

**EUROPEAN COMMUNITIES (PROCESSED CEREAL-BASED FOODS AND BABY
FOODS FOR
INFANTS AND YOUNG CHILDREN) REGULATIONS 1998**

ARRANGEMENT OF SECTIONS

Articles

1-3 Title, Commencement and Interpretation
4-6 Conditions for the Marketing of Processed Cereal-Based Foods and Baby Foods
7-10 Composition of Processed Cereal-Based Foods and Baby Foods
11-12 Labeling of Processed Cereal-Based Foods and Baby Foods
13-14 Enforcement
15-19 Offences

SCHEDULE I — Essential Composition of Processed Cereal-Based Foods for Infants and Young Children

SCHEDULE II — Essential Composition of Baby Foods for Infants and Young Children

SCHEDULE III — Amino Acid Composition of Casein

SCHEDULE IV — Nutritional Substances

SCHEDULE V — Reference Values for Nutrition Labelling for Foods Intended for Infants and Young Children

S.I. No. 241 of 1998.

I, BRIAN COWEN, Minister for Health and Children in exercise of the powers conferred on me by Section 3 of the European Communities Act, 1972 (No. 27 of 1972) having regard to Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses as amended by Directive 96/84/EC of the European Parliament and of the Council of 19 December 1996 and for the purposes of giving effect to Commission Directive 96/5/EC of the 16th of February 1996, hereby make the following Regulations:—

1 OJ No. L186, 30.6.1989, p.27.

2 OJ No. L48, 19.2.1997, p.20.

3 OJ No. L49, 28.2.1996, pp.17-28.

REG 1

Title, Commencement and Interpretation

1. These Regulations may be cited as the European Communities (Processed Cereal-Based Foods and Baby Foods for Infants and Young Children) Regulations, 1998.

REG 2

2. (1) These Regulations shall come into operation on the 17th day of July, 1998.

(2) Trade in products which do not comply with these Regulations is prohibited with effect from 31 March 1999.

REG 3

3. (1) In these Regulations:

"authorised officer" means:

- (a) an officer of the Minister for Health and Children who is authorised in writing by the Minister for Health and Children to be an authorised officer for the purposes of these Regulations, or
- (b) an officer of a health board who is authorised in writing by the Chief Executive Officer of the health board to be an authorised officer for the purposes of these Regulations.

"export" means to market a product in a country outside the European Union;

"functional area", in relation to a health board, means the functional area of the board as defined in the Health Board Regulations, 1970 (S.I. No. 170 of 1970);

"health board" means a health board established under Section 4(1) of the Health Act, 1970 (No. 1 of 1970);

"infants" mean children under the age of twelve months;

"to market" includes to supply, whether or not for profit, offer, expose for sale, and/or have in possession for sale and cognate words shall be construed accordingly;

"Minister" means the Minister for Health and Children;

"young children" means children aged between one and three years.

(2) In these Regulations, any reference to an article or Schedule shall be construed as a reference to an article contained in these Regulations, or as the case may be, to a Schedule thereto and any reference in an article to a sub-article shall be construed as a reference to a sub-article of that article, unless otherwise stated.

(3) A word or expression that is used in these Regulations and is also used in Council Directive 89/398/EEC and/or Commission Directive No. 96/5/EC and/or Directive 96/84/EC of the European Parliament and of the Council has, unless the contrary intention appears, the meaning in these Regulations that it has in the Council and Commission Directives.

REG 4

Conditions for the Marketing of Processed Cereal-Based Foods and Baby Foods

4. These Regulations relate to foodstuffs for particular nutritional use fulfilling the particular requirements of infants and young children in good health and 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 of:

- (1) "Processed cereal-based foods" which are divided into the following four categories:

- (a) simple cereals which are or have to be reconstituted with milk or other appropriate nutritious liquids;
 - (b) cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid;
 - (c) pastas which are to be used after cooking in boiling water or other appropriate liquids;
 - (d) rusks and biscuits which are to be used either directly or, after pulverisation, with the addition of water, milk or other suitable liquids.
- (2) "Baby foods" other than processed cereals-based foods.

REG 5

5. These Regulations do not apply to milks intended for young children.

REG 6

6. The products referred to in Article 4 may be marketed only if they conform to the provisions laid down in these Regulations.

REG 7

Composition of Processed Cereal-Based Foods and Baby Foods

7. Processed cereal-based foods and baby foods shall be manufactured from ingredients whose suitability for particular nutritional use by infants and young children has, in the opinion of the Minister, been established by generally accepted scientific data.

REG 8

8. (1) Processed cereal-based foods must comply with the compositional criteria specified in Schedule I.
- (2) Baby foods which are described in Schedule II must comply with the compositional criteria specified therein.
- (3) Only the nutritional substances listed in Schedule IV may be added in the manufacture of processed cereal-based foods and baby foods.

REG 9

9. Processed cereal-based foods and baby foods shall not contain any substance in such quantity which, in the opinion of the Minister, endangers the health of infants and young children.

REG 10

10. (1) The Minister may, by order, stipulate the maximum levels of any substance included in infant formulae or follow-on formulae.

(2) The Minister may, by order, establish such microbiological criteria as he considers appropriate.

REG 11

Labelling of Processed Cereal-Based Foods and Baby Foods

11. The labelling of foodstuffs as set out in Article 4 shall bear the following particulars in addition to EU and general food labelling requirements:

(1) A statement as to the appropriate age from which the product may be used, with regard to its composition, texture or other particular properties. The stated age may not be less than four months for any product.

(2) 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.

(3) If the indicated age from which the product may be used is below six months, the label must contain information as to the presence or absence of gluten.

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

(5) The average quantity of each mineral substance and of each vitamin governed by a specific level in Schedule I and Schedule II respectively, expressed in numerical form, per 100g or 100ml of the product as sold and, where appropriate, per specified quantity of the product as proposed for consumption.

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

REG 12

12. The labelling may bear:

(1) The average quantity of the nutrients set out in Schedule IV when such declaration is not covered by the provisions of Article 11(5), expressed in numerical form, per 100g or 100ml of the product as sold and where appropriate, per specified quantity of the product as proposed for consumption.

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

REG 13

Enforcement

13. These Regulations shall be enforced and executed by each health board in respect of its functional area through its authorised officers and/or the officers of the Minister for Health and Children who are authorised officers for the purposes of these Regulations.

REG 14

14. For the purposes of ensuring compliance with these Regulations, the provisions of the European Communities (Official Control of Foodstuffs) Regulations, 1998 (S.I. No. 85 of 1998) shall apply.

REG 15

Offences

15. (1) A person shall not manufacture, prepare, import, distribute, market and/or label any product which does not comply with these Regulations.

(2) Any person who contravenes any article or sub-article of these Regulations shall be guilty of an offence.

(3) A person guilty of an offence under these Regulations shall be liable on summary conviction to a fine not exceeding £1,000 or at the discretion of the Court, to imprisonment for a term not exceeding six months or to both.

(4) Where an offence under these Regulations is committed by a body corporate and is proved to have been so committed with the consent or connivance of or to be attributable to any neglect on the part of a director, secretary or other officer of the body corporate, the director, secretary or other officer or any person purporting to act in such capacity shall, as well as the body corporate, be guilty of an offence and shall be liable to be proceeded against

and punished accordingly.

(5) Notwithstanding Section 10(4) of the Petty Sessions (Ireland) Act, 1851, proceedings for an offence under these Regulations may be instituted within twelve months from the date of the offence or any time within twelve months from the date on which knowledge of the commission of the offence came to the attention of an authorised officer.

REG 16

16. An offence under these Regulations may be prosecuted by—

- (a) the Minister, or
- (b) a health board within whose functional area the offence was committed.

REG 17

17. (1) An authorised officer shall be furnished with a certificate of his appointment as an authorised officer and when exercising any power conferred on an authorised officer by these Regulations shall, if so requested by a person affected, produce the certificate for the inspection of the person.

(2) It shall be offence for a person falsely to represent himself to be an authorised officer.

REG 18

18. A health board shall

- (a) forward to the Minister such information as he may request in respect of the exercise of the functions conferred on it by or under these Regulations;
- (b) comply with any directions given by the Minister from time to time as the exercise of its powers or the performance of its functions and duties under these Regulations.

SCHEDULE I

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 Article 4(1)(b) and (d), the protein content shall not exceed 1.3 g/100 kJ (5.5 g/100 kcal).

2.2 For products mentioned in Article 4(1)(b), the added protein shall not be less than 0.48 g/100 kJ (2 g/100 kcal).

2.3 For biscuits mentioned in Article 4(1)(d), 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 (1.5/100 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 Schedule III), 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 Article 4(1)(a) and (d):

— 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 Article 4(1)(b),

— 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 Article 4(1)(a) and (d), the lipid content shall not exceed 0.8 g/100 kJ (3.3 g/100 kcal).

4.2 For products mentioned in Article 4(1)(b), 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/100 kcal).

5.2 Calcium

5.2.1 For products mentioned in Article 4(1)(b), 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 4(1)(d), 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 2.5 µg/100 kJ (100 µg/100 kcal).

6.2 For products mentioned in Article 4(1)(b)

Per 100 kJ	Per 100 kcal	Minimum	Maximum	Minimum	Maximum	Vitamin A (µg RE)
114	436	0180	Vitamin D (µg)	20.25	0.75	13

1 RE = all trans retinol equivalents.

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

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

SCHEDULE II

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).

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.

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 point 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 should 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 100 g.

Vitamin A

In vegetable juices, the final content of vitamin A in the product should be not less than 25 µg RE/100 kJ (100 µg RE/100 kcal)¹

Vitamin A shall not be added to other baby foods.

Vitamin D

Vitamin D shall not be added to baby foods.

1 RE=all trans retinol equivalents.

SCHEDULE III

AMINO ACID COMPOSITION OF CASEIN

(g per 100 g of

protein) Arginine 3.7 Cystine 0.3 Histidine 2.9 Isoleucine 5.4 Leucine 9.5 Lysine 8.1 Methionine 2.8 P
henylalanine 5.2 Threonine 4.7 Tryptophan 1.6 Tyrosine 5.8 Valine 6.7

SCHEDULE IV

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
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 their
hydrochlorides L-cystine L-histidine L-isoleucine L-leucine L-lysine L-cysteine 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
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

SCHEDULE V

REFERENCE VALUES FOR NUTRITION LABELLING FOR FOODS INTENDED FOR INFANTS AND YOUNG CHILDREN

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

GIVEN under the Official Seal of the Minister for Health and Children, this 16th day of July, 1998.

BRIAN COWEN,
Minister for Health and Children

EXPLANATORY NOTE.

These Regulations give effect to Commission Directive 96/5/EC of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children.

These Regulations come into effect on the 17th of July, 1998.