

COMMISSION DIRECTIVE 96/5/EC
of 16 February 1996
on processed cereal-based foods and baby foods for infants and young children
 (Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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⁽¹⁾, and in particular Article 4 thereof,

Whereas the Community measures envisaged by this Directive do not exceed what is necessary for the attainment of the objectives already provided for by Directive 89/398/EEC;

Whereas processed cereal-based foods and baby foods for infants and young children are used as part of a diversified diet and do not constitute the sole source of nourishment of infants and young children;

Whereas there is a great variety of the products in question reflecting the widely varied diet of infants being weaned and young children owing to social and cultural circumstances existing in the Community;

Whereas the essential composition of the products in question must be appropriate for the nutritional requirements of infants and young children in good health as established by generally accepted scientific data, account being taken of the abovementioned factors;

Whereas the essential nutritional requirements for the composition of the two broad categories of these products, namely processed cereal-based foods and baby foods should be laid down;

Whereas although, because of the nature of such products, a number of mandatory requirements and other restrictions as to the level of vitamins, minerals and other nutrients should be imposed, such nutrients may be added voluntarily by manufacturers provided that they use exclusively the substances listed in Annex IV to this Directive;

Whereas the use of the products to which such nutrients have been voluntarily added at levels currently observed in the Community do not appear to result in excessive intakes of those nutrients by infants and young children; whereas attention will be paid to any future developments

of the situation, and if necessary, appropriate measures will be taken;

Whereas the provisions relating to the use of additives in the manufacture of processed cereal-based foods and baby foods will be laid down in a Council Directive;

Whereas the use of novel food ingredients will be dealt with horizontally for all foodstuffs in a separate measure;

Whereas this Directive reflects current knowledge about these products; whereas any amendment, to allow for innovation based on scientific and technical progress, will be decided by the procedure laid down in Article 13 of Directive 89/398/EEC;

Whereas, in view of the persons for whom the products are intended, the necessary microbiological criteria and maximum levels for contaminants should be laid down without delay;

Whereas pursuant to Article 7 of Directive 89/398/EEC the products covered by this Directive are subject to the general rules laid down by Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs⁽²⁾, as last amended by Commission Directive 93/102/EC⁽³⁾;

Whereas in this Directive the additions and exceptions to those general rules are adopted and expanded upon, where appropriate;

Whereas, in particular, the nature and destination of the products covered by this Directive require nutritional labelling showing the energy value and principal nutrients they contain; whereas, on the other hand, the method of use should be specified in accordance with point 8 of Article 3 (1) and Article 10 of Directive 79/112/EEC, in order to prevent inappropriate uses liable to harm the health of infants;

Whereas, whilst claims not specifically prohibited may generally be made for the products in question in conformity with the rules applicable for all foodstuffs, such claims should, where appropriate, take into account the compositional criteria specified in this Directive;

⁽¹⁾ OJ No L 186, 30. 6. 1989, p. 27.

⁽²⁾ OJ No L 33, 8. 2. 1979, p. 1.

⁽³⁾ OJ No L 291, 25. 11. 1993, p. 14.

Whereas the Scientific Committee for Food has, in accordance with Article 4 of Directive 89/398/EEC, been consulted on the provisions liable to affect public health;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive is a 'specific Directive' within the meaning of Article 4 of Directive 89/398/EEC.

2. This Directive covers foodstuffs for particular nutritional use fulfilling the particular requirements of infants and young children in good health in the Community 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:

(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 pulverization, with the addition of water, milk or other suitable liquids.

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

3. This Directive does not apply to milks intended for young children.

4. For the purpose of this Directive:

— 'infants' shall mean children under the age of twelve months,

— 'young children' shall mean children aged between 1 and 3 years.

Article 2

Member States shall ensure that the products referred to in Article 1 are marketed within the Community only if they conform to the rules laid down in this Directive.

Article 3

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.

Article 4

1. Processed cereal-based foods shall comply with the compositional criteria specified in Annex I.

2. Baby foods which are described in Annex II shall comply with the compositional criteria specified therein.

Article 5

Only the nutritional substances listed in Annex IV may be added in the manufacture of processed cereal-based foods and baby foods. Within 12 months of the entry into force of this Directive maximum levels, in addition to those already stipulated, shall be laid down where necessary.

The purity criteria for those substances shall be laid down at a later stage.

Article 6

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. Necessary maximum levels shall be established without delay.

Microbiological criteria shall also be established as necessary.

Article 7

1. The labelling of the products concerned shall bear in addition to the particulars provided for in Article 3 of Directive 79/112/EEC, the following mandatory particulars:

(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 Annex I and Annex II 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 Annex IV when such declaration is not covered by the provisions of point (d) of paragraph 1, 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 Annex V, 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.

Article 8

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with

this Directive by 30 September 1997. They shall forthwith inform the Commission thereof.

Those laws, regulations and administrative provisions shall be applied in such a way as to:

- permit trade in products complying with this Directive, by 1 October 1997,
- prohibit trade in products which do not comply with this Directive, with effect from 31 March 1999.

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Article 9

This Directive shall enter into force on the twentieth day following its publication in the *Official Journal of the European Communities*.

Article 10

This Directive is addressed to the Member States.

Done at Brussels, 16 February 1996.

For the Commission

Martin BANGEMANN

Member of the Commission

ANNEX 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 points (a) (ii) and (a) (iv) of Article 1 (2), the protein content shall not exceed 1,3 g/100 kJ (5,5 g/100 kcal).

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

2.3. For biscuits mentioned in point (a) (iv) of Article 1 (2), 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 Annex 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 points (a) (i) and (a) (iv) of Article 1 (2):

— 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 point (a) (ii) of Article 1 (2),

— 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 points (a) (i) and (a) (iv) of Article 1 (2) the lipid content shall not exceed 0,8 g/100 kJ (3,3 g/100 kcal).

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

5.2.2. For products mentioned in point (a) (iv) of Article 1 (2), 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 point (a) (ii) of Article 1 (2):

	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.

⁽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.

ANNEX 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 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/100kcal).

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 Annex:**

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.

ANNEX 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
Phenylalanine	5,2
Threonine	4,7
Tryptophan	1,6
Tyrosine	5,8
Valine	6,7

ANNEX 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
L-cystine
L-histidine
L-isoleucine
L-leucine
L-lysine
L-cysteine
L-methionine
L-phenylalanine
L-threonine
L-tryptophan
L-tyrosine
L-valine

} and their hydrochlorides

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 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.

ANNEX V

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