

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

**Processed Cereal-based Foods and Other Foods for Infants and
Young Children Regulations, 2002**

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

Citation and
commencement.

1.1 These regulations may be cited as the Processed Cereal-based Foods and Other Foods for Infants and Young Children Regulations 2002.

1.2 These Regulations shall come into force on the 1st August, 2002.

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.

2.2 These regulations shall not apply to milks intended for young children.

2.3 For the purposes of these regulations:

- 'infants' shall mean children under the age of twelve months,
- 'young children' shall mean children aged between 1 and 3 years,
- '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 Council Directive 91/414/EEC ⁽¹⁾, including its metabolites and products resulting from its degradation or reaction.

3.1 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.

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

4.1 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.

4.2 Processed cereal-based foods shall comply with the compositional criteria specified in the First Schedule.

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

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

4.5 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.

4.6 Processed cereal-based foods and baby foods shall not contain residues of individual pesticides at levels exceeding 0.01 mg/kg of the product as proposed ready for consumption or as reconstituted according to the instructions of the manufacturer.

4.7 Analytical methods for determining the levels of pesticide residues shall be generally acceptable standardised methods.

¹ OJ L 230, 19.8.1991, p.1.

4.8 The maximum limits for vitamins, minerals and trace elements laid down in the Sixth Schedule shall be observed if such vitamins, minerals and trace elements are added to processed cereal-based foods and baby foods intended for infants and young children.

Labelling of
Processed Cereal-
based Foods and
Baby Foods
intended for infants
and young children

5.1 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 in the First and Second Schedule 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.

5.2 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 regulation 5.1 paragraph (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.

6.1 The Processed Cereal-based Foods and Other Foods for Repeal of L.N.258
of 1998. Infants and Young Children Regulations, 1998 are hereby repealed.

6.2 References in other regulations to the Processed Cereal-based Foods and Other Foods for Infants and Young Children Regulations, 1998 shall henceforth be construed as references to these regulations.

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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 paragraphs (a) (ii) and (a) (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 paragraph (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 Regulation 2.1 paragraph (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 energy 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 is 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 paragraphs (a) (i) and (a) (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 paragraph (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 paragraphs (a) (i) and (a) (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 paragraph (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):

- (a) the amount of lauric acid shall not exceed 15% of the total lipid content;
- (b) the amount of myristic acid shall not exceed 15% of the total lipid content;
- (c) 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/ kcal).

5.2 Calcium

5.2.1 For products mentioned in regulation 2.1 paragraph (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 regulation 2.1 paragraph (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).

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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 paragraph (a) (ii):

| | Per 100 kJ | | Per 100 kcal | |
|---------------------------------|------------|---------|--------------|---------|
| | Minimum | Maximum | Minimum | Maximum |
| Vitamina A (µg RE) ² | 14 | 43 | 60 | 180 |
| Vitamina D (µg) ³ | 0.25 | 0.75 | 1 | 3 |

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

² RE = all trans retinol equivalents.

³ In the form of cholecalciferol, of which 10 µg = 400 i.u. of vitamin D.

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 meat, 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).

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1.4 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, then:

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

1.6 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).

1.7 Sauces presented as an accompaniment to a meal are exempt from the requirements of paragraphs 1.1 to 1.4 above.

1.8 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 are exempt from the requirements in sections 1.1 to 1.4 above.

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.

3. Fat

3.1 For products referred to in paragraph 1.1 of this Schedule:

If meat or cheese are the only ingredients or are mentioned first in the name of a product, then:

- 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 should not exceed 1.1 g/100 kJ (4.5 g/100 kcal).

4. Sodium

4.1 The final sodium content in the product should 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 should 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 should be either not less than 6 mg/100 kJ (25 mg/100 kcal) or not less than 25 mg per 100g.

Vitamin A

In vegetable juices, the final content of vitamin A in the product should not be less than 25 µg RE/100 kJ (100 µg RE/100 kcal).⁴

Vitamin A shall not be added to other baby foods.

Vitamin D

Vitamin D shall not be added to baby foods.

⁴ RE = all trans retinol equivalents.

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

Vitamin A

Retinol
Retinyl acetate
Retinyl palmitate
beta carotene

Vitamin D

Vitamin D2 (= ergocalciferol)
Vitamin D3 (= cholecalciferol)

Vitamin B1

Thiamin hydrochloride
Thiamin mononitrate

Vitamin B2

Riboflavin
Riboflavin-5'-phosphate, sodium

Niacin

Nicotinamide
Nicotinic acid

Vitamin B6

Pyridoxine hydrochloride
Pyridoxine-5-phosphate
Pyridoxine dipalmitate

Pantothenic acid

D-pantothenate, calcium
D-pantothenate, sodium
Dexpanthenol

Folate

Folic acid

Vitamin B12

Cyanocobalamin
Hydroxocobalamin

Biotin

D-biotin

B 3120

Vitamin C

L-Ascorbic acid

Sodium L-ascorbate

Calcium L-ascorbate

6-Palmityl-L-ascorbic acid (ascorbyl palmitate)

potassium ascorbate

Vitamin K

Phylloquinone (Phytomenadione)

Vitamin E

D-alpha tocopherol

DL-alpha tocopherol

D-alpha tocopherol acetate

DL-alpha tocopherol acetate

2. Amino acids

L-arginine (and hydrochloride)

L-cystine (and hydrochloride)

L-histidine (and hydrochloride)

L-isooleucine (and hydrochloride)

L-leucine (and hydrochloride)

L-lysine (and hydrochloride)

L-cysteine (and hydrochloride)

L-methionine

L-phenylalanine

L-threonine

L-tryptophan

L-tyrosine

L-valine

3. Others

Choline

Choline chloride

Choline citrate

Choline bitartrate

Inositol

L-Carnitine

L-Carnitine hydrochloride

4. Salts of minerals and trace elements

Calcium

Calcium carbonate

Calcium chloride

Calcium salts of citric acid

Calcium gluconate

Calcium glycerophosphate

Calcium lactate
Calcium oxide
Calcium hydroxide
Calcium salts of orthophosphoric acid

Magnesium

Magnesium carbonate
Magnesium chloride
Magnesium salts of citric acid
Magnesium gluconate
Magnesium oxide
Magnesium hydroxide
Magnesium salts of orthophosphoric acid
Magnesium sulphate
Magnesium lactate
Magnesium glycerophosphate

Potassium

Potassium chloride
Potassium salts of citric acid
Potassium gluconate
Potassium lactate
Potassium glycerophosphate

Iron

Ferrous citrate
Ferric ammonium citrate
Ferrous gluconate
Ferrous lactate
Ferrous sulphate
Ferrous fumarate
Ferric diphosphate (ferric pyrophosphate)
Elemental iron (carbonyl + electrolytic + hydrogen-reduced)
Ferric saccharate
Sodium ferric diphosphate
Ferrous carbonate

Copper

Copper-lysine complex
Cupric carbonate
Cupric citrate
Cupric gluconate
Cupric sulphate

Zinc

Zinc acetate

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Zinc citrate
Zinc lactate
Zinc sulphate
Zinc oxide
Zinc gluconate

Manganese
Manganese carbonate
Manganese chloride
Manganese citrate
Manganese gluconate
Manganese sulphate
Manganese glycerophosphate

Iodine
Sodium iodide
Potassium iodide
Potassium iodate
Sodium iodate

FIFTH SCHEDULE

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

| <i>Nutrient</i> | <i>Labelling Reference Value</i> |
|--------------------|----------------------------------|
| 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

Maximum Limits for Vitamins, Minerals and Trace Elements, if added, in Processed Cereal-based Foods and Baby Foods intended 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, except for potassium and calcium for which the requirements refer to the product as sold.

| Nutrient | Massimu kull 100 kcal |
|-----------------------|--|
| Vitamin A (µg RE) | 180 ⁵ |
| Vitamin E (mg a-TE) | 3 |
| Vitamin C (mg) | 12.5/25 ⁶ /125 ⁷ |
| Thiamin (mg) | 0.25/0.5 ⁸ |
| Riboflavin (mg) | 0.4 |
| Niacin (mg NE) | 4.5 |
| Vitamin B6 (mg) | 0.35 |
| Folic acid (µg) | 50 |
| Vitamin B12 (mg) | 0.35 |
| Pantothenic acid (mg) | 1.5 |
| Biotin (µg) | 10 |
| Potassium (mg) | 160 |
| Calcium (mg) | 80/160 ⁹ /100 ¹⁰ |
| Magnesium (mg) | 40 |
| Iron (mg) | 3 |
| Zinc (mg) | 2 |
| Copper (µg) | 40 |
| Iodine (µg) | 35 |
| Manganese (mg) | 0.6 |

⁵ In accordance with the provisions of the First and Second Schedules.

⁶ Limit applicable to fruit based dishes and for products fortified with iron.

⁷ Limit applicable to fruit juices, nectars and vegetable juices.

⁸ Limit applicable to processed cereal-based foods.

⁹ Limit applicable to products mentioned in regulation 2.1 (a) (ii).

¹⁰ Limit applicable to products mentioned in regulation 2.1 (a) (iv).