Approval of Composition and Quality Requirements for Food Intended for Particular Nutritional Uses, Requirements for Substances Used in Manufacture of Such Food and Requirements for Handling of Such Food, and Special Requirements and Procedure for Labelling of and Presentation of Information in Any Other Manner Concerning Such Food

Regulation No. 436 of the Government of the Republic of 29 December 1999

(RT* I 2000, 2, 6),

entered into force 13 January 2000,

amended by the following Regulations:

17.12.2002 entered into force 09.01.2003 - RT I 2003, 1, 4;

05.02.2002 entered into force 16.02.2002 - RT I 2002, 18, 101.

Pursuant to subsection 14 (5) and subsection 38 (5) of the Food Act (RT I 1999, 30, 415; 2002, 13, 81; 79; 61, 375; 63, 387; 102, 603), and having regard to the requirements of the Directives 89/398/EEC (OJ L 186, 30.06.89, p. 27), 91/321/EEC (OJ L 175, 04.07.1991, p. 35), 96/5/EEC (OJ L 049, 28.02.1996, p. 17) and 96/8/EEC (OJ L 055, 06.03.1996, p.22) of the European Economic Communities, the Government of the Republic resolves:

1. To approve the "Requirements for Substances Used in Manufacture of Food Intended for Particular Nutritional Uses, Requirements for Handling of Food Intended for Particular Nutritional Uses, and Special Requirements and Procedure for Labelling of and Presentation of Information in Any Other Manner Concerning Food Intended for Particular Nutritional Uses" (annexed).

(17.12.2002 entered into force 09.01.2003 - RT I 2003, 1, 4)

2. To approve the "Composition and Quality Requirements for Infant Formulae and Follow-on Formulae, Requirements for Substances Used in Manufacture of Such Formulae and Requirements for Handling of Such Formulae, and Special Requirements and Procedure for Labelling of and Presentation of Information in Any Other Manner Concerning Such Formulae" (annexed).

3. To approve the "Composition and Quality Requirements for Foods for Infants and Young Children, Requirements for Substances Used in Manufacture of Such Foods and Requirements for Handling of Such Foods, and Special Requirements and Procedure for Labelling of and Presentation of Information in Any Other Manner Concerning Such Foods" (annexed).

4. To approve the "Composition and Quality Requirements for Energy-restricted Foods for Weight Reduction, Requirements for Substances Used in Manufacture of Such Foods and Requirements for Handling of Such Foods, and Special Requirements and Procedure

for Labelling of and Presentation of Information in Any Other Manner Concerning Such Foods" (annexed).

5. To establish that:

1) until 1 January 2001, the manufacture, marketing and labelling of food intended for particular nutritional uses may continue in non-compliance of the composition and quality requirements for food intended for particular nutritional uses, the requirements for substances used in manufacture of such food and requirements for handling of such food, and the special requirements and procedure for labelling of and presentation of information in any other manner concerning food intended for particular nutritional uses approved by this Regulation, but it must be in accordance with other legislation in force regulating the handling of food;

2) food intended for particular nutritional uses manufactured and labelled before 1 January 2001 may be marketed until the stocks run out but not after expiry of the date of minimum durability.

3) food intended for particular nutritional uses which does not comply with the requirements set out in clauses 9–18 of the "Requirements for Substances Used in Manufacture of Food Intended for Particular Nutritional Uses, Requirements for Handling of Food Intended for Particular Nutritional Uses, and Special Requirements and Procedure for Labelling of and Presentation of Information in Any Other Manner Concerning Food Intended for Particular Nutritional Uses" approved by clause 1 may be manufactured and marketed until 1 April 2004.

(17.12.2002 entered into force 09.01.2003 - RT I 2003, 1, 4)

Approved by Government of the Republic Regulation No. 436 of 29 December 1999

Requirements for Substances Used in Manufacture of Food Intended for Particular Nutritional Uses, Requirements for Handling of Food Intended for Particular Nutritional Uses, and Special Requirements and Procedure for Labelling of and Presentation of Information in Any Other Manner Concerning Food Intended for Particular Nutritional Uses

(17.12.2002 entered into force 09.01.2003 - RT I 2003, 1, 4)

1. These special requirements and procedure (hereinafter special requirements) establish the requirements for food which are intended for persons with nutritional needs differing from normal nutritional needs and which are therefore prepared using a special manufacturing process or which has a different composition from food for normal consumption.

2. Food intended for particular nutritional uses are prescribed for:

1) certain categories of persons with nutritional needs differing from normal nutritional needs who due to disturbed digestive processes or metabolism or due to a special

physiological condition need food with controlled consumption of one or several substances;

2) infants (children of up to 12 months of age) and young children (children between 1 and 3 years of age).

3. In retail business, food intended for particular nutritional uses shall be marketed only in sales packaging and shall be labelled according to the requirements for the labelling of food, and according to the special requirements for the labelling of food intended for particular nutritional uses approved by this Regulation.

4. The name of food intended for particular nutritional uses shall include a reference to the particular qualities of such food, or in the case of foods for infants and young children, the purposes of use of such food.

5. The labelling of food intended for particular nutritional uses and information concerning such food provided in any other manner may not attribute properties for the prevention, treatment or cure of human disease to such food or imply such properties. Information to this effect may be provided to persons having qualifications in medicine, pharmacy or nutrition.

6. The food intended for particular nutritional uses specified in subclause 2 1) of these special requirements may be characterised as "*dieet*" [dietetic or dietary]. The use of the adjective "*dieet*" [dietetic or dietary] either alone or in conjunction with other words is only allowed on the labelling of food intended for particular nutritional uses and upon providing of information concerning such food in any other manner. The characteristics specified in clauses 1 and 2 of these special requirements may only be attributed to food intended for particular nutritional uses. If food for normal consumption have any characteristics described in clauses 1 and 2 of these special requirements, and there is a wish to refer to such characteristics on the labelling of the food and upon providing of information concerning such food, the food for normal consumption are deemed to be food intended for particular nutritional uses and a licence for handling of food intended for particular nutritional uses shall be obtained for the handling thereof pursuant to the procedure established on the basis of subsection 14 (4) of the Food Act.

7. The labelling of food intended for particular nutritional uses for which no specific requirements are established by this Regulation, shall bear the following mandatory particulars:

1) a description of the composition or the special manufacturing process which gives the products the particular nutritional characteristics of food intended for particular nutritional uses;

2) the available energy value expressed in kilojoules and kilocalories, and the protein, carbohydrate and fat content expressed in numerical form per 100 grams or 100 millilitres of the product and, where appropriate, per specified quantity of the product as proposed for consumption.

8. If the energy value is less than 50 kilojoules (12 kilocalories) per 100 grams or 100 millilitres of the product, the particulars specified in subclause 7 2) of these special requirements may be replaced either by the words "*energiasisaldus on väiksem kui 50 kJ (12 kcal)/100 g*" [energy value less than 50 kilojoules (12 kilocalories) per 100 grams] or by the words "*energiasisaldus on väiksem kui 50 kJ (12 kcal)/100 ml*" [energy value less than 50 kilojoules (12 kilocalories) per 100 millilitres].

9. In the manufacture of food intended for particular nutritional uses (except for infant formulae and follow-on formulae, and baby foods for infants and young children) the following vitamins expressed as the following compounds may be used:

1) vitamin A	–	retinyl acetate, retinyl palmitate, beta-carotene, retinol;
2) vitamin D	–	vitamin D_2 (ergocalciferol), vitamin D_3 (cholecalciferol);
3) vitamin B1	–	thiamin hydrochloride, thiamin mononitrate;
4) vitamin B2	–	riboflavin, riboflavin- 5'-phosphate;
5) niacin or nicotinic acid	–	nicotinamide, nicotinic acid;
6) vitamin B6	–	pyridoxine hydrochloride, pyridoxine 5'-phosphate, pyridoxine dipalmitate;
7) folic acid	–	pteroylmonoglutamic acid;
8) pantothenic acid	–	D-pantothenate, calcium; D-pantothenate, sodium; dexpanthenol;
9) vitamin B_{12}	–	cyanocobalamin, hydroxocobalamin;
10) biotin	–	D-biotin;
11) vitamin C	–	L-ascorbic acid, sodium L-ascorbate, calcium L-ascorbate, L-ascorbyl 6-palmitate, potassium-L-ascorbate;
12) vitamin E	–	D-alpha-tocopherol, DL-alpha-tocopherol, D-alpha-tocopherol acetate; DL-alpha-tocopherol acetate, D-alpha-tocopheryl acid succinate;
13) vitamin K	–	phylloquinone (phytomenadione).

(17.12.2002 entered into force 09.01.2003 - RT I 2003, 1, 4)

10. In the manufacture of food intended for particular nutritional uses (except for infant formulae and follow-on formulae, and baby foods for infants and young children) the following mineral elements expressed as the following salts may be used:

1) calcium	–	calcium carbonate, calcium chloride, calcium salts of citric acid, calcium gluconate, calcium glycerophosphate, calcium lactate, calcium salts of orthophosphoric acid, calcium hydroxide, calcium oxide;
2) magnesium	–	magnesium acetate, magnesium carbonate, magnesium chloride, magnesium oxide, magnesium salts of citric acid, magnesium sulphate, magnesium gluconate, magnesium glycerophosphate, magnesium hydroxide, magnesium lactate, magnesium salts of orthophosphoric acid;
3) iron	–	ferrous carbonate, ferrous citrate, ferrous gluconate, ferrous lactate, ferrous sulphate, ferric ammonium citrate, ferrous fumarate, ferric diphosphate, sodium ferric diphosphate, ferric saccharate, elemental iron (carbonyl + electrolytic + hydrogen-reduced);
4) copper	–	cupric citrate, cupric gluconate, cupric sulphate, copper-lysine complex, cupric carbonate;
5) iodine	–	potassium iodide, sodium iodide, potassium iodate, sodium iodate;
6) zinc	–	zinc acetate, zinc chloride, zinc lactate, zinc sulphate, zinc citrate, zinc gluconate, zinc oxide, zinc carbonate;
7) manganese	–	manganese carbonate, manganese chloride, manganese citrate, manganese sulphate, manganese gluconate, manganese glycerophosphate;
8) sodium	–	sodium bicarbonate, sodium chloride, sodium citrate, sodium gluconate, sodium carbonate, sodium lactate, sodium salts of orthophosphoric acid, sodium hydroxide;
9) potassium	–	potassium bicarbonate, potassium carbonate, potassium chloride, potassium salts of citric acid, potassium gluconate, potassium glycerophosphate, potassium lactate, potassium salts of orthophosphoric acid, potassium hydroxide;
10) selenium	–	sodium selenate, sodium hydrogen selentine, sodium selenite;
11) chromium (III) and their hexahydrates	–	chromium chloride, chromium sulphate;
12) molybdenum (VI)	–	ammonium molybdate, sodium molybdate;
13) fluorine	–	potassium fluoride, sodium fluoride.

(17.12.2002 entered into force 09.01.2003 - RT I 2003, 1, 4)

11. In the manufacture of food intended for particular nutritional uses (except for infant formulae and follow-on formulae, and baby foods for infants and young children) the following amino acids may be used:

1) L-alanine;

2) L-arginine;

3) L-cysteine;

4) Cystine;

5) L-histidine;

6) L-glutamic acid;

7) L-glutamine;

8) L-isoleucine;

9) L-leucine;

10) L-lysine;

11) L-lysine acetate;

12) L-methionine;

13) L-ornithine;

14) L-phenylalanine;

15) L-threonine;

16) L-tryptophan;

17) L-tyrosine;

18) L-valine.

(17.12.2002 entered into force 09.01.2003 - RT I 2003, 1, 4)

12. For amino acids specified in clause 11 of these special requirements, also the sodium, potassium, calcium and magnesium salts as well as their hydrochlorides may be used.

(17.12.2002 entered into force 09.01.2003 - RT I 2003, 1, 4)

13. In addition to the amino acids specified in clause 11 of these special requirements, L-aspartic acid, L-citrulline, glycine and L-proline may be added to food intended for particular nutritional uses prescribed for medical reasons.

(17.12.2002 entered into force 09.01.2003 - RT I 2003, 1, 4)

14. In the manufacture of food intended for particular nutritional uses (except for infant formulae and follow-on formulae, and baby foods for infants and young children) carnitine and taurine expressed as the following compounds may be used:

1) L-carnitine;

2) L-carnitine hydrochloride;

3) taurine.

(17.12.2002 entered into force 09.01.2003 - RT I 2003, 1, 4)

15. In the manufacture of food intended for particular nutritional uses (except for infant formulae and follow-on formulae, and baby foods for infants and young children) choline and inositol expressed as the following compounds may be used:

1) choline;

2) choline hydrochloride;

3) choline citrate;

4) choline bitartrate;

5) inositol.

(17.12.2002 entered into force 09.01.2003 - RT I 2003, 1, 4)

16. In the manufacture of food intended for particular nutritional uses (except for infant formulae and follow-on formulae, and baby foods for infants and young children) the following nucleotides and their sodium salts may be used:

1) adenosine 5'-monophosphate;

2) cytidine 5'-monophosphate;

3) guanosine 5'-monophosphate;

4) inosine 5'-monophosphate;

5) uridine 5'-monophosphate.

(17.12.2002 entered into force 09.01.2003 - RT I 2003, 1, 4)

17. In the manufacture of food intended for particular nutritional uses, other substances which are not vitamins, mineral elements, amino acids, nucleotides, carnitine, choline or inositol may be added to increase the nutritional value of such food, taking into account the provisions of § 13 of the Food Act concerning novel foods.

(17.12.2002 entered into force 09.01.2003 - RT I 2003, 1, 4)

18. The substances used in the manufacture of food intended for particular nutritional purposes specified in clauses 9–16 of these special requirements shall be in compliance with the Government of the Republic Regulation No. 192 of 10 June 1999 “Approval of Requirements for Additives Permitted in Foodstuffs and of Analytical Methods of Verification of Compliance with these Requirements” (RT I 1999, 63, 639; 2001, 30, 167; 2002, 65, 394).

(17.12.2002 entered into force 09.01.2003 - RT I 2003, 1, 4)

Approved by Government of the Republic Regulation No. 436 of 29 December 1999

Composition and Quality Requirements for Infant Formulae and Follow-on Formulae, Requirements for Substances Used in Manufacture of Such Formulae and Requirements for Handling of Such Formulae, and Special Requirements and Procedure for Labelling of and Presentation of Information in Any Other Manner Concerning Such Formulae

I.General Provisions

1. These special requirements and procedure (hereinafter special requirements) shall be based on the following classification:

1) infant formulae are intended for particular nutritional use by infants during the first four to six months of life and satisfy by themselves the nutritional requirements of infants of that age;

2) follow-on formulae are intended for particular nutritional use by infants aged over four months and constituting the principal liquid element in a progressively diversified diet of infants of that age.

2. Infant formulae and follow-on formulae shall not contain any substance in such quantity as to endanger the health of infants (children of up to 12 months of age) and young children (children between 1 and 3 years of age).

3. The composition and quality requirements for infant formulae and follow-on formulae apply only to the product ready for use.

II Composition and Quality Requirements for Infant Formulae

4. The available energy value of infant formulae shall be between 250kJ/100 ml (60 kcal/100 ml) and 315 kJ/100 ml (75 kcal/100 ml).

5. The protein content of infant formulae manufactured from cows' milk proteins (protein content = nitrogen content by the Kjeldahl method × 6,38) shall be between 0, 45 g/100 kJ (1,8 g/100 kcal) and 0,7 g/100 kJ (3 g/100 kcal).

6. The protein content of infant formulae manufactured from protein hydrolysates (protein content = nitrogen content by the Kjeldahl method × 6,25) shall be between 0, 56 g/100 kJ (2,25 g/100 kcal) and 0,7 g/100 kJ (3 g/100 kcal). Such infant formulae shall also meet the following requirements:

1) the protein efficiency ratio (PER) and the net protein utilization (NPU) must be equal to at least those of casein;

2) the taurine content shall be equal to at least 10 µmoles/100 kJ (42 µmoles/100 kcal) and the L-carnitine content shall be equal to at least 1,8 µmoles/100 kJ (7,5 µmoles/100 kcal).

7. The infant formulae specified in clauses 5 and 6 of these special requirements must contain an available quantity of each essential and semi-essential amino acid equal to at least that contained in the reference protein. The reference protein shall be breast milk as defined in Annex 1 to these special requirements. For calculation purposes, the concentrations of methionine and cystine may be added together.

8. The protein content of infant formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins (protein content = nitrogen content by the Kjeldahl method × 6,25) shall be between 0, 56 g/100 kJ (2,25 g/100 kcal) and 0,7 g/100 kJ (3 g/100 kcal). Such infant formulae shall also meet the following requirements:

1) the chemical index (chemical index shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein and the quantity of each corresponding amino acid of the reference protein) of proteins present shall be equal to at least 80% of that of the reference protein. The reference protein shall be breast milk as defined in Annex 2 to these special requirements;

2) for an equal energy value, the infant formula must contain an available quantity of methionine equal to at least that contained in the reference protein. The reference protein shall be breast milk as defined in Annex 1 to these special requirements;

3) the L-carnitine content shall be equal to at least 1,8 µmoles/100 kJ (7,5 µmoles/100 kcal);

4) only soya protein isolates must be used in manufacturing these formulae.

9. The addition of amino acids to infant formulae is permitted solely for the purpose of improving the nutritional value of the proteins, and only in the proportions necessary for that purpose.

10. The fat content of infant formulae shall be between 1,05 g/100 kJ (4,4 g/100 kcal) and 1,5 g/100 kJ (6,5 g/100 kcal).

11. The use of sesame seed oil and cotton seed oil is prohibited in the content of infant formulae.

12. The content of lauric acid and myristic acid may be up to 15% of the total fat content.

13. The linoleic acid content (in the form of glycerol trilinolate) shall be between 70 mg/100 kJ (300 mg/100 kcal) and 285 mg/100 kJ (1200 mg/100 kcal).

14. The alpha-linolenic acid content shall not be less than 12 mg/100 kJ (50 mg/100 kcal) and the linoleic/alpha-linolenic acid ratio shall not be less than 5 nor greater than 15.

15. The trans fatty acid content shall not exceed 4% of the total fat content.

16. The erucic acid content shall not exceed 1% of the total fat content.

17. Long-chain (20 and 22 carbon atoms) polyunsaturated fatty acids (LCP) may be added to infant formulae in which case their content shall not exceed:

1) 1% of the total fat content for n-3 LCP and;

2) 2% of the total fat content for n-6 LCP (1% of the total fat content for arachidonic acid);

3) the eicosapentaenoic acid (20:5 n-3) content shall not exceed that of docosahexaenoic (22:6 n-3) acid content.

18. The carbohydrates content of infant formulae shall be between 1,7 g/100 kJ (7 g/100 kcal) and 3,4 g/100 kJ (14 g/100 kcal).

19. Only the following sugars and sugar products may be used in infant formulae:

1) lactose;

2) maltose;

3) sucrose;

4) maltodextrins;

5) glucose syrup or dried glucose syrup;

6) pre-cooked starch (free of gluten);

7) gelatinized starch (free of gluten).

20. The lactose content shall be equal to at least 0,85 g /100 kJ (3,5 g /100 kcal). This provision does not apply to formulae in which soya proteins represent more than 50% of the total protein content.

21. The sucrose content shall not exceed 20% of the total carbohydrate content.

22. The pre-cooked starch and gelatinized starch content shall not exceed 2 g/100 ml, and 30% of the total carbohydrate content.

23. The mineral substances content in infant formulae manufactured from cows' milk proteins shall be the following:

1) sodium	–	5 mg/100 kJ (20 mg/100 kcal) up to 14 mg/100 kJ (60 mg/100 kcal);
2) potassium	–	15 mg/100 kJ (60 mg/100 kcal) up to 35 mg/100 kJ (145 mg/100 kcal);

3) chloride – 12 mg/100 kJ (50 mg/100 kcal) up to 29 mg/100 kJ (125 mg/100 kcal);

4) calcium – at least 12 mg/100 kJ (50 mg/100 kcal);

5) phosphorus – 6 mg/100 kJ (25 mg/100 kcal) up to 22 mg/100 kJ (90 mg/100 kcal);

6) magnesium – 1,2 mg/100 kJ (5 mg/100 kcal) up to 3,6 mg/100 kJ (15 mg/100 kcal);

7) iron – 0,12 mg/100 kJ (0,5 mg/100 kcal) up to 0,36 mg/100 kJ (1,5 mg/100 kcal);

8) zinc – 0,12 mg/100 kJ (0,5 mg/100 kcal) up to 0,36 mg/100 kJ (1,5 mg/100 kcal);

9) copper – 4,8 µg/100 kJ (20 µg/100 kcal) up to 19 µg/100 kJ (80 µg/100 kcal);

10) iodine – at least 1,2 µg/100 kJ (5 µg/100 kcal);

11) selenium – up to 0,7 µg/100 kJ (3 µg/100 kcal).

24. The calcium/phosphorus ratio shall not be less than 1,2 nor greater than 2,0.

25. The requirements specified in clauses 23 and 24 of these Requirements are applicable to infant formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins, except those concerning iron and zinc. The iron and zinc content of such infant formula shall be as follows:

1) iron – 0,25 mg/100 kJ (1 mg/100 kcal) up to 0,5 mg/100 kJ (2 mg/100 kcal);

2) zinc – 0,18 mg/100 kJ (0,75 mg/100 kcal) up to 0,6 mg/100 kJ (2,4 mg/100 kcal).

26. The vitamin content in infant formulae shall be the following:

1) vitamin A – 14 µg-RE/100 kJ (60 µg-RE/100 kcal) up to 43 µg-RE/100 kJ (180 µg-RE/100 kcal). RE = trans retinol equivalent = 3,33 IU = 1 µg retinol = 6 µg beta-carotene;

2) vitamin D (in the form of cholecalciferol, of which 10 µg = 400 i.u. of vitamin D) – 0,25 µg/100 kJ (1 µg/100 kcal) up to 0,65 µg/100 kJ (2,5 µg/100 kcal);

3) thiamin – at least 10 µg/100 kJ (40 µg/100 kcal);

4) riboflavin – at least 14 µg/100 kJ (60 µg/100 kcal);

5) niacin	– at least 0,2 mg-NE/100 kJ (0,8 µg-NE/100 kcal). NE = niacin equivalent = 1 mg niacin = 60 mg tryptophan;
6) pantothenic acid	– at least 70 µg/100 kJ (300 µg/100 kcal);
7) vitamin B_6	– at least 9 µg/100 kJ (35 µg/100 kcal);
8) biotin	– at least 0,4 µg/100 kJ (1,5 µg/100 kcal);
9) folic acid	– at least 1 µg/100 kJ (4 µg/100 kcal);
10) vitamin B_{12}	– at least 0,025 µg/100 kJ (0,1 µg/100 kcal);
11) vitamin C	– at least 1,9 mg/100 kJ (8 mg/100 kcal);
12) vitamin K	– at least 1 µg/100 kJ (4 µg/100 kcal);
13) vitamin E	– 0,5/g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0,1 mg per 100 available kJ - 0,5/g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0,5 mg per 100 available kcal. α-TE = tocopherol equivalent (international unit) = 0,67 mg d-α tocopherol.

(05.02.2002 entered into force 16.02.2002 - RT I 2002, 18, 101)

27. The nucleotide content of infant formulae shall be up to 1,2 mg/100 kJ (5 mg/100 kcal), whereas their content as compounds shall be the following:

1) cytidine 5'-monophosphate	– up to 0,6 mg/100 kJ (2,5 mg/100 kcal);
2) uridine 5'-monophosphate	– up to 0,36 mg/100 kJ (1,75 mg/100 kcal);
3) adenosine 5'-monophosphate	– up to 0,36 mg/100 kJ (1,5 mg/100 kcal);
4) guanosine 5'-monophosphate	– up to 0,12 mg/100 kJ (0,5 mg/100 kcal);
5) inosine 5'-monophosphate	– up to 0,24 mg/100 kJ (1 mg/100 kcal).

28. Infant formulae must not contain any pesticide residue in the amount exceeding 0,01 mg/kg.

III Composition and Quality Requirements for Follow-on Formulae

29. The energy value of follow-on formulae shall be between 250 kJ/100 ml (60 kcal/100 ml) and 335 kJ/100 ml (80 kcal/100 ml).

30. The protein content of follow-on formulae (protein content = nitrogen content by the Kjeldahl method × 6,38 for cows' milk proteins and protein content = nitrogen content by the Kjeldahl method × 6,25 for soya protein isolates) shall be between 0, 5 g/100 kJ (2,25 g/100 kcal) and 1 g/100 kJ (4,55 g/100 kcal). Follow-on formula shall also meet the following requirements:

1) the chemical index (chemical index shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein and the quantity of each corresponding amino acid of the reference protein) of proteins shall be equal to at least 80% of that of the reference protein. The reference protein shall be breast milk or caseine as defined in Annex 2 to these special requirements;

2) only soya protein isolates may be used in manufacturing these formulae;

3) the addition of amino acids is permitted solely for the purpose of improving the nutritional value of the proteins, and only in the proportions necessary for that purpose;

4) for an equal energy value, follow-on formulae must contain an available quantity of methionine equal to at least that contained in the reference protein. The reference protein shall be breast milk as defined in Annex 1 to these special requirements.

31. The fat content of follow-on formulae shall be between 0,8 g/100 kJ (3,3 g/100 kcal) and 1,5 g/100 kJ (6,5 g/100 kcal).

32. The use of sesame seed oil and cotton seed oil is prohibited in the content of follow-on formulae.

33. The content of lauric acid and myristic acid may be up to 15% of the total fat content.

34. The linoleic acid content of follow-on formulae containing vegetable oils shall be equal to at least 70 mg/100 kJ (300 mg/100 kcal).

35. The trans fatty acid content shall not exceed 4% of the total fat content.

36. The erucic acid content shall not exceed 1% of the total fat content.

37. The carbohydrates content of follow-on formulae shall be between 1,7 g/100 kJ (7 g/100 kcal) and 3,4 g/100 kJ (14 g/100 kcal).

38. The use of ingredients containing gluten is prohibited in follow-on formulae.

39. The lactose content of follow-on formulae shall be equal to at least 0,45 g /100 kJ (1,8 g /100 kcal). This provision does not apply to follow-on formulae in which soya proteins represent more than 50% of the total protein content.

40. The sucrose, fructose and honey content of follow-on formulae shall not exceed 20% of the total carbohydrate content.

41. The iron and iodine content of follow-on formulae shall be as follows:

1) iron – 0,25 mg/100 kJ (1 mg/100 kcal) up to 0,5 mg/100 kJ (2 mg/100 kcal);

2) iodine – at least 0,2 µg/100 kJ (5 µg/100 kcal).

42. The zinc content of follow-on formulae manufactured entirely from cows' milk shall be equal to at least 0,12 mg/100 kJ (0,5 mg/100 kcal).

43. The zinc content of follow-on formulae containing soya protein isolates, or mixed with cow's milk shall be equal to at least 0,18 mg/100 kJ (0,75 mg/100 kcal).

44. The content of mineral substances not specified in clauses 41-43 of these special requirements of follow-on formulae shall be at least equal to the mineral content of cows' milk. If necessary, the mineral content of follow-on formulae may be reduced in correspondence to the proteins and cows' milk proteins ratio of a follow-on formula. The typical mineral content of cows' milk is given in Annex 3 to these special requirements.

(05.02.2002 entered into force 16.02.2002 - RT I 2002, 18, 101)

45. The calcium/phosphorus ratio shall not be greater than 2.

46. The A, D, C and E vitamin content of follow-on formulae of shall be as follows:

1) vitamin A	– 14 µg-RE/100 kJ (60 µg-RE/100 kcal) up to 43 µg-RE/100 kJ (180 µg-RE/100 kcal). RE = trans retinol equivalent = 3,33 IU = 1 µg retinol = 6 µg beta-carotene;
2) vitamin D in the form of cholecalciferol, of which 10 µg = 400 i.u. of vitamin D	– 0,25 µg/100 kJ (1 µg/100 kcal) up to 0,75 µg/100 kJ (3 µg/100 kcal);
3) vitamin C	– at least 1,9 mg/100 kJ (8 mg/100 kcal);
4) vitamin E	– 0,5/g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0,1 mg per 100 available kJ - 0,5/g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0,5 mg per 100 available kcal. α-TE = tocopherol equivalent (international unit) = 0,67 mg d-α-tocopherol.

(05.02.2002 entered into force 16.02.2002 - RT I 2002, 18, 101)

47. The nucleotide content of follow-on formulae shall be up to 1,2 mg/100 kJ (5 mg/100 kcal), whereas the listed nucleotides may be added as follows:

1) cytidine 5'-monophosphate – up to 0,6 mg/100 kJ (2,5 mg/100 kcal);

2) uridine 5'-monophosphate – up to 0,42 mg/100 kJ (1,75 mg/100 kcal);

3) adenosine 5'-monophosphate – up to 0,36 mg/100 kJ (1,50 mg/100 kcal);

4) guanosine 5'-monophosphate – up to 0,12 mg/100 kJ (0,50 mg/100 kcal);

5) inosine 5'-monophosphate – up to 0,24 mg/100 kJ (1 mg/100 kcal).

48. Follow-on formulae must not contain any pesticide residue in the amount exceeding 0,01 mg/kg.

IV Requirements for Substances Used in Manufacture of Infant Formulae and Follow-on Formulae and Requirements for Handling of Such Formulae

49. Upon the manufacture of infant formulae and follow-on formulae, only the following vitamins expressed as the following compounds may be used:

1) vitamin A – retinyl acetate, retinyl palmitate, beta-carotene, retinol;

2) vitamin D – vitamin D_2 (ergocalciferol), vitamin D_3 (cholecalciferol);

3) vitamin B_1 – thiamin hydrochloride, thiamin mononitrate;

4) vitamin B_2 – riboflavin, riboflavin-5-phosphate;

5) niacin or nicotinic acid – nicotinamide, nicotinic acid;

6) vitamin B_6 – pyridoxine hydrochloride, pyridoxine-5-phosphate;

7) folic acid – folate;

8) pantothenic acid – D-pantothenate, calcium; D-pantothenate, sodium; dexpanthenol;

9) vitamin B_{12} – cyanocobalamin, hydroxocobalamin;

10) biotin – D-biotin;

11) vitamin C – L-ascorbic acid, sodium L-ascorbate, calcium L-ascorbate, 6-palmityl-L-ascorbic acid (ascorbyl palmitate), potassium ascorbate;

12) vitamin E – D-alpha tocopherol, DL-alpha tocopherol, D-alpha tocopherol acetate; D,L-alpha tocopherol acetate;

13) vitamin K – phylloquinone (phytomenadione).

50. Upon the manufacture of infant formulae and follow-on formulae, only the following mineral substances expressed as the following salts may be used:

1) calcium – calcium carbonate, calcium chloride, calcium salts of citric acid, calcium gluconate, calcium glycerophosphate, calcium lactate, calcium salts of orthophosphoric acid, calcium hydroxide;

2) magnesium – magnesium carbonate, magnesium chloride, magnesium oxide, magnesium salts of citric acid, magnesium sulphate, magnesium gluconate, magnesium hydroxide, magnesium salts of orthophosphoric acid;

3) iron – ferrous citrate, ferrous gluconate, ferrous lactate, ferrous sulphate, ferric ammonium citrate, ferrous fumarate, ferric diphosphate;

4) copper – cupric citrate, cupric gluconate, cupric sulphate, copper-lysine complex, cupric carbonate;

5) iodine – potassium iodide, sodium iodide, potassium iodate;

6) zinc – zinc acetate, zinc chloride, zinc lactate, zinc sulphate, zinc citrate, zinc gluconate, zinc oxide;

7) manganese – manganese carbonate, manganese chloride, manganese citrate; manganese sulphate, manganese gluconate;

8) sodium – sodium bicarbonate, sodium chloride, sodium citrate, sodium gluconate, sodium carbonate, sodium lactate, sodium salts of orthophosphoric acid, sodium hydroxide;

9) potassium – potassium bicarbonate, potassium carbonate, potassium chloride, potassium salts of citric acid, potassium gluconate, potassium lactate, potassium salts of orthophosphoric acid, potassium hydroxide;

10) selenium – sodium selenate, sodium selenite.

51. Upon the manufacture of infant formulae and follow-on formulae, only the following amino acids and other nitrogen compounds may be used:

1) L-arginine and its hydrochloride;

2) L-arginine hydrochloride;

3) L-cystine and its hydrochloride;

4) L-histidine and its hydrochloride;

5) L-isoleucine and its hydrochloride;

6) L-leucine and its hydrochloride;

7) L-lysine and its hydrochloride;

8) L-cysteine and its hydrochloride;

9) L-methionine;

10) L-phenylalanine;

11) L-threonine;

12) L-tryptophan;

13) L-tyrosine;

14) L-valine;

15) L-carnitine and its hydrochloride;

16) taurine;

17) cytidine 5'-monophosphate and its sodium salt;

18) uridine 5'-monophosphate and its sodium salt;

19) adenosine 5'-monophosphate and its sodium salt;

20) guanosine 5'-monophosphate and its sodium salt;

21) inosine 5'-monophosphate and its sodium salt.

52. Upon the manufacture of infant formulae and follow-on formulae, also choline, choline chloride, choline citrate, choline bitartrate and inositol may be used.

V.Special Requirements for Labelling of Infant Formulae and Follow-on Formulae

53. Upon the labelling of infant formulae and follow-on formulae, these special requirements for labelling shall be adhered to in addition to the requirements concerning the labelling of food.

54. The labelling of the sales packaging of infant formulae and follow-on formulae shall be designed to provide the necessary information about the appropriate use of the products so as not to discourage breast-feeding.

55. The name under which infant formulae and follow-on formulae are sold shall be:

1) in the case of the foodstuffs specified in subclause 1 1) of these special requirements, “*Imiku piimasegu*” [infant formula] or if the products are manufactured entirely from cows' milk proteins, “*Piimal põhinev imiku piimasegu*” [infant milk];

2) in the case of the food specified in subclause 1 2) of these special requirements, “*Jätkupiimasegu*” [follow-on formula] or if the products are manufactured entirely from cows' milk proteins, “*Piimal põhinev jätkupiimasegu*” [follow-on milk].

56. The labelling of the sales packaging of infant formulae and follow-on formulae shall bear the following mandatory particulars:

1) a statement as to the appropriate age of infant or young child from which the product may be used;

2) instructions for appropriate preparation of the product and a warning against the health hazards of inappropriate preparation;

3) the available energy value, expressed in kJ and kcal, and the content of proteins, carbohydrates and lipids per 100 ml of the product ready for use;

4) the average quantity of each mineral substance and of each vitamin specified in Chapters II and III respectively of these special requirements, and where applicable of choline, inositol, carnitine and taurine per 100 ml of the product ready for use;

5) in the case of infant formulae that do not contain added iron, a statement to the effect that, when the product is given to infants over the age of four months, their total iron requirements must be met from other additional sources;

6) in the case of follow-on formulae, a statement to the effect that the product is suitable only for particular nutritional use by infants over the age of four months, that it shall form only part of a diversified diet and that it is not to be used during the first four months of life;

7) (Repealed - 05.02.2002 entered into force 16.02.2002 - RT I 2002, 18, 101)

57. The use of the terms "*rinnapiimasarnane*" [humanized], "*emapiimasarnane*" [maternalized], or similar terms on the labelling of the sales packaging of infant formulae and follow-on formulae shall be prohibited. The word "*adapteeritud*" [adapted] shall only be used pursuant to subclause 60 1) of these special requirements.

(05.02.2002 entered into force 16.02.2002 - RT I 2002, 18, 101)

58. The labelling of the sales packaging of infant formulae shall in addition bear the following mandatory particulars, preceded by the words "*pane tähele*" [Important Notice] or their equivalent:

1) a statement concerning the superiority of breast-feeding expressed by the words *“Rinnapiim on imikule parim. See toidab, kaitseb ja arendab”* [Breast milk is best for babies. It nourishes, protects and stimulates development] (this statement shall be printed in capital letters not less than 2 mm high);

2) a statement as to the importance of following the instructions for appropriate use and a statement recommending that the product be used only on the advice of independent persons having qualifications in medicine expressed by the words *"Järgige hoolikalt tarvitamisjuhendit. Enne segu kasutamist pidage nõu arstiga. Lutipudeli kasutamisel võib laps võõrduda rinnast"* [Follow the instructions carefully. Before using the formula consult your pediatrician. Using the bottle may wean the baby from the breast] (this statement shall be printed in capital letters not less than 2 mm high).

59. The sales packaging of infant formulae may include graphic representations illustrating methods of preparation. It shall not, however, include pictures of infants, nor pictures or text which idealise the use of the product.

(05.02.2002 entered into force 16.02.2002 - RT I 2002, 18, 101)

60. The labelling of the sales packaging of infant formulae may bear only the following claims concerning the special composition of an infant formula and in accordance with the following conditions:

(05.02.2002 entered into force 16.02.2002 - RT I 2002, 18, 101)

1) adapted protein – the protein content is lower than 0,6 g/100 kJ (2,5 g/100 kcal) and the whey protein/casein ratio is not less than 1;

(05.02.2002 entered into force 16.02.2002 - RT I 2002, 18, 101)

2) low sodium – the sodium content is lower than 9 mg/100 kJ (39 mg/100 kcal);

3) sucrose free – no sucrose is present;

4) lactose only – lactose is the only carbohydrate present;

5) lactose free – no lactose is present;

6) iron enriched – iron is added;

7) reduced risk of allergies caused by milk proteins (the statement may contain words or expressions which refer to reduction of allergen content) – infant formula shall be in compliance with the requirements provided for in clauses 6 and 7 of these special requirements. The immunoreactive protein content shall be lower than 1% of the nitrogen content of the ingredients of an infant formula. The statement shall contain information to the effect that the infant formula must not be fed to infants who are allergic to the intact proteins contained in the formula, unless internationally recognised clinical tests confirm that over 90% of the infants who are sensitive to the proteins used in the given hydrolysate tolerate such infant formulae.

(05.02.2002 entered into force 16.02.2002 - RT I 2002, 18, 101)

61. The labelling of the sales packaging of infant formulae and follow-on formulae may bear information, expressed in numerical form per 100 ml of the product ready for use, on the average quantities of the nutrients specified in Chapter IV of these special

requirements indication of which is not mandatory pursuant to subclause 56 4) of these special requirements. The labelling of the sales packaging of follow-on formulae may bear information on the quantities of the following vitamins and minerals expressed as a percentage of the following reference values per 100 ml of the product ready for use:

1) vitamin A – 400 μg;

2) vitamin D – 10 μg;

3) vitamin C – 25 mg;

4) thiamin – 0,5 mg;

5) riboflavin – 0,8 mg;

6) niacin – 9 mg;

7) vitamin B6 – 0,7 mg;

8) folic acid – 100 μg;

9) vitamin B_{12} – 0,7 μg;

10) calcium – 400 mg;

11) iron – 6 mg;

12) zinc – 4 mg;

13) iodine – 70 μg;

14) selenium – 10 μg;

15) copper – 0,4 mg.

(05.02.2002 entered into force 16.02.2002 - RT I 2002, 18, 101)

62. The labelling of follow-on formulae shall bear information on the quantities of the vitamins and minerals shown in clause 61 of these special requirements, provided that the quantities present are equal to at least 15% of the reference values.

VI. Special Requirements and Procedure for Presentation of Information in Any Other Manner Concerning Infant Formulae and Follow-on Formulae

63. Informational materials (including educational materials) shall include clear information on the following points:

1) the benefits and superiority of breast-feeding;

2) maternal nutrition and the preparation for and maintenance of breast-feeding;

3) the possible negative effect on breast-feeding of introducing partial bottle-feeding and the difficulty of reversing the decision not to breast-feed;

4) the proper use of infant formulae or follow-on formulae if needed for feeding the infant.

64. When such materials contain information about the use of infant formulae or follow-on formulae, they shall include the health hazards of improper use of infant formulae and the health hazards of inappropriate food or feeding methods. Also the average cost of using the formulae per a definite unit of time shall be indicated.

65. Such informational materials shall not use any pictures or texts which idealise the use of infant formulae or follow-on formulae.

66. The distribution of samples of infant formulae and follow-on formulae (individual samples or small amounts produced for distribution purposes), and also of utility articles the practical value of which is connected with the use of the infant formulae or follow-on formulae shall not be allowed.

67. There shall be no advertising, discount coupons, premiums, or other such special offers, tie-in sales, offers or demonstration of visual advertisement containing instructions of use or any other promotional device to induce the distribution of infant formulae and follow-on formulae.

68. The providing of information concerning infant formulae and follow-on formulae to employees of health care institutions shall be permitted. The information forwarded to employees of health care institutions by the distributors of infant formulae and follow-on formulae shall contain only information of a scientific and factual nature and shall not imply or create a belief that bottle-feeding is equivalent or superior to breast-feeding, and shall include the information described in clauses 63-65 of these special requirements. The employees of health care institutions are permitted to receive samples of infant formulae and follow-on formulae and samples of dishes intended for the preparation and use thereof only in the cases where this is necessary for professional assessment carried out within the scope of research work performed by the given institution.

69. Training in the use of infant formulae and follow-on formulae may be provided only by health-care professionals employed by health care institutions and such training shall be directed exclusively to the mothers and family members of infants who have to be fed on infant formulae or follow-on formulae. Such training shall include information concerning the possible hazards of using infant formulae and follow-on formulae, and precautionary measures to prevent such hazards.

* RT = *Riigi Teataja = State Gazette*

Annex 1 to the "Composition and Quality Requirements for Infant Formulae and Follow-on Formulae, Requirements for Substances Used in Manufacture of Such Formulae and Requirements for Handling of Such Formulae, and Special Requirements and Procedure for Labelling of and Presentation of Information in Any Other Manner Concerning Such Formulae"

Essential and semi-essential amino acid composition of breast milk

Amino acids	mg/100 kJ (1 kJ = 0,239 kcal)	mg/100 kcal
Arginine	16	69
Cystine	6	24
Histidine	11	45
Isoleucine	17	72
Leucine	37	156
Lysine	29	122
Methionine	7	29
Phenylalanine	15	62
Threonine	19	80
Tryptophan	7	30
Tyrosine	14	59
Valine	19	80

Annex 2 to the "Composition and Quality Requirements for Infant Formulae and Follow-on Formulae, Requirements for Substances Used in Manufacture of Such Formulae and Requirements for Handling of Such Formulae, and Special Requirements and Procedure for Labelling of and Presentation of Information in Any Other Manner Concerning Such Formulae"

Amino acid and semi-essential amino acid composition of casein and breast milk protein

Amino acids	Amino acid composition of casein (g/100 g)	Amino acid composition of breast milk protein (g/100 g)
Arginine	3,7	3,8
Cystine	0,3	1,3
Histidine	2,9	2,5

Isoleucine	5,4	4,0
Leucine	9,5	8,5
Lysine	8,1	6,7
Methionine	2,8	1,6
Phenylalanine	5,2	3,4
Threonine	4,7	4,4
Tryptophan	1,6	1,7
Tyrosine	5,8	3,2
Valine	6,7	4,5

Annex 3 to the "Composition and Quality Requirements for Infant Formulae and Follow-on Formulae, Requirements for Substances Used in Manufacture of Such Formulae and Requirements for Handling of Such Formulae, and Special Requirements and Procedure for Labelling of and Presentation of Information in Any Other Manner Concerning Such Formulae"

The mineral elements in cows' milk

Mineral elements	Mineral elements content expressed per 100 g of solids-non-fat	Mineral elements content expressed per 1 of proteins
Sodium (mg)	550	15
Potassium (mg)	1680	43
Chloride (mg)	1050	28
Calcium (mg)	1350	35
Phosphorus (mg)	1070	28
Magnesium (mg)	135	3,5
Copper (μg)	225	6

Iodine	Non-specified	Non-specified

(05.02.2002 entered into force 16.02.2002 - RT I 2002, 18, 101)

Approved by Government of the Republic Regulation No. 436 of 29 December 1999

Composition and Quality Requirements for Foods for Infants and Young Children, Requirements for Substances Used in Manufacture of Such Foods and Requirements for Handling of Such Foods, and Special Requirements and Procedure for Labelling of and Presentation of Information in Any Other Manner Concerning Such Foods

I.General Provisions

1. These special requirements and procedure (hereinafter special requirements) covers food for particular nutritional use fulfilling the particular requirements of infants and young children and are intended for use by infants and young children as a supplement to their diet and/or for their progressive adaptation to ordinary food. These special requirements shall be based on the following classification of foods for infants and young children:

1) cereals and cereal-based products intended for infants and young children (hereinafter processed cereal-based foods);

2) baby foods for infants and young children other than processed cereal-based foods.

2. These special requirements shall be based on the following classification of processed cereal-based foods:

1) simple cereals which are or have to be reconstituted with milk or other appropriate nutritious liquids or as such have been made ready for use;

2) cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid;

(05.02.2002 entered into force 16.02.2002 - RT I 2002, 18, 101)

3) pastas which are to be used after cooking in appropriate liquids;

4) rusks and biscuits which are to be used either directly or, after pulverisation, with the addition of water, milk or other suitable liquids.

3. These special requirements do not apply to milks intended for young children and to infant formulae and follow-up formulae.

4. Foods for infants and young children shall not contain any substance in such quantity as to endanger the health of infants and young children.

5. 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.

6. Composition and quality requirements for foods for infants and young children apply to the product ready for use.

II Composition and Quality Requirements for Processed Cereal-based Foods for Infants and Young Children

7. 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.

(05.02.2002 entered into force 16.02.2002 - RT I 2002, 18, 101)

8. The protein content of processed cereal-based foods shall be the following:

1) for products specified in subclauses 2 2) and 4) of these special requirements, the protein content shall not exceed 1,3 g/100 kJ (5,5 g/100 kcal);

2) for products specified in subclause 2 2) of these special requirements, the added protein shall not be less than 0,48 g/100 kJ (2 g/100 kcal);

3) for biscuits specified in subclause 2 4) of these special requirements, 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);

4) the chemical index of the added protein shall be equal to at least 80% of that of the reference protein, 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. The reference protein shall be casein as defined in Annex 1 to these special requirements. The addition of amino acids to processed cereal-based foods is permitted solely for the purpose of improving the nutritional value of the protein mixture, and only in the proportions necessary for that purpose.

9. The content of sucrose, fructose, glucose, glucose syrups or honey added to processed cereal-based foods shall be the following:

1) the amount of added carbohydrates shall not exceed 1,8 g/100 kJ (7,5 g/100 kcal) for processed cereal-based foods specified in subclauses 2 1) and 4) of these special requirements, and the amount of added fructose shall not exceed 0,9 g/100 kJ (3,75 g/100 kcal);

2) the amount of added carbohydrates shall not exceed 1,2 g/100 kJ (5 g/100 kcal) for processed cereal-based foods specified in subclause 2 2) of these special requirements, and the amount of added fructose shall not exceed 0,6 g/100 kJ (2,5 g/100 kcal).

10. For products specified in subclauses 2 1) and 4) of these special requirements, the lipid content shall not exceed 0,8 g/100 kJ (3,3 g/100 kcal).

11. For products specified in subclause 2 2) of these special requirements, the lipid content shall not exceed 1,1 g/100 kJ (4,5 g/100 kcal). If the lipid content of processed cereal-based foods exceeds 0,8 g/100 kJ (3,3 g/100 kcal), the amount of both lauric acid and myristic acid shall not exceed 15% of the total lipid content, and the amount of linoleic acid (in the form of glycerol trilinolate) 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).

12. 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).

13. For products specified in subclause 2 2) of these special requirements, the amount of calcium shall not be less than 20 mg/100 kJ (80 mg/100 kcal) and for products specified in subclause 2 4) of these special requirements, 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).

14. For processed cereal-based foods the amount of thiamin shall not be less than 0,025 mg/100 kJ (0,1 mg/100 kcal).

(05.02.2002 entered into force 16.02.2002 - RT I 2002, 18, 101)

15. For processed cereal-based foods specified in subclause 2 2) of these special requirements, the vitamin A and vitamin D content shall be the following:

1) vitamin A	– 14 µg-RE/100 kJ (60 µg-RE/100 kcal) up to 43 µg-RE/100 kJ (180 µg-RE/100 kcal). RE = trans retinol equivalent = 3,33 IU = 1 µg retinol = 6 µg beta-carotene;
2) vitamin D in the form of cholecalciferol, of which 10 µg = 400 i.u. of vitamin D	– 0,25 µg/100 kJ (1 µg/100 kcal) up to 0,75 µg/100 kJ (3 µg/100 kcal).

(05.02.2002 entered into force 16.02.2002 - RT I 2002, 18, 101)

16. The limits set out in clause 15 of these special requirements are also applicable if vitamins A and D are added to other processed cereal-based foods specified in clause 2 of these special requirements.

17. The maximum vitamin and mineral content of processed cereal-based foods to which vitamins and minerals have been added is set out in Annex 2 to these requirements.

18. Processed cereal-based foods must not contain any pesticide residue in the amount exceeding 0,01 mg/kg.

III Composition and Quality Requirements for Other Baby Foods for Infants and Young Children

19. Baby foods for infants and young children where meat, poultry, fish or other traditional source of protein are the only ingredients specified in the name of the product, shall be in compliance with the following requirements:

1) the named meat, poultry, fish, or other foodstuffs, in total, shall constitute not less than 40% by weight of the total product;

2) each named meat, poultry, fish, or other foodstuffs, in total, shall constitute not less than 25%, by weight, of total named protein sources;

3) the total protein from the named sources shall not be less than 1,7 g/100 kJ (7 g/100 kcal).

20. Baby foods for infants and young children where meat, poultry, fish or other traditional source of protein, singularly or in combination, are specified first in the name of the product, be in compliance with the following requirements:

1) the named meat, poultry, fish, or other foodstuffs, in total, shall constitute not less than 10% by weight of the total product;

2) each named meat, poultry, fish, or other foodstuffs, in total, shall constitute not less than 25%, by weight, of total named protein sources;

3) the total protein from the named sources shall not be less than 1 g/100 kJ (4 g/100 kcal).

21. Baby foods for infants and young children where meat, poultry, fish or other traditional source of protein, singularly or in combination are specified, but not first, in the name of the product, shall be in compliance with the following requirements:

1) the named meat, poultry, fish, or other foodstuffs, in total, shall constitute not less than 8% by weight of the total product;

2) each named meat, poultry, fish, or other foodstuffs, in total, shall constitute not less than 25%, by weight, of total named protein sources;

3) the protein from the named sources shall not be less than 0,5 g/100 kJ (2,2 g/100 kcal);

4) the total protein in the product from all sources shall not be less than 0,7 g/100 kJ (3 g/100 kcal).

22. If cheese is specified together with other ingredients in the name of a savoury product intended for infants or young children, then the protein from dairy sources shall not be less than 0,5 g/100 kJ (2,2 g/100 kcal), and the total protein in the product from all sources shall not be less than 0,7 g/100 kJ (3 g/100 kcal).

23. Baby foods for infants and young children which are designated on the label as a meal, but where meat, poultry, fish or other traditional source of protein are not specified in the name of the product, shall have a protein content of not less than 0,7 g/100 kJ (3 g/100kcal).

24. Sauces for infants and young children presented as an accompaniment to a meal are exempt from the requirements of clauses 19-23 of these special requirements.

25. Sweet dishes for infants and young children that mention dairy products as an ingredient in the name shall contain not less than 2,2 dairy protein/100 kcal. All other sweet dishes are exempt from the requirements of clauses 19-23 of these special requirements.

26. The addition of amino acids to baby foods for infants and young children is permitted solely for the purpose of improving the nutritional value of the protein present, and only in the proportions necessary for that purpose.

27. The total fat content of baby food for infants and young children, referred to in clause 19 of these special requirements, where meat or cheese are the only ingredients or are specified first in the name of a product, shall not exceed 1,4 g/100 kJ (6 g/100 kcal). For all other baby foods for infants and young children, the total fat content shall not exceed 1,1 g/100 kJ (4,5 g/100 kcal).

28. The sodium content in baby foods for infants and young children shall be either not more than 48 mg/100 kJ (200 mg/100 kcal) or not more than 200 mg per 100 g. If cheese is the only ingredient specified in the name of the baby foods for infants and young children, the final sodium content in the product shall not be more than 70 mg/100 kJ (300 mg/100 kcal).

29. Sodium salts may not be added to desserts, puddings intended for infants and young children, nor to baby foods for infants and young children based on fruit or berries except for technological purposes and in the minimum necessary quantity.

30. The quantities of total carbohydrates present in fruit, berry and vegetable juices and nectars, fruit-only dishes, berry-only dishes, and desserts or puddings intended for infants and young children shall not exceed:

1) 10 g/100 ml for vegetable juices and drinks based on them;

2) 15 g/100 ml for fruit and berry juices and nectars and drinks based on them;

3) 20 g/100 g for berry- or fruit-only dishes;

4) 25 g/100 g for desserts and puddings;

5) 5 g/100 g for other non-milk-based drinks.

31. In a fruit or berry juice, nectar, or vegetable juice intended for infants and young children, 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.

32. Vitamin A shall not be added to baby foods (except vegetable juices) for infants and young children. 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).

33. Upon the manufacture of baby foods for infants and young children, vitamin D shall not be added to the baby foods.

34. The maximum vitamin and mineral content of baby foods for infants and young children to which vitamins and minerals have been added is set out in Annex 2 to these special requirements.

35. Baby foods for infants and young children must not contain any pesticide residue in the amount exceeding 0,01 mg/kg.

IV Requirements for Substances Used in Manufacture of Foods for Infants and Young Children and Requirements for Handling of Such Foods

36. Upon the manufacture of foods for infants and young children, only the following vitamins expressed as the following compounds may be used:

1) vitamin A	–	retinol, retinyl acetate, retinyl palmitate, beta-carotene;
2) vitamin D	–	vitamin D_2 (ergocalciferol), vitamin D_3 (cholecalciferol);
3) vitamin B_1	–	thiamin hydrochloride, thiamin mononitrate;
4) vitamin B_2	–	riboflavin, riboflavin-5-phosphate, sodium;
5) niacin	–	nicotinamide, nicotinic acid;
6) vitamin B_6	–	pyridoxine hydrochloride, pyridoxine-5-phosphate, pyridoxine dipalmitate;
7) pantothenic acid	–	D-pantothenate, calcium; D-pantothenate, sodium; dexpanthenol;
8) folic acid	–	folate;
9) vitamin B_{12}	–	cyanocobalamin, hydroxocobalamin;
10) biotin	–	D-biotin;
11) vitamin C	–	L-ascorbic acid, sodium L-ascorbate, calcium L-ascorbate, 6-palmityl-L-ascorbic acid (ascorbyl palmitate), potassium ascorbate;
12) vitamin K	–	phylloquinone (phytomenadione);
13) vitamin E	–	D-alpha tocopherol, D,L-alpha tocopherol, D-alpha tocopherol acetate; D,L-alpha tocopherol acetate.

37. Upon the manufacture of foods for infants and young children, only the following amino acids may be used:

1) L-arginine and its hydrochlorides;

2) L-cystine and its hydrochlorides;

3) L-histidine and its hydrochlorides;

4) L-isoleucine and its hydrochlorides;

5) L-leucine and its hydrochlorides;

6) L-lysine and its hydrochlorides;

7) L-cysteine and its hydrochlorides;

8) L-methionine;

9) L-phenylalanine;

10) L-threonine;

11) L-tryptophan;

12) L-tyrosine;

13) L-valine.

38. Upon the manufacture of foods for infants and young children, also choline, choline chloride, choline citrate, choline bitartrate, inositol, L-carnitine and L-carnitine hydrochloride may be used.

39. Upon the manufacture of foods for infants and young children, only the following elements expressed as the following compounds may be used:

1) 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;
2) 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;
3) potassium	–	potassium chloride, potassium salts of citric acid, potassium gluconate, potassium lactate, potassium glycerophosphate;
4) iron	–	ferrous citrate, ferric ammonium citrate, ferrous gluconate, ferrous lactate, ferrous sulphate, ferrous fumarate, ferric diphosphate, elemental iron (carbonyl + electrolytic + hydrogen-reduced), ferric saccharate, sodium ferric

diphosphate, ferrous carbonate;

5) copper	–	copper-lysine complex, cupric carbonate, cupric citrate, cupric gluconate, cupric sulphate;
6) zinc	–	zinc acetate, zinc citrate, zinc lactate, zinc sulphate, zinc oxide, zinc gluconate;
7) manganese	–	manganese carbonate, manganese chloride, manganese citrate, manganese gluconate, manganese sulphate, manganese glycerophosphate;
8) iodine	–	sodium iodide, potassium iodide, sodium iodate, potassium iodate.

V.Special Requirements and Procedure for Labelling of and Presentation of Information in Any Other Manner Concerning Foods for Infants and Young Children

40. Upon the labelling of foods for infants and young children, these special requirements for labelling shall be adhered to in addition to requirements concerning the labelling of food.

41. The labelling of the sales packaging of foods for infants and young children shall bear the following mandatory particulars:

1) a statement as to the appropriate age of infants or young children from which the given product may be used. The stated age shall not be less than four months for any product. The stated age shall not be less than four months for any food for infants or young children. 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 advise otherwise;

2) information as to the presence or absence of gluten if the indicated age from which the product may be used is below six months;

3) 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 recommended quantity of the food for infants and young children as proposed for consumption;

(05.02.2002 entered into force 16.02.2002 - RT I 2002, 18, 101)

4) the average quantity of each mineral substance and of each vitamin governed by Chapter II and Chapter III of these special requirements respectively (except clauses 17 and 34), expressed in numerical form, per 100 g or 100 ml of the product as sold and, where appropriate, per recommended quantity of the food for infants and young children as proposed for consumption;

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

42. The labelling of the sales packaging of food for infants and young children may also bear:

1) the average quantity of the nutrients set out in Chapter IV of these special requirements when such declaration is not covered by the provisions of subclause 41 4), expressed in numerical form, per 100 g or 100 ml of the product as sold and, where appropriate, the recommended quantity of the food for infants and young children as proposed for consumption;

2) information on vitamins and minerals shown in Annex 3 of these special requirements, expressed as a percentage of the reference values, per 100 g or 100 ml of the products as sold, and where appropriate, the recommended quantity of the food for infants and young children as proposed for consumption. The labelling shall bear information on the quantities of the vitamins and minerals where the quantities present are equal to at least 15% of the reference values.

Annex 1 to the "Composition and Quality Requirements for Foods for Infants and Young Children, Requirements for Substances Used in Manufacture of Such Foods and Requirements for Handling of Such Foods, and Special Requirements and Procedure for Labelling of and Presentation of Information in Any Other Manner Concerning Such Foods"

Amino acid composition of casein

Amino acids	g per 100 g of casein
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 2 to the "Composition and Quality Requirements for Foods for Infants and Young Children, Requirements for Substances Used in Manufacture of Such Foods and Requirements for Handling of Such Foods, and Special Requirements and Procedure for Labelling of and Presentation of Information in Any Other Manner Concerning Such Foods"

Maximum vitamin and mineral content of foods for infants and young children to which vitamins and minerals have been added

Vitamins and minerals	Unit		Maximum content 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	0,25/0,5[4]
Riboflavin		mg	0,4
Niacin		mg-NE	4,5
Vitamin B_6		mg	0,35
Folic acid	µg		50
Vitamin B_{12}	µg		0,35
Pantothenic acid		mg	1,5
Biotin	µg		10
Potassium		mg	160
Calcium		mg	80/180[5]/100[6]
Magnesium		mg	40

Iron		mg	3
Zinc		mg	2
Copper	µg		40
Iodine	µg		35
Manganese		mg	0,6

The maximum levels specified in this table apply to the product ready for use, except for the maximum levels set for potassium and calcium which apply to foods sold or transferred to the consumer in any other manner..

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[1] In compliance with the requirements provided for in Chapters II and III of these special requirements.

[2] The requirement applies to processed cereal-based foods and baby foods for infants and young children enriched with iron.

[3] The requirement applies to baby food based on fruit and berries, fruit, berry and vegetable juices and nectars.

[4] The requirement applies to processed cereal-based foods.

[5] The requirement applies to the foods specified in subclauses 2 1) and 2) of these special requirements.

(05.02.2002 entered into force 16.02.2002 - RT I 2002, 18, 101)

[6] The requirement applies to the foods specified in subclause 2 4) of these special requirements.

Annex 3 to the "Composition and Quality Requirements for Foods for Infants and Young Children, Requirements for Substances Used in Manufacture of Such Foods and Requirements for Handling of Such Foods, and Special Requirements and Procedure for Labelling of and Presentation of Information in Any Other Manner Concerning Such Foods"

Reference values for vitamins and mineral nutrients in food for infants and young children

Vitamins and minerals	Unit		Reference values
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 B_6		mg	0,7
Folic acid	µg		100
Vitamin B_{12}	µg		0,7
Calcium		mg	400
Iron		mg	6
Zinc		mg	4
Iodine	µg		70
Selenium	µg		10
Copper		mg	0,4

Approved by Government of the Republic Regulation No. 436 of 29 December 1999

Composition and Quality Requirements for Energy-restricted Foods for Weight Reduction, Requirements for Substances Used in Manufacture of Such Foods and Requirements for Handling of Such Foods, and Special Requirements and Procedure for Labelling of and Presentation of Information in Any Other Manner Concerning Such Foods

I.General Provisions

1. Foods for use in energy-restricted diets intended for weight reduction (hereinafter energy-restricted foods) are specially formulated foods which, when used as instructed by the manufacturer, replace the whole or part of the total daily diet. These special requirements and procedure (hereinafter special requirements) shall be based on the following classification of energy-restricted foods:

1) food intended for particular nutritional uses intended as a replacement for the whole of the daily diet and for provision of adequate amounts of all essential nutrients;

2) food intended for particular nutritional uses intended as a replacement for one or more meals of the daily diet and for provision of adequate amounts of all essential nutrients.

2. The energy-restricted foods referred to in subclause 1 1) of these special requirements, as sold, shall be contained in the same package.

3. The composition and quality requirements for energy-restricted foods apply to the product ready for use.

II Composition and Quality Requirements for Energy-restricted Food, Requirements for Substances Used in Manufacture of Such Foods and Requirements for Handling of Such Foods

4. The energy provided by an energy-restricted food specified in subclause 1 1) of these special requirements shall not be less than 3360 kJ (800 kcal) and shall not exceed 5040 kJ (1200 kcal) for the total daily ration.

5. The energy provided by an energy-restricted food specified in subclause 1 2) of these special requirements shall not be less than 840 kJ (200 kcal) and shall not exceed 1680 kJ (400 kcal) per meal.

6. The protein contained in energy-restricted foods shall provide not less than 25% and not more than 50% of the total energy of the product. In any case the amount of protein of the energy-restricted foods specified in subclause 1 1) shall not exceed 125 g.

7. The provisions on protein set out in clause 6 of these special requirements refer to a protein the chemical index of which is equal to 100% (the chemical index shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein in and the quantity of each corresponding amino acid of the reference protein). If the chemical index is lower than 100% of the reference protein provided for in Annex 1 to these special requirements, the minimum protein levels shall be correspondingly increased. In any case the chemical index of the protein shall be equal to at least 80% of that of the reference protein.

8. In all cases, the addition of amino acids to energy-restricted foods is permitted solely for the purpose of improving the nutritional value of the proteins, and only in the proportions necessary for that purpose.

9. The energy derived from fat shall not exceed 30% of the total available energy of the energy-restricted foods.

10. For the energy-restricted foods specified in subclause 1 1) of these special requirements, the linoleic acid (in the form of glycerol trilinolate) shall not be less than 4,5 g.

11. For the energy-restricted foods specified in subclause 1 2) of these special requirements, the linoleic acid (in the form of glycerol trilinolate) shall not be less than 1 g.

12. The dietary fibre content of the energy-restricted foods specified in subclause 1 1) of these special requirements shall not be less than 10 g and shall not exceed 30 g for the daily ration.

13. The energy-restricted foods specified in subclause 1 1) of these special requirements shall provide at least 100% of the amounts of vitamins and minerals specified in Annex 2 to these special requirements for the whole of the daily diet.

14. The energy-restricted foods specified in subclause 1 2) of these special requirements shall provide at least 30% of the amounts of vitamins and minerals specified in Annex 2 to these special requirements per meal; however, the amount of potassium per meal provided by these products shall be at least 500 mg.

III Special Requirements and Procedure for Labelling of and Presentation of Information in Any Other Manner Concerning Energy-restricted Foods

15. Upon the labelling of energy-restricted foods, these special requirements for labelling shall be adhered to in addition to the requirements concerning the labelling of food.

16. The name under which energy-restricted foods are sold shall be:

1) for energy-restricted foods specified in subclause 1 1) of these special requirements, "*Päevase toidu asendaja kehakaalu alandamise eesmärgil*" [Total diet replacement for weight control];

2) for energy-restricted foods specified in subclause 1 2) of these special requirements, "*Toidukorra toidu asendaja kehakaalu alandamise eesmärgil*" [Meal replacement for weight control].

17. The labelling of the sales packaging of energy-restricted foods shall bear the following mandatory particulars:

1) the available energy value expressed in kJ and kcal, and the content of proteins, carbohydrates and fat, expressed in numerical form, per specified quantity of the product ready for use as proposed for consumption;

2) the average quantity of each mineral and each vitamin specified in Annex 2 to these special requirements, expressed in numerical form, per specified quantity of the product ready for use as proposed for consumption. In addition, for the energy-restricted foods specified in subclause 1 2) of these special requirements, the abovementioned information shall also be expressed as a percentage of the daily requirement values proposed for adults as defined in Annex 3 to these special requirements;

3) instructions for appropriate preparation, when necessary, and a statement as to the importance of following those instructions;

4) if an energy-restricted food, when used as instructed by the manufacturer, provides a daily intake of polyols in excess of 20 g per day, there shall be a statement to the effect that the food may have a laxative effect;

5) a statement on the importance of maintaining an adequate daily fluid intake;

6) the sales packaging of the energy-restricted foods specified in subclause 1 1) of these special requirements shall include a statement that the product provides adequate amounts of all essential nutrients for the day and a statement that the product shall not be used for more than three weeks without medical advice;

7) the sales packaging of the energy-restricted foods specified in subclause 1 2) of these special requirements shall include a statement to the effect that the products are useful for the intended use only as part of an energy-restricted diet and that other foodstuffs shall be a necessary part of such diet.

18. The labelling of energy-restricted foods and information provided in any other manner concerning such foods shall not make any reference to the rate or amount of weight loss which may result from their use or to a reduction in the sense of hunger or an increase in the sense of satiety.

Annex 1 to the "Composition and Quality Requirements for Energy-restricted Foods for Weight Reduction, Requirements for Substances Used in Manufacture of Such Foods and Requirements for Handling of Such Foods, and Special Requirements and Procedure for Labelling of and Presentation of Information in Any Other Manner Concerning Such Foods"

Amino acid content in reference protein

Amino acids	g per 100 g of protein
Cystine + methionine	1,7
Histidine	1,6
Isoleucine	1,3
Leucine	1,9
Lysine	1,6
Phenylalanine + tyrosine	1,9
Threonine	0,9
Tryptophan	0,5
Valine	1,3

Annex 2 to the "Composition and Quality Requirements for Energy-restricted Foods for Weight Reduction, Requirements for Substances Used in Manufacture of Such Foods and Requirements for Handling of Such Foods, and Special Requirements and Procedure for Labelling of and Presentation of Information in Any Other Manner Concerning Such Foods"

Proposed daily quantities for vitamins and mineral nutrients

Vitamins and minerals	Unit		Quantity
Vitamin A	µg-RE		700
Vitamin D	µg		5
Vitamin E		mg-TE	10
Vitamin C		mg	45
Thiamin		mg	1,1
Riboflavin		mg	1,6
Niacin		mg-NE	18
Vitamin B_6		mg	1,5
Folic acid	µg		200
Vitamin B_{12}	µg		1,4
Biotin	µg		15
Pantothenic acid		mg	3
Calcium		mg	700
Phosphorus		mg	550
Potassium		mg	3100
Iron		mg	16
Zinc		mg	9,5
Copper		mg	1,1

Iodine	µg		130
Selenium	µg		55
Sodium		mg	575
Magnesium		mg	150
Manganese		mg	1

Annex 3 to the "Composition and Quality Requirements for Energy-restricted Foods for Weight Reduction, Requirements for Substances Used in Manufacture of Such Foods and Requirements for Handling of Such Foods, and Special Requirements and Procedure for Labelling of and Presentation of Information in Any Other Manner Concerning Such Foods"

Daily requirement values for vitamins and mineral nutrients for adults

Vitamins and minerals	Unit		Quantity
Vitamin A	µg-eq		800
Vitamin D	µg		5
Vitamin E		mg	10
Vitamin C		mg	60
Thiamin		mg	1,4
Riboflavin		mg	1,6
Pantothenic acid		mg	18
Vitamin B_6		mg	2
Folic acid	µg		200
Vitamin B_{12}	µg		1
Biotin		mg	0,15
Pantothenic acid		mg	6

Calcium		mg	800
Phosphorus		mg	800
Magnesium		mg	300
Iron		mg	14
Zinc		mg	15
Iodine	µg		150