

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 Article 1(2)(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 Article 1(2)(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 1(2)(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 Annex III), 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 Article 1(2)(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 Article 1(2)(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 Article 1(2)(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 Article 1(2)(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,

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- 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 Article 1(2)(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 1(2)(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 Article 1(2)(a)(ii):

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamin A (µg RE)^a	14	43	60	180
Vitamin D (µg)^b	0,25	0,75	1	3

a RE = all trans retinol equivalents.

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

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.

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Nutrient	Maximum per 100 kcal
Vitamin A (µg RE)	180
Vitamin E (mg α-TE) ^a	3
Vitamin D (µg)	3
Vitamin C (mg)	12,5/25 ^b
Thiamin (mg)	0,5
Riboflavin (mg)	0,4
Niacin (mg NE) ^c	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 ^d /100 ^e
Magnesium (mg)	40
Iron (mg)	3
Zinc (mg)	2
Copper (µg)	40
Iodine (µg)	35
Manganese (mg)	0,6

a α-TE = d-α-tocopherol equivalent.

b Limit applicable to products fortified with iron.

c NE = Niacin equivalents = mg nicotinic acid + mg tryptophan/60.

d Limit applicable to products mentioned in Article 1(2)(a)(i) and (ii).

e Limit applicable to products mentioned in Article 1(2)(a)(iv).

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:

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- 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,

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- 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:

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 (µg RE)	180 ^a
Vitamin E (mg α-TE)	3
Vitamin C (mg)	12,5/25 ^b /125 ^c
Thiamin (mg)	0,25

a In accordance with the provisions of point 5.

b Limit applicable to products fortified with iron.

c Limit applicable to fruit-based dishes, fruit juices, nectars and vegetable juices.

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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
a	In accordance with the provisions of point 5.
b	Limit applicable to products fortified with iron.
c	Limit applicable to fruit-based dishes, fruit juices, nectars and vegetable juices.

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
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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

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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	and their hydrochlorides
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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

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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 chloride

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

ANNEX VI

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

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Propineb/propylenethiourea (sum of propineb and propylenethiourea)	0,006
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ANNEX VII

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

Haloxypop (sum of haloxypop, its salts and esters including conjugates, expressed as haloxypop)

Heptachlor and *trans*-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

ANNEX VIII

PART A

REPEALED DIRECTIVE WITH ITS SUCCESSIVE AMENDMENTS

(referred to in Article 9)

Commission Directive 96/5/EC	(OJ L 49, 28.2.1996, p. 17)
Commission Directive 98/36/EC	(OJ L 167, 12.6.1998, p. 23)
Commission Directive 1999/39/EC	(OJ L 124, 18.5.1999, p. 8)
Commission Directive 2003/13/EC	(OJ L 41, 14.2.2003, p. 33)

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PART B

LIST OF TIME-LIMITS FOR TRANSPOSITION INTO NATIONAL LAW

(referred to in Article 9)

Directive	Time-limit for transposition	Permission of trade in products complying with this Directive	Prohibition of trade in products not complying with this Directive
96/5/EC	30 September 1997	1 October 1997	31 March 1999
98/36/EC	31 December 1998	1 January 1999	1 January 2000
1999/39/EC	30 June 2000	30 June 2000	1 July 2002
2003/13/EC	6 March 2004	6 March 2004	6 March 2005

ANNEX IX

CORRELATION TABLE

Directive 96/5/EC	This Directive
Article 1(1), (2) and (3)	Article 1(1), (2) and (3)
Article 1(4), introductory phrase	Article 2, introductory phrase
Article 1(4), first indent	Article 2(a)
Article 1(4), second indent	Article 2(b)
Article 1(4), third indent	Article 2(c)
Article 2	Article 3
Article 3	Article 4
Article 4	Article 5
Article 5	Article 6
Article 6(1)	Article 7(1)
Article 6(2), first subparagraph	Article 7(2), first subparagraph
Article 6(2), second subparagraph	Article 7(4)
Article 6(2), third subparagraph	Article 7(2) second subparagraph
Article 6(3)(a), first subparagraph, introductory phrase	Article 7(3), introductory phrase
Article 6(3)(a), first subparagraph, (i)	Article 7(3)(a)
Article 6(3)(a), first subparagraph, (ii)	Article 7(3)(b)
Article 6(3)(a), second subparagraph	Article 7(4)
Article 6(3)(b)	Article 7(5)

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Article 6(4)	Article 7(6)
Article 7	Article 8
Article 8	—
—	Article 9
Article 9	Article 10
Article 10	Article 11
Annex I, introductory phrase	Annex I, introductory phrase
Annex I, points 1, 2 and 3	Annex I, points 1, 2 and 3
Annex I, point 4	Annex I, point 4
Annex I, point 4.1	Annex I, point 4.1
Annex I, point 4.2	Annex I, point 4.2
Annex I, point 4.2(a)	Annex I, point 4.2, first indent
Annex I, point 4.2(b)	Annex I, point 4.2, second indent
Annex I, point 4.2(c)	Annex I, point 4.2, third indent
Annex I, points 5 and 6	Annex I, points 5 and 6
Annex II, introductory phrase	Annex II, introductory phrase
Annex II, point 1	Annex II, point 1
Annex II, points 1.1-1.3	Annex II, points 1.1-1.3
Annex II, point 1.3a	Annex II, point 1.4
Annex II, point 1.4	Annex II, point 1.5
Annex II, point 1.4a	Annex II, point 1.6
Annex II, point 1.4b	Annex II, point 1.7
Annex II, point 1.5	Annex II, point 1.8
Annex II, points 2 to 5	Annex II, points 2 to 5
Annex III	Annex III
Annex IV	Annex IV
Annex V	Annex V
Annex VI	Annex I, point 7, and Annex II, point 6
Annex VII	Annex VI
Annex VIII	Annex VII
—	Annex VIII
—	Annex IX