

COMMISSION DIRECTIVE 2006/125/EC
of 5 December 2006
on processed cereal-based foods and baby foods for infants and young children
 (Text with EEA relevance)
 (Codified version)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

namely processed cereal-based foods and baby foods, should be laid down.

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(1) thereof,

(6) 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, it should be allowed that such nutrients are added voluntarily by manufacturers, provided that they use exclusively certain substances to be specified by this Directive.

Whereas:

(1) Commission Directive 96/5/EC of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children ⁽²⁾ has been substantially amended several times ⁽³⁾. In the interests of clarity and rationality the said Directive should be codified.

(7) 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. Attention should be paid to any future developments of the situation, and if necessary, appropriate measures should be taken.

(2) 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.

(8) Different rules on the maximum levels of pesticide residues in processed cereal-based foods and baby foods cause trade barriers between certain Member States.

(3) 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.

(9) Maximum levels for pesticide residues stipulated in Council Directive 76/895/EEC of 23 November 1976 relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables ⁽⁴⁾, in Council Directive 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals ⁽⁵⁾, in Council Directive 86/363/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin ⁽⁶⁾, and in Council Directive 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables ⁽⁷⁾, are without prejudice to specific provisions applicable to processed cereal-based foods and baby foods.

(4) 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.

(5) The essential nutritional requirements for the composition of the two broad categories of these products,

⁽⁴⁾ OJ L 340, 9.12.1976, p. 26. This Directive is repealed by Regulation (EC) No 396/2005 of the European Parliament and of the Council (OJ L 70, 16.3.2005, p. 1).

⁽¹⁾ OJ L 186, 30.6.1989, p. 27. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

⁽⁵⁾ OJ L 221, 7.8.1986, p. 37. This Directive is repealed by Regulation (EC) No 396/2005.

⁽²⁾ OJ L 49, 28.2.1996, p. 17. Directive as last amended by Directive 2003/13/EC (OJ L 41, 14.2.2003, p. 33).

⁽⁶⁾ OJ L 221, 7.8.1986, p. 43. This Directive is repealed by Regulation (EC) No 396/2005.

⁽³⁾ See Annex VIII, Part A.

⁽⁷⁾ OJ L 350, 14.12.1990, p. 71. This Directive is repealed by Regulation (EC) No 396/2005.

- (10) Taking into account the Community's international obligations, in cases where the relevant scientific evidence is insufficient, the precautionary principle allows the Community to provisionally adopt measures on the basis of available pertinent information, pending an additional assessment of risk and a review of the measure within a reasonable period of time.
- (11) On the basis of the two opinions given by the Scientific Committee for Food on 19 September 1997 and 4 June 1998 there are at present doubts as to the adequacy of existing acceptable daily intake values (ADI) of pesticides and pesticide residues for the protection of the health of infants and young children. Therefore, as far as foodstuffs for particular nutritional uses intended for infants and young children are concerned, it is appropriate to adopt a very low common limit for all pesticides pending case-by-case scientific screening and evaluation of substances. This very low common limit should be fixed at 0,01 mg/kg which normally is in practice the minimum detectable level.
- (12) Severe limitations on pesticide residues should be required. With careful selection of raw materials, and given that processed cereal-based foods and baby foods undergo extensive processing during their manufacture, it is feasible to produce products containing very low levels of pesticide residues. However, in the case of a small number of pesticides or metabolites of pesticides even a maximum residue level of 0,01 mg/kg might, under worst-case intake conditions, allow infants and young children to exceed the ADI. This is the case for pesticides or metabolites of pesticides with an ADI lower than 0,0005 mg/kg body weight.
- (13) This Directive establishes the principle of the prohibition of the use of these pesticides in the production of agricultural products intended for processed cereal-based foods and baby foods. However, this prohibition does not necessarily guarantee that products are free from such pesticides, since some pesticides contaminate the environment and their residues may be found in the products concerned.
- (14) The health of infants and young children can be better protected by applying additional requirements which can be enforced by analysis regardless of a product's origin.
- (15) Most of the pesticides which have ADI values lower than 0,0005 mg/kg body weight are already prohibited in the Community. The prohibited pesticides should not be detectable in processed cereal-based foods and baby foods by state of the art analytical methods. However, some pesticides degrade slowly and still contaminate the environment. They might be present in processed cereal-based foods and baby foods even if they have not been used. For the purposes of control, a harmonised approach should be followed.
- (16) Pending Commission Decisions on whether they satisfy the safety requirements of Article 5 of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market⁽¹⁾, the continued use of authorised pesticides should be permitted as long as their residues comply with the maximum residue levels established in this Directive. The latter should be set at levels ensuring that their respective ADI values are not exceeded by infants and young children under worst-case intake conditions.
- (17) The use of novel food ingredients should be dealt with horizontally for all foodstuffs in a separate measure.
- (18) This Directive reflects current knowledge about the products concerned. Any amendment, to allow for innovation based on scientific and technical progress, should be decided by the procedure referred to in Article 13(2) of Directive 89/398/EEC.
- (19) In view of the persons for whom the products are intended, the necessary microbiological criteria and maximum levels for contaminants should be laid down.
- (20) Pursuant to Article 7(1) of Directive 89/398/EEC, the products covered by this Directive are subject to the general rules laid down by Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs⁽²⁾.
- (21) In this Directive the additions and exceptions to those general rules should be adopted and expanded upon, where appropriate.

⁽¹⁾ OJ L 230, 19.8.1991, p. 1. Directive as last amended by Regulation (EC) No 396/2005.

⁽²⁾ OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2003/89/EC (OJ L 308, 25.11.2003, p. 15).

- (22) 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. On the other hand, the method of use should be specified in accordance with point 9 of Article 3(1) and Article 11 of Directive 2000/13/EC, in order to prevent inappropriate uses liable to harm the health of infants.
- (23) 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.
- (24) On the provisions liable to affect public health, the consultation in accordance with Article 4 of Directive 89/398/EEC has taken place.
- (25) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health.
- (26) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Annex VIII, Part B,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive is a 'specific Directive' within the meaning of Article 4(1) 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 pulverisation, 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.

Article 2

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, including its metabolites and products resulting from its degradation or reaction.

Article 3

Member States shall ensure that the products referred to in Article 1(2) are marketed within the Community only if they conform to the rules laid down in this Directive.

Article 4

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 5

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 6

Only the nutritional substances listed in Annex IV may be added in the manufacture of processed cereal-based foods and baby foods.

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

Article 7

1. 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 for substances other than those referred to in paragraphs 2 and 3 shall be established.

2. 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 Annex VI, in which case these specific levels shall apply.

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

3. The pesticides listed in Annex VII 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 1 of Annex VII 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 2 of Annex VII 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.

4. The levels referred to in paragraphs 2 and 3 shall apply to the products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers.

5. For pesticides listed in Annex VI, where a decision concerning the non-inclusion of an active substance in Annex I to Directive 91/414/EEC is taken, Annex VI and Annex VII to this Directive shall be amended accordingly.

6. Microbiological criteria shall be established as necessary.

Article 8

1. The labelling of the products concerned shall bear in addition to the particulars provided for in Article 3 of Directive 2000/13/EC, 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 as specified 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 paragraph 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 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 9

Directive 96/5/EC, as amended by the Directives listed in Annex VIII, Part A, is repealed, without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Annex VIII, Part B.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex IX.

Article 10

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 11

This Directive is addressed to the Member States.

Done at Brussels, 5 December 2006.

For the Commission

The President

José Manuel BARROSO

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,
 - 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) ⁽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 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 (µg RE) | 180 |
| Vitamin E (mg α-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 |

| Nutrient | Maximum per 100 kcal |
|-----------------------|---|
| 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⁾ α-TE = d-α-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 Article 1(2)(a)(i) and (ii).

⁽⁵⁾ 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:

- 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.

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 ⁽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.

⁽³⁾ Limit applicable to fruit-based dishes, fruit juices, nectars and vegetable juices.

ANNEX III

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 |

ANNEX IV

NUTRITIONAL SUBSTANCES

| | | |
|---------------------------------|---|----------------------------|
| 1. VITAMINS | <i>Vitamin C</i> | |
| <i>Vitamin A</i> | L-ascorbic acid | |
| Retinol | Sodium L-ascorbate | |
| Retinyl acetate | Calcium L-ascorbate | |
| Retinyl palmitate | 6-palmityl-L-ascorbic acid (ascorbyl palmitate) | |
| Beta carotene | Potassium ascorbate | |
| <i>Vitamin D</i> | <i>Vitamin K</i> | |
| Vitamin D2 (= ergocalciferol) | Phylloquinone (Phytomenadione) | |
| Vitamin D3 (= cholecalciferol) | <i>Vitamin E</i> | |
| <i>Vitamin B1</i> | D-alpha tocopherol | |
| Thiamin hydrochloride | DL-alpha tocopherol | |
| Thiamin mononitrate | D-alpha tocopherol acetate | |
| <i>Vitamin B2</i> | DL-alpha tocopherol acetate | |
| Riboflavin | | |
| Riboflavin-5'-phosphate, sodium | 2. AMINO ACIDS | |
| <i>Niacin</i> | L-arginine | } and their hydrochlorides |
| Nicotinamide | L-cystine | |
| Nicotinic acid | L-histidine | |
| | 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 | |
| <i>Pantothenic Acid</i> | L-tryptophan | |
| D-pantothenate, calcium | L-tyrosine | |
| D-pantothenate, sodium | L-valine | |
| Dexpanthenol | | |
| <i>Folate</i> | 3. OTHERS | |
| Folic acid | Choline | |
| <i>Vitamin B12</i> | Choline chloride | |
| Cyanocobalamin | Choline citrate | |
| Hydroxocobalamin | Choline bitartrate | |
| <i>Biotin</i> | Inositol | |
| D-biotin | 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 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 |
| Propineb/propylenethiourea (sum of propineb and propylenethiourea) | 0,006 |

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 <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 |

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) |

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) |
| 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 |