that distinguishes them as follows:
 - (i) Partially cooked flours requiring a second short cooking before use;
 - (ii) cooked flours, for immediate use, as such not requiring any further cooking before use; and
 - (iii) dextrinised flours, the starch content of which has in part been transformed into dextrin by heat treatment;
- (c) enzyme treated flours of cereals, that is flours prepared with enzymes, the starch content of which has been transformed into dextrin, maltodextrin, maltose and glucose;
- (d) pasta, that is foodstuffs prepared from milled cereal products and suitable for weaning period; and
- (e) rusks and biscuits, that is cereal-based foodstuffs produced by baking which may be used either directly or, after pulveisation, with the addition of water or milk or other suitable liquid, and milk biscuits consisting mainly of cereals and containing milk solids;

“serving”, in relation to a foodstuff, shall mean a reasonable quantity of food suitable for consumption as part of a meal by infants or young children or children;

“sugar” shall mean sucrose, glucose (or dextrose), fructose (or levulose), maltose, lactose, sorbitol, mannitol and xylitol; and

“young children” shall mean persons from the age of 12 months up to the age of three years.

Prohibition on the sale of certain Foodstuffs for Infants and Young Children

- 2. No person shall sell any infant formula—
 - (a) the composition of which does not comply with the minimum and maximum levels of vitamins, minerals in an available form, choline, proteins and linoleate, per 100 available kilojoules, as specified in Annex A: Provided that nutrients other than the vitamins and minerals listed in Annex A may be added to any such formula in amounts based on levels of such nutrients in human milk, provided the usefulness thereof can be scientifically proved;
 - (b) in the processing of which water is used which contains more than 10 mg/P of nitrate as N (equivalent to 45 mg/P No_3);
 - (c) which—
 - (aa) contains—
 - (i) pathogenic micro-organisms and/or toxins thereof;
 - (ii) added hormones, antibiotics or other antimicrobial substances;

- (iii) more of any chemical substance registered in terms of section 3 (2) of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947), than the tolerances laid down by the Act;
 - (iv) more than 0,2 mg/kg of lead in the ready-to-eat form of such formula or more than 0,5 mg/kg of lead in the dehydrated concentrated form of such formula;
 - (v) any food additive, except those specified in column II of Annex B, complying with the conditions and not exceeding the limits laid down in column III;
- (bb) is not packed in a hermetically sealed package.

3. No person shall sell any canned foodstuff for infants and young children—

- (a) which—
 - (i) contains added nutrients, unless the usefulness thereof can be scientifically proved;
 - (ii) contains any nitrites in such foodstuffs prepared with meat, except where bacon or ham is a constituent thereof in which case the nitrite content shall not exceed 20 mg/kg;
 - (iii) does not comply with the requirements laid down in regulation 2(b) and (c);
- (b) the total sodium content of which exceeds 200 mg Na⁺/100 g on the ready-to-eat basis: Provided that no table salt (NaCl) shall be added to such products having a fruit base or to such products intended specifically as introductory foodstuffs or as dessert products.

4. (1) No person shall sell any of the following as products intended for infants and young children:

- (a) Dry cereals, simple or composite cooked flours of cereals, enzyme-treated flours of cereals and pasta; or
- (b) rusks and biscuits;

if the sodium content exceeds, in the case of (a), 100 mg/100 g of the ready-to-eat product and, in the case of (b) 300 mg/100 g of the product as sold.

- (2) (a) Where any product in (1) (a) and (b) of this regulation is intended to be mixed with water before consumption, the minimum protein content shall be not less than 15 per cent on a dry weight basis and the quality of the protein shall be not less than 70 per cent of that of casein.
 - (b) Milk biscuits shall contain not less than 10 per cent mass/mass milk proteins.
- (3) In addition to the raw ingredients mentioned in paragraphs (a), (d) and (e) of the definition of “processed cereal-based foodstuff” in regulation 1, the following ingredients only, where appropriate, may be added to dry cereals, pasta, rusks and biscuits:
- (a) Protein concentrates and other high-protein ingredients suitable for consumption by infants and young children: Provided that essential amino acids shall be added only in such amounts as may be necessary for the purpose of improving the protein quality and that only natural L-forms of amino acids shall be used;
 - (b) salt (sodium chloride);
 - (c) milk and milk products;

- (d) eggs;
- (e) meat;
- (f) fats and oils;
- (g) fruits and vegetables;
- (h) sugars (nutritive carbohydrate sweeteners);
- (i) malt;
- (j) honey;
- (k) cocoa (only in products to be consumed after nine months of age and at a maximum level of 5 % m/m on a dry basis);
- (l) potatoes; and
- (m) starches, including enzyme-modified starches and starches treated by physical means.

Labelling requirements

5. The requirements specified in paragraphs (1), (2) and (3) of this regulation are supplementary to the other labelling requirements laid down by the Act.

(1) The label of any infant formula shall bear the following information:

- (a) The heading "Nutrition Information", reflecting—
 - (i) an indication of the mass or volume of a serving of the ready-to-eat product, if not given elsewhere on the label;
 - (ii) the energy content, to the nearest kilojoule, of 100mP of the ready-to-eat product;
 - (iii) the amount of choline, and the amount of each of the vitamins, minerals and other nutrients, referred to in regulation 3 and Annex A, present in 100mP of the ready-to-eat product;
 - (iv) what percentage of the RDA specified in Annex C each of the undermentioned nutrients represents, if present in 100mP of the ready-to-eat product in amounts of more than 2 percent, listed in the following order:

Vitamin A;	Phosphorus;
Vitamin D;	Magnesium;
Vitamin E;	Potassium;
Vitamin K1;	Sodium;
Vitamin C;	Chloride;
Vitamin B1;	Iron;
Vitamin B2;	Copper;
Nicotine acid;	Iodine;
Biotin;	Manganese;
Folic acid;	Zinc;
Pantothenic acid;	Fluoride;

Vitamin B6;	Chromium;
Vitamin B12;	Selenium;
Calcium;	Molybdenum;

- (v) the amounts in grams of the proteins, carbohydrates and fats present in 100 g of the ready-to-eat product: Provided that the type of sugar shall be mentioned separately in the list of ingredients.
 - (b) the sources of the proteins mentioned in the list of ingredients.
 - (c) Directions for—
 - (i) preparation and use, including the application of sterilised equipment;
 - (ii) the storage and keeping before and after the package has been opened.
 - (d) An indication on the main panel, in both official languages and in letters at least 4,0 mm in height, that breast feeding should be the first choice.
 - (e) If the formula contains neither milk nor any milk product, the words “Free from milk and milk products”.
 - (f) If the formula contains more than 0,25 mg Iron (Fe) per 100 available kilojoules, the words “infant formula with Iron”.
 - (g) If the formula contains gluten, an indication of the presence thereof.
 - (h) If the formula contains the maximum concentration of NaCl as specified in Annex A, the following on the main panel in both official languages in letters at least 2,0 mm in height: “*Warning: Do not add salt/Waarskuwing: Moenie sout byvoeg nie.*”.
- (2) The label of any canned foodstuff for infants and young children shall reflect the following information:
- (a) In the case of any nutrient added in accordance with regulation 3 (a)(i)—
 - (i) the heading “Nutrition Information”;
 - (ii) an indication of the mass or volumes of a serving;
 - (iii) the amounts of added nutrients present in a serving when packed: Provided that—
 - (a) the total protein, carbohydrate and fat values shall be indicated in grams; and
 - (b) each type of added sugar shall be named separately;
 - (iv) an indication of what percentage of the RDA specified in Annex C each of the added nutrients represents when packed.
 - (b) Directions for—
 - (i) preparation and use; and
 - (ii) storage and keeping before and after the package has been opened.
 - (c) In the case of canned beetroot and spinach intended as foodstuffs for infants, the following instruction in both official languages in letters not less than 2 mm in height: “Do not use before the age of 12 weeks/Moenie voor die ouderdom van 12 weke gebruik nie.”.
 - (d) If the foodstuff contains the maximum concentration NaCl as specified in regulation (3)(b), the following on the main panel in both official languages in letters not less than 2,0 mm in height: “*Warning: Do not add salt/Waarskuwing: Moenie sout byvoeg nie.*”.

- (e) If such foodstuff contains no gluten, the words “gluten free”, clearly stated on the label.
- (3) The label of any processed cereal-based foodstuff intended for infants and young children shall bear the following information:
- (a) In the case of added nutrients the usefulness of which can be scientifically proved—
 - (i) the heading “Nutrition Information”;
 - (ii) an indication of the mass or volume of a serving;
 - (iii) the amounts present in a serving when packed: Provided that—
 - (a) the total protein and fat values shall be indicated in grams; and
 - (b) each type of sugar shall be named separately and not as part of any carbohydrate values;
 - (iv) an indication of what percentage of the RDA specified in Annex C each of the added nutrients represents.
 - (b) Directions for—
 - (i) the preparation and use of the foodstuff; and
 - (ii) the storage and keeping before and after the package has been opened.
 - (c) If such foodstuff contains more than 15 percent protein, a direction stating that water, milk or formula may be used for dilution or mixing.
 - (d) If the foodstuff concerned contains less than 15 per cent protein and the quality thereof is less than 70 per cent of that of casein, a direction containing the following statement or words of a similar meaning: “Milk or a formula, but no water, shall be used for dilution or mixing in accordance with medical advice”.
 - (e) If such foodstuff contains no gluten, the words “gluten-free” clearly visible on the label.
 - (f) If the foodstuff concerned contains the maximum amount of NaCl, the following on the main panel in both official languages in letters not less than 2,0 mm in height: “*Warning: Do not add salt/Waarskuwing: Moenie sout byvoeg nie.*”.
6. The provisions of regulations 2(b), 2(c) and 5(3)(e) apply also to any foodstuff purporting or represented to be intended for consumption by children.

ANNEX A		
Nutrient	Amounts per 100 available kilojoules	
	Minimum	Maximum
Vitamins		
Vitamin A.....	60 I.E. or 18µg expressed as retinol.....	120 I.E. of 37µg expressed as retinol
Vitamin D.....	10 I.E.....	19 I.E.
Vitamin E (a-tocopherol compounds)	0.7 I.E./g linoleic acid but in no case less than 0,15 I.E./100 available kilojoules.....	Not specified
Ascorbic acid (Vitamin C).....	1,9 mg.....	Not specified
Thiamine (Vitamin B ₁).....	10 µg.....	Not specified
Riboflavin (Vitamin B ₂).....	14 µg.....	Not specified
Nicotinamide.....	60 µg.....	Not specified
Vitamin B ₆ ⁽²⁾	9 µg.....	Not specified
Folic acid.....	1 µg.....	Not specified
Pantothenic acid.....	70 µg.....	Not specified
Vitamin B ₁₂ (Cyanocobalamin).....	0,04 µg.....	Not specified
*Vitamin K.....	1 µg.....	Not specified
Biotin (Vitamin H).....	0,4 µg.....	Not specified
Minerals		
Sodium (Na).....	5 mg.....	12 mg
Potassium (K).....	20 mg.....	50 mg
Chloride (Cl).....	14 mg.....	35 mg
Calcium (Ca) ⁽³⁾	12 mg.....	Not specified
Phosphorus (P) ⁽³⁾	6 mg.....	Not specified
Magnesium (Mg).....	1,4 mg.....	Not specified
*Iron (Fe).....	0,25 mg.....	Not specified
Iodine (I).....	1,2 µg.....	Not specified
*Copper (Cu).....	14 µg.....	Not specified
*Zinc (Zn).....	0,12 mg.....	Not specified
*Manganese (Mn).....	1,2 µg.....	Not specified
Choline	1,7 mg.....	Not specified
Protein ⁽⁴⁾	0,43 g.....	0,96 g
Fat ⁽⁵⁾	0,8 g.....	1,5 g
Linoleate ⁽⁴⁾	70 mg.....	Not specified

* Only in the chelated form.

⁽¹⁾ Or per gram of polyunsaturated fatty acids, expressed as linoleic acid.

⁽²⁾ Formulae with a higher protein content than 0,43 g protein/100 kJ shall contain a minimum of 15 µg Vitamin B₆ per gram of protein.

⁽³⁾ The Ca:P ratio shall not be less than 1,2:1 and not more than 2,0:1.

⁽⁴⁾ (i) The nutritional quality shall be equivalent to that of casein or a greater quantity of other protein in proportion to its biological value. The quality of the protein shall be not less than 85 per cent of that of casein.

(ii) Isolated amino acids shall be added to an infant formula for the sole purpose of improving its nutritional value for infants.

Essential amino acids may be added for the purpose of improving the protein quality. Provided that they shall be only in amounts necessary for such purpose and that only natural L-forms of amino acids shall be used.

⁽⁵⁾ The product shall contain linoleic acid in the form of glycerides.

ANNEX B		
I	II	III
Foodstuff	Food additive	Conditions and maximum level in 100 mP of the ready-to-eat product
Infant formula	Antioxidants L-Ascorbyl palmitate..... Tocopherols, concentrate.....	1 mg
	pH-adjusting agents Potassium carbonate..... Potassium citrate..... Potassium hydrogen carbonate.....	K not to exceed 145 mg

Canned foodstuffs for infants, young children and children	Sodium carbonate	Na not to exceed 35 mg	
	Sodium citrate.....		
	Sodium hydrogen carbonate.....		
	Citric acid	Good manufacturing practice	
	L (+) Lactic acid.....		
	L (+) Lactic acid producing cultures		
	Emulsifiers		
	Lecithin.....	0,5 g	
	Mono- and diglycerides.....	0,4 g	
	Thickeners		
	Carrageenan.....	0,03 g in regular milk- and soy-based liquid infant formulae only, 0,1 g in hydrolysed protein and/or amino acid-based liquid infant formulae only	
	Distarch phosphate.....	0,5 g singly or in combination in soy-base infant formulae only	
	Distarch phosphate, acetylated.....	2,5 g singly or in combination in hydrolysed protein and/or amino acid-based liquid infant formulae only	
	Distarch phosphate phosphated.....		
Hydroxypropyl starch.....			
Guar gum.....	100 mg		
Locust bean gum.....			
<i>pH-adjusting agents</i>	Good manufacturing practice		
Calcium hydroxide.....	Provided that the limits for Na and K specified in Annex A shall not be exceeded		
Potassium hydroxide.....			
Sodium hydroxide.....			
<i>pH-adjusting agents</i>	Conditions and maximum levels in 100 g of the ready-to-eat product		

	<p>Acetic acid 500 m g</p> <p>Calcium carbonate..... Potassium hydrogen carbonate..... Good manufacturing practice</p> <p>L (+) Lactic acid 200 m g</p> <p>Sodium carbonate Sodium hydrogen carbonate..... The total sodium content of the product not to exceed 200mg</p> <p>Citric acid and Na salt..... 500mg, the sodium content not to exceed 200 m g</p> <p>Antioxidant</p> <p>L-Ascorbic acid and its Na and K salts. 500 mg/kg, expressed as ascorbic acid, the total sodium content not to exceed 200 m g</p> <p>L-ascorbyl palmitate..... 200 m g/kg fat Alpha-Tocopherol..... 300 m g/kg fat, singly or in combination Tocopherol concentrate, mixed.....</p> <p>Emulsifiers</p> <p>Lecithin..... 500 m g Mono- and diglycerides..... 1 500 mg/100 g fat</p> <p>Flavourants</p> <p>Ethyl vanillin 7 m g Natural and nature identical flavourants Good manufacturing practice, only in canned foodstuffs for young children and children</p> <p>Vanillin 7 m g Vanilla extract..... Good manufacturing practice</p> <p>Thickeners</p> <p>Distarch adipate, acetylated..... Distarch glycerol..... Distarch glycerol, acetylated.....</p> <p>L-Ascorbyl palmitate 200 m g/kg fat Alpha-Tocopherol..... 300 m g/kg fat, singly or in combination Tocopherols, concentrate, mixed.....</p>	
	<p>Emulsifiers</p> <p>Lecithin..... 1 500 mg Mono- and diglycerides.....</p> <p>Enzymes</p> <p>Malt carbohydrates..... Good manufacturing practice</p> <p>Flavourants</p> <p>Ethyl vanillin 7 m g on a ready-to-eat basis Natural and nature identical flavourants Good manufacturing practice, only in cereal-based foodstuffs for young children and children</p> <p>Vanillin 7 m g on a ready-to-eat basis Vanilla-extract..... Good manufacturing practice</p>	

ANNEX C						
RECOMMENDED DAILY DIETARY ALLOWANCES (RDA)						
	Unit	Infants		Children		
		0,0-0,5 yr	0,5-1,0 yr	1-3 yr	4-6 yr	7-10 yr
Energy*.....	kJ	480/kg body mass	440/kg body mass	5600	7100	10000
Protein.....	g	2.2/kg body mass	2.0/kg body mass	23	30	34
Vitamin A-activity: (1) Vitamin A.....	IU	2200	2000	2000	2500	3500
(2) Retinol-equivalent...	µg RE	420	400	400	500	700
Vitamin D.....	IU	400	400	400	400	400
	µg	10	10	10	10	10
Vitamin E-activity.....	IU	4.5	6	7.5	9	10.4
	mg %TE	3	4	5	6	7
Ascorbic acid (Vit. C)...	mg	35	35	45	45	45
Biotin (Vit. H).....	µg	35	50	65	85	120
Folic acid.....	µg	30	45	100	200	300
Pantothenic acid.....	mg	2	3	3	4	5
Nicotinic acid (Vit. B ₃)..	mg	6	8	9	11	16
Riboflavin (Vit. B ₂).....	mg	0.4	0.6	0.8	1.0	1.4

* Approximately 4,2 kilojoules = 1 calorie

	Unit	Infants		Children		
		0,0-0,5 yr	0,5-1,0 yr	1-3 yr	4-6 yr	7-10 yr
Tiamin (Vit. B ₁).....	mg	0.3	0.5	0.7	0.9	1.2
Pyridoxine (Vit. B ₆).....	mg	0.3	0.6	0.9	1.3	1.6
Cyanocobalamin (Vit. B ₁₂)..	µg	0.5	1.5	2.0	2.5	3.0
Vitamin K.....	µg	12	15	25	30	50
Calcium.....	mg	360	540	800	800	800
Phosphorus.....	mg	240	360	800	800	800
Iodine.....	µg	40	50	70	90	120
Iron.....	mg	10	15	15	10	10
Magnesium.....	mg	50	70	150	200	250
Copper.....	mg	0.7	1.0	1.5	2.0	2.5
Zinc.....	mg	3	5	10	10	10
Potassium.....	mg	925	1275	1650	2325	3000
Sodium.....	mg	350	750	975	1350	1800
Chloride.....	mg	700	1200	1500	2100	2775
Manganese.....	mg	0.7	1.0	1.5	2.0	3.0
Fluoride.....	mg	0.5	1.0	1.5	2.5	2.5
Chromium.....	mg	0.04	0.06	0.08	0.12	0.2
Selenium.....	mg	0.04	0.06	0.08	0.12	0.2
Molybdenum.....	mg	0.06	0.08	0.1	0.15	0.3