

L.N. 227 of 2007

**FOOD SAFETY ACT
(CAP. 449)**

**Processed Cereal-Based Foods and Other Foods for Infants and
Young Children Regulations, 2007**

IN exercise of the powers conferred by article 10 of the Food Safety Act, the Minister of Health, the Elderly and Community Care has made the following regulations:-

Title.

1. The title of these regulations is Processed Cereal-based Foods and Other Foods for Infants and Young Children Regulations, 2007.

Applicability of these regulations.

2. (1) These regulations shall apply to foodstuffs for particular nutritional use fulfilling the particular requirements of infants and young children in good health and which are intended for use by infants while they are being weaned, and by young children as a supplement to their diet and, or for their progressive adaptation to ordinary food. They comprise:

(a) “Processed cereal-based foods” which are divided into the following four categories:

(i) simple cereals which are or have to be reconstituted with milk or other appropriate nutritious liquids;

(ii) cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid;

(iii) pastas which are to be used after cooking in boiling water or other appropriate liquids;

(iv) rusks and biscuits which are to be used either directly or, after pulverisation, with the addition of water, milk or other suitable liquids;

(b) “Baby foods” other than processed cereal-based foods.

(2) These regulations do not apply to milks intended for young children.

Definitions.

3. For the purpose of this Directive, the following definitions shall apply:

(a) “infants” means children under the age of 12 months;

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

(c) “pesticide residue” means the residue in processed cereal-based foods and baby foods of a plant protection product, as defined in point 1 of Article 2 of Directive 91/414/EEC (OJ L230, 19.8.1991, p.1), including its metabolites and products resulting from its degradation or reaction.

4. (1) No person shall import, keep or sell any processed cereal-based food or other baby food intended for infants and young children which does not comply with the requirements of these regulations.

Sales of processed cereal-based foods and baby foods for infants and young children.

5. (1) Processed cereal-based foods shall comply with the compositional criteria specified in the First Schedule.

Compositional criteria.

(2) Baby foods which are described in the Second Schedule shall comply with the compositional criteria specified therein.

6. (1) Processed cereal-based foods and baby foods shall be manufactured from ingredients whose suitability for particular nutritional use by infants and young children has been established by generally accepted scientific data.

Manufacture of processed cereal-based foods and baby foods for infants and young children.

(2) Only the nutritional substances listed in the Fourth Schedule may be added in the manufacture of processed cereal-based foods and baby foods.

(3) Processed cereal-based foods and baby foods shall not contain any substance in such quantity as to endanger the health of infants and young children.

(4) Processed cereal-based foods and baby foods shall not contain residues of individual pesticides at levels exceeding 0,01 mg/kg, except for those substances for which specific levels have been set in the Sixth Schedule, in which case these specific levels shall apply. Analytical methods for determining the levels of pesticide residues shall be generally acceptable standardised methods.

(5) The pesticides listed in the Seventh Schedule shall not be used in agricultural products intended for the production of processed cereal-based foods and baby foods.

However, for the purpose of control:

(a) pesticides listed in Table I of the Seventh Schedule are considered not to have been used if their residues do not exceed a level of 0,003 mg/kg. This level, which is considered to be the limit of quantification of the analytical methods, shall be kept under regular review in the light of technical progress;

(b) pesticides listed in Table II of the Seventh Schedule are considered not to have been used if their residues do not exceed a level of 0,003 mg/kg. This level shall be kept under regular review in the light of data on environmental contamination.

(6) The levels referred to in paragraphs 6(4) and 6(5) shall apply to the products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers.

Labelling of processed cereal-based foods and baby foods for infants and young children.

7. (1) The labelling of the products concerned shall bear in addition to the particulars provided for in the Labelling and Presentation of Foodstuffs Regulations, the following mandatory particulars, in Maltese, English or Italian:

(a) a statement as to the appropriate age from which the product may be used, regard being had to its composition, texture or other particular properties. The stated age shall not be less than four months for any product. Products recommended for use from the age of four months may indicate that they are suitable from that age unless independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care, advise otherwise;

(b) information as to the presence or absence of gluten if the indicated age from which the product may be used is below six months;

(c) the available energy value expressed in kJ and kcal, and the protein, carbohydrate and lipid content, expressed in numerical form, per 100 g or 100 ml of the product as sold and, where appropriate, per specified quantity of the product as proposed for consumption;

(d) the average quantity of each mineral substance and of each vitamin governed by a specific level as specified in the First and Second Schedules respectively, expressed in numerical form, per 100 g or 100 ml of the product as sold and, where appropriate, per specified quantity of the product as proposed for consumption;

(e) instructions for appropriate preparation, when necessary, and a statement as to the importance of following those instructions.

(2) The labelling may bear:

(a) the average quantity of the nutrients set out in the Fourth Schedule when such declaration is not covered by the provisions of paragraph 7(1)(d), expressed in numerical form, per 100 g or 100 ml of the product as sold and, where appropriate, per specified quantity of the product as proposed for consumption;

(b) in addition to numerical information, information on vitamins and minerals shown in the Fifth Schedule, expressed as a percentage of the reference values given therein, per 100 g or 100 ml of the product as sold, and where appropriate, per specified quantity of the product as proposed for consumption, provided that the quantities present are at least equal to 15 % of the reference values.

8. The Processed Cereal-based Foods and Other Foods for Infants and Young Children Regulations, 2002 are hereby repealed and any reference to those regulations shall be construed as a reference to these regulations.

Repeal of L.N. 207
of 2002.

First Schedule

ESSENTIAL COMPOSITION OF PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN

The requirements concerning nutrients refer to the products ready for use marketed as such or reconstituted as instructed by the manufacturer.

1. CEREAL CONTENT

Processed cereal-based foods are prepared primarily from one or more milled cereals and/or starchy root products.

The amount of cereal and/or starchy root shall not be less than 25 % of the final mixture on a dry weight for weight basis.

2. PROTEIN

2.1. For products mentioned in regulation 2(1)(a)(ii) and (iv), the protein content shall not exceed 1,3 g/100 kJ (5,5 g/100 kcal).

2.2. For products mentioned in regulation 2(1)(a)(ii), the added protein shall not be less than 0,48 g/100 kJ (2 g/100 kcal).

2.3. For biscuits mentioned in Article 2(1)(a)(iv), made with the addition of a high protein food, and presented as such, the added protein shall not be less than 0,36 g/100 kJ (1,5 g/100 kcal).

2.4. The chemical index of the added protein shall be equal to at least 80 % of that of the reference protein (casein as defined in the Third Schedule), or the protein efficiency ratio (PER) of the protein in the mixture shall be equal to at least 70 % of that of the reference protein. In all cases, the addition of amino acids shall be permitted solely for the purpose of improving the nutritional value of the protein mixture, and only in the proportions necessary for that purpose.

3. CARBOHYDRATES

3.1. If sucrose, fructose, glucose, glucose syrups or honey are added to products mentioned in regulation 2(1)(a)(i) and (iv):

— the amount of added carbohydrates from these sources shall not exceed 1,8 g/100 kJ (7,5 g/100 kcal),

— the amount of added fructose shall not exceed 0,9 g/100 kJ (3,75 g/100 kcal).

3.2. If sucrose, fructose, glucose syrups or honey are added to products mentioned in regulation 2(1)(a)(ii):

— the amount of added carbohydrates from these sources shall not exceed 1,2 g/100 kJ (5 g/100 kcal),

— the amount of added fructose shall not exceed 0,6 g/100 kJ (2,5 g/100 kcal).

4. LIPIDS

4.1. For products mentioned in regulation 2(1)(a)(i) and (iv), the lipid content shall not exceed 0,8 g/100 kJ (3,3 g/100 kcal).

4.2. For products mentioned in regulation 2(1)(a)(ii), the lipid content shall not exceed 1,1 g/100 kJ (4,5 g/100 kcal). If the lipid content exceeds 0,8 g/100 kJ (3,3 g/100 kcal):

— the amount of lauric acid shall not exceed 15 % of the total lipid content,

— the amount of myristic acid shall not exceed 15 % of the total lipid content,

— the amount of linoleic acid (in the form of glycerides = linoleates) shall not be less than 70 mg/100 kJ (300 mg/100 kcal) and shall not exceed 285 mg/100 kJ (1 200 mg/100 kcal).

5. MINERALS

5.1. Sodium

— sodium salts may only be added to processed cereal-based foods for technological purposes,

— the sodium content of processed cereal-based foods shall not exceed 25 mg/100 kJ (100 mg/100 kcal).

5.2. Calcium

5.2.1. For products mentioned in regulation 2(1)(a)(ii), the amount of calcium shall not be less than 20 mg/100 kJ (80 mg/100 kcal).

5.2.2. For products mentioned in Article 2(1)(a)(iv), manufactured with the addition of milk (milk biscuits) and presented as such, the amount of calcium shall not be less than 12 mg/100 kJ (50 mg/100 kcal).

6. VITAMINS

6.1. For processed cereal-based foods, the amount of thiamin shall not be less than 25 µg/100 kJ (100 µg/100 kcal).

6.2. For products mentioned in regulation 2(1)(a)(ii):

	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

(1) RE = all trans retinol equivalents.

These limits shall also be applicable if vitamins A and D are added to other processed cereal-based foods.

7. MAXIMUM LIMITS FOR VITAMINS, MINERALS AND TRACE ELEMENTS, IF ADDED

The requirements concerning nutrients refer to the products ready for use, marketed as such or reconstituted as instructed by the manufacturer, except for potassium and calcium for which the requirements refer to the product as sold.

Nutrient	Maximum per 100 kcal
Vitamin A ($\mu\text{g RE}$)	180
Vitamin E (mg -TE) ⁽¹⁾	3
Vitamin D (μg)	3
Vitamin C (mg)	12,5/25 (2)
Thiamin (mg)	0,5
Riboflavin (mg)	0,4
Niacin (mg NE) ⁽³⁾	4,5
Vitamin B6 (mg)	0,35
Folic acid (μg)	50
Vitamin B12 (μg)	0,35
Pantothenic acid (mg)	1,5
Biotin (μg)	10
Potassium (mg)	160
Calcium (mg)	80/180 ⁽⁴⁾ /100 ⁽⁵⁾
Magnesium (mg)	40
Iron (mg)	3
Zinc (mg)	2
Copper (μg)	40
Iodine (μg)	35
Manganese (mg)	0,6

(1) -TE = d- -tocopherol equivalent.

(2) Limit applicable to products fortified with iron.

(3) NE = Niacin equivalents = mg nicotinic acid + mg tryptophan/60.

(4) Limit applicable to products mentioned in paragraph 2(1)(a)(i) and (ii).

(5) Limit applicable to products mentioned in paragraph 2(1)(a)(iv).

SECOND SCHEDULE

ESSENTIAL COMPOSITION OF BABY FOODS FOR INFANTS AND YOUNG CHILDREN

The requirements concerning nutrients refer to the products ready for use, marketed as such or reconstituted as instructed by the manufacturer.

1. PROTEIN

1.1. If meat, poultry, fish, offal or other traditional source of protein, are the only ingredients mentioned in the name of the product, then:

- the named meat, poultry, fish, offal or other traditional protein source, in total, shall constitute not less than 40 % by weight of the total product,
- each named meat, poultry, fish, offal or other traditional source of protein shall constitute not less than 25 %, by weight, of total named protein sources,
- the total protein from the named sources shall not be less than 1,7 g/100 kJ (7 g/100 kcal).

1.2. If meat, poultry, fish, offal or other traditional source of protein, singularly or in combination, are mentioned first in the name of the product, whether or not the product is presented as a meal, then:

- the named poultry, fish, offal or other traditional protein source, in total, shall constitute not less than 10 %, by weight of the total product,
- each named meat, poultry, fish, offal or other traditional source of protein shall constitute not less than 25 %, by weight, of total named protein sources,
- the protein from the named sources shall not be less than 1 g/100 kJ (4 g/100 kcal).

1.3. If meat, poultry, fish, offal or other traditional source of protein, singularly or in combination are mentioned, but not first, in the name of the product, whether or not the product is presented as a meal, then:

- the named meat, poultry, fish, offal or other traditional protein source, in total, shall constitute not less than 8 %, by weight of the total product,
- each named meat, poultry, fish, offal or other traditional source of protein shall constitute not less than 25 %, by weight, of total named protein sources,

— the protein from the named sources shall not be less than 0,5 g/100 kJ (2,2 g/100 kcal),

— the total protein in the product from all sources shall not be less than 0,7 g/100 kJ (3 g/100 kcal).

1.4. If cheese is mentioned together with other ingredients in the name of a savoury product, whether or not the product is presented as a meal, then:

— the protein from the dairy sources shall not be less than 0,5 g/100 kJ (2,2 g/100 kcal),

— the total protein in the product from all sources shall not be less than 0,7 g/100 kJ (3 g/100 kcal).

1.5. If the product is designated on the label as a meal, but does not mention meat, poultry, fish, offal or other traditional source of protein in the name of the product, the total protein in the product from all sources shall not be less than 0,7 g/100 kJ (3 g/100 kcal).

1.6. Sauces presented as an accompaniment to a meal shall be exempt from the requirements of points 1.1 to 1.5 inclusive.

1.7. Sweet dishes that mention dairy products as the first or only ingredient in the name shall contain not less than 2,2 g dairy protein/100 kcal. All other sweet dishes shall be exempt from the requirements in 1.1 to 1.5.

1.8. The addition of amino acids shall be permitted solely for the purpose of improving the nutritional value of the protein present, and only in the proportions necessary for that purpose.

2. CARBOHYDRATES

The quantities of total carbohydrates present in fruit and vegetable juices and nectars, fruit-only dishes, and desserts or puddings shall not exceed:

— 10 g/100 ml for vegetable juices and drinks based on them,

— 15 g/100 ml for fruit juices and nectars and drinks based on them,

— 20 g/100 g for fruit-only dishes,

— 25 g/100 g for desserts and puddings,

— 5 g/100 g for other non-milk-based drinks.

B 3032

3. FAT

3.1. For products referred to in point 1.1:

If meat or cheese are the only ingredients or are mentioned first in the name of a product, the total fat in the product from all sources shall not exceed 1,4 g/100 kJ (6 g/100 kcal).

3.2. For all other products, the total fat in the product from all sources shall not exceed 1,1 g/100 kJ (4,5 g/100 kcal).

4. SODIUM

4.1. The final sodium content in the product shall be either not more than 48 mg/100 kJ (200 mg/100 kcal) or not more than 200 mg per 100 g. However if cheese is the only ingredient mentioned in the name of the product, the final sodium content in the product shall not be more than 70 mg/100 kJ (300 mg/100 kcal).

4.2. Sodium salts may not be added to products based on fruit, nor to desserts, puddings except for technological purposes.

5. VITAMINS

Vitamin C

In a fruit juice, nectar, or vegetable juice the final content of vitamin C in the product shall be either not less than 6 mg/100 kJ (25 mg/100 kcal) or not less than 25 mg per 100 g.

Vitamin A

In vegetable juices, the final content of vitamin A in the product shall be not less than 25 µg RE/100 kJ (100 µg RE/100 kcal).

Vitamin A shall not be added to other baby foods.

Vitamin D

Vitamin D shall not be added to baby foods.

6. MAXIMUM LIMITS FOR VITAMINS, MINERALS AND TRACE ELEMENTS, IF ADDED

The requirements concerning nutrients refer to the products ready for use, marketed as such or reconstituted as instructed by the manufacturer, except for potassium and calcium for which the requirements refer to the product as sold.

Nutrient	Maximum per 100 kcal
Vitamin A ($\mu\text{g RE}$)	180 (1)
Vitamin E (mg α -TE)	3
Vitamin C (mg)	12,5/25 (2)/125 (3)
Thiamin (mg)	0,25
Riboflavin (mg)	0,4
Niacin (mg NE)	4,5
Vitamin B6 (mg)	0,35
Folic acid (μg)	50
Vitamin B12 (μg)	0,35
Pantothenic acid (mg)	1,5
Biotin (μg)	10
Potassium (mg)	160
Calcium (mg)	80
Magnesium (mg)	40
Iron (mg)	3
Zinc (mg)	2
Copper (μg)	40
Iodine (μg)	35
Manganese (mg)	0,6

(1) In accordance with the provisions of point 5.

(2) Limit applicable to products fortified with iron.

THIRD SCHEDULE**AMINO ACID COMPOSITION OF CASEIN**

	<i>(g per 100 g of protein)</i>
Arginine	3,7
Cystine	0,3
Histidine	2,9
Isoleucine	5,4
Leucine	9,5
Lysine	8,1
Methionine	2,8
Phenylalanine	5,2
Threonine	4,7
Tryptophan	1,6
Tyrosine	5,8
Valine	6,7

FOURTH SCHEDULE

NUTRITIONAL SUBSTANCES

1. VITAMINS	
<i>Vitamin A</i>	<i>Vitamin C</i>
Retinol	L-ascorbic acid
Retinyl acetate	Sodium L-ascorbate
Retinyl palmitate	Calcium L-ascorbate
Beta carotene	6-palmityl-L-ascorbic acid (ascorbyl palmitate)
	Potassium ascorbate
<i>Vitamin D</i>	
Vitamin D2 (= ergocalciferol)	<i>Vitamin K</i>
Vitamin D3 (= cholecalciferol)	Phylloquinone (Phytomenadione)
<i>Vitamin B1</i>	<i>Vitamin E</i>
Thiamin hydrochloride	D-alpha tocopherol
Thiamin mononitrate	DL-alpha tocopherol
	D-alpha tocopherol acetate
<i>Vitamin B2</i>	DL-alpha tocopherol acetate
Riboflavin	
Riboflavin-5'-phosphate, sodium	2. AMINO ACIDS
	L-arginine
<i>Niacin</i>	L-cystine
Nicotinamide	L-histidine
Nicotinic acid	L-isoleucine
	L-leucine
	L-lysine
<i>Vitamin B6</i>	L-cysteine
Pyridoxine hydrochloride	L-methionine
Pyridoxine-5-phosphate	L-phenylalanine
Pyridoxine dipalmitate	L-threonine
	L-tryptophan
<i>Pantothenic Acid</i>	L-tyrosine
D-pantothenate, calcium	L-valine
D-pantothenate, sodium	
Dexpanthenol	3. OTHERS
	Choline
<i>Folate</i>	Choline chloride
Folic acid	Choline citrate
	Choline bitartrate
<i>Vitamin B12</i>	Inositol
Cyanocobalamin	L-carnitine
Hydroxocobalamin	L-carnitine hydrochloride
<i>Biotin</i>	
D-biotin	

4. SALTS OF MINERALS AND TRACE ELEMENTS	
<i>Calcium</i>	Ferrous fumarate
Calcium carbonate	Ferric diphosphate (ferric pyrophosphate)
Calcium chloride	Elemental iron (carbonyl + electrolytic + hydrogenreduced)
Calcium salts of citric acid	Ferric saccharate
Calcium gluconate	Sodium ferric diphosphate
Calcium glycerophosphate	Ferrous carbonate
Calcium lactate	
Calcium oxide	<i>Copper</i>
Calcium hydroxide	Copper-lysine complex
Calcium salts of orthophosphoric acid	Cupric carbonate
	Cupric citrate
<i>Magnesium</i>	Cupric gluconate
Magnesium carbonate	Cupric sulphate
Magnesium chloride	
Magnesium salts of citric acid	<i>Zinc</i>
Magnesium gluconate	Zinc acetate
Magnesium oxide	Zinc chloride
Magnesium hydroxide	Zinc citrate
Magnesium salts of orthophosphoric acid	Zinc lactate
Magnesium sulphate	Zinc sulphate
Magnesium lactate	Zinc oxide
Magnesium glycerophosphate	Zinc gluconate
<i>Potassium</i>	<i>Manganese</i>
Potassium chloride	Manganese carbonate
Potassium salts of citric acid	Manganese chloride
Potassium gluconate	Manganese citrate
Potassium lactate	Manganese gluconate
Potassium glycerophosphate	Manganese sulphate
	Manganese glycerophosphate
<i>Iron</i>	
Ferrous citrate	<i>Iodine</i>
Ferric ammonium citrate	Sodium iodide
Ferrous gluconate	Potassium iodide
Ferrous lactate	Potassium iodate
Ferrous sulphate	Sodium iodate

FIFTH SCHEDULE**REFERENCE VALUES FOR NUTRITION LABELLING FOR FOODS INTENDED FOR
INFANTS AND YOUNG CHILDREN**

Nutrient	Labelling reference value
Vitamin A	(µg) 400
Vitamin D	(µg) 10
Vitamin C	(mg) 25
Thiamin	(mg) 0,5
Riboflavin	(mg) 0,8
Niacin equivalents	(mg) 9
Vitamin B6	(mg) 0,7
Folate	(µg) 100
Vitamin B12	(µg) 0,7
Calcium	(mg) 400
Iron	(mg) 6
Zinc	(mg) 4
Iodine	(µg) 70
Selenium	(µg) 10
Copper	(mg) 0,4

SIXTH SCHEDULE

SPECIFIC MAXIMUM RESIDUE LEVELS OF PESTICIDES OR METABOLITES OF
PESTICIDES IN PROCESSED CEREAL-BASED FOODS AND BABY FOODS

Chemical name of the substance	Maximum residue level (mg/kg)
Cadusafos	0,006
Demeton-S-methyl/demeton-S-methyl sulfone/oxydemeton-methyl (individually or combined, expressed as demeton-S-methyl)	0,006
Ethoprophos	0,008
Fipronil (sum of fipronil and fipronil-desulfinyl, expressed as fipronil)	0,004
Propineb/propylenethiourea (sum of propineb and propylenethiourea)	0,006

SEVENTH SCHEDULE

PESTICIDES WHICH SHALL NOT BE USED IN AGRICULTURAL PRODUCTION INTENDED FOR THE PRODUCTION OF PROCESSED CEREAL-BASED FOODS AND BABY FOODS

Table 1

Chemical name of the substance (residue definition)
Disulfoton (sum of disulfoton, disulfoton sulfoxide and disulfoton sulfone expressed as disulfoton)
Fensulfothion (sum of fensulfothion, its oxygen analogue and their sulfones, expressed as fensulfothion)
Fentin, expressed as triphenyltin cation
Haloxyfop (sum of haloxyfop, its salts and esters including conjugates, expressed as haloxyfop)
Heptachlor and <i>trans</i> -heptachlor epoxide, expressed as heptachlor
Hexachlorobenzene
Nitrofen
Omethoate
Terbufos (sum of terbufos, its sulfoxide and sulfone, expressed as terbufos)

Table 2

Chemical name of the substance
Aldrin and dieldrin, expressed as dieldrin
Endrin

