

Changes to legislation: There are outstanding changes not yet made to Commission Delegated Regulation (EU) 2016/128. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

ANNEX I

COMPOSITIONAL REQUIREMENTS REFERRED TO IN ARTICLE 2(3)

PART A

Food for special medical purposes developed to satisfy the nutritional requirements of infants

1. Products referred to in Article 2(1)(a) developed to satisfy the nutritional requirements of infants shall contain the vitamins and mineral substances as specified in Table 1.
2. Products referred to in Article 2(1)(b) developed to satisfy the nutritional requirements of infants shall contain the vitamins and mineral substances as specified in Table 1, without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.
3. Maximum levels of vitamins and mineral substances present in products referred to in Article 2(1)(c) developed to satisfy the nutritional requirements of infants shall not exceed those specified in Table 1, without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.
4. Where this is not contrary to the requirements dictated by the intended use, food for special medical purposes developed to satisfy the nutritional requirements of infants shall comply with the provisions relating to other nutrients applicable to infant formula and follow-on formula, as the case may be, laid down in Commission Delegated Regulation (EU) 2016/127⁽¹⁾.

TABLE 1

Values for vitamins and minerals in food for special medical purposes developed to satisfy the nutritional requirements of infants

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamins				
Vitamin A (µg-RE) ^a	16,7	43	70	180
Vitamin D (µg)	0,48	0,72	2	3
Vitamin K (µg)	0,24	6	1	25
Vitamin C (mg)	0,96	7,2	4	30
Thiamin (µg)	9,6	72	40	300

a Preformed vitamin A; RE = all *trans* retinol equivalent.

b Preformed niacin.

c Dietary folate equivalent: 1 µg DFE = 1 µg food folate = 0,6 µg folic acid from food for special medical purposes.

d Based on vitamin E activity of RRR-α-tocopherol.

e The calcium:available phosphorus molar ratio shall not be less than 1 nor greater than 2.

f Total phosphorus.

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Riboflavin (µg)	14,3	107	60	450
Vitamin B ₆ (µg)	4,8	72	20	300
Niacin (mg) ^b	0,1	0,72	0,4	3
Folate (µg-DFE) ^c	3,6	11,4	15	47,6
Vitamin B ₁₂ (µg)	0,02	0,12	0,1	0,5
Panthenic Acid (mg)	0,1	0,48	0,4	2
Biotin (µg)	0,24	4,8	1	20
Vitamin E (mg α-tocopherol) ^d	0,14	1,2	0,6	5
Minerals				
Sodium (mg)	6	14,3	25	60
Chloride (mg)	14,3	38,2	60	160
Potassium (mg)	19,1	38,2	80	160
Calcium (mg) ^e	12	60	50	250
Phosphorus (mg) ^f	6	24	25	100
Magnesium (mg)	1,2	3,6	5	15
Iron (mg)	0,07	0,6	0,3	2,5
Zinc (mg)	0,12	0,6	0,5	2,4
Copper (µg)	14,3	29	60	120
Iodine (µg)	3,6	8,4	15	35
Selenium (µg)	0,72	2	3	8,6
Manganese (µg)	0,24	24	1	100
Chromium (µg)	—	2,4	—	10
Molybdenum (µg)	—	3,3	—	14
Fluoride (µg)	—	47,8	—	200

a Preformed vitamin A; RE = all *trans* retinol equivalent.

b Preformed niacin.

c Dietary folate equivalent: 1 µg DFE = 1 µg food folate = 0,6 µg folic acid from food for special medical purposes.

d Based on vitamin E activity of RRR-α-tocopherol.

e The calcium:available phosphorus molar ratio shall not be less than 1 nor greater than 2.

f Total phosphorus.

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PART B

Food for special medical purposes other than that developed to satisfy the nutritional requirements of infants

1. Products referred to in Article 2(1)(a) other than those developed to satisfy the nutritional requirements of infants shall contain the vitamins and mineral substances as specified in Table 2.
2. Products referred to in Article 2(1)(b) other than those developed to satisfy the nutritional requirements of infants shall contain the vitamins and mineral substances as specified in Table 2, without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.
3. Maximum levels of vitamins and mineral substances present in products referred to in Article 2(1)(c) other than those developed to satisfy the nutritional requirements of infants shall not exceed those specified in Table 2, without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.

TABLE 2

Values for vitamins and minerals in food for special medical purposes other than that developed to satisfy the nutritional requirements of infants

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamins				
Vitamin A (µg-RE)	8,4	43	35	180
Vitamin D (µg)	0,12	0,65/0,75 ^a	0,5	2,5/3 ^a
Vitamin K (µg)	0,85	5	3,5	20
Vitamin C (mg)	0,54	5,25	2,25	22
Thiamin (mg)	0,015	0,12	0,06	0,5
Riboflavin (mg)	0,02	0,12	0,08	0,5
Vitamin B ₆ (mg)	0,02	0,12	0,08	0,5
Niacin (mg NE)	0,22	0,75	0,9	3
Folic Acid (µg)	2,5	12,5	10	50
Vitamin B ₁₂ (µg)	0,017	0,17	0,07	0,7
Panhotenic Acid (mg)	0,035	0,35	0,15	1,5
Biotin (µg)	0,18	1,8	0,75	7,5
Vitamin E (mg α-TE)	0,5/g of polyunsaturated fatty acids expressed as	0,75	0,5/g of polyunsaturated fatty acids expressed as	3

^a For products intended for children of 1 to 10 years of age.

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	linoleic acid but in no case less than 0,1 mg per 100 available kJ		linoleic acid but in no case less than 0,5 mg per 100 available kcal	
Minerals				
Sodium (mg)	7,2	42	30	175
Chloride (mg)	7,2	42	30	175
Potassium (mg)	19	70	80	295
Calcium (mg)	8,4/12 ^a	42/60 ^a	35/50 ^a	175/250 ^a
Phosphorus (mg)	7,2	19	30	80
Magnesium (mg)	1,8	6	7,5	25
Iron (mg)	0,12	0,5	0,5	2
Zinc (mg)	0,12	0,36	0,5	1,5
Copper (µg)	15	125	60	500
Iodine (µg)	1,55	8,4	6,5	35
Selenium (µg)	0,6	2,5	2,5	10
Manganese (mg)	0,012	0,12	0,05	0,5
Chromium (µg)	0,3	3,6	1,25	15
Molybdenum (µg)	0,84	4,3	3,5	18
Fluoride (mg)	—	0,05	—	0,2

^a For products intended for children of 1 to 10 years of age.

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- (1) Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding (see page 1 of this Official Journal).

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Changes and effects yet to be applied to the whole legislation item and associated provisions

- Art. 8(7) inserted by S.I. 2019/651, reg. 72(5)(c) (as substituted) by [S.I. 2020/1476 reg. 6\(7\)\(b\)](#)
- Art. 9(1) words substituted in earlier amending provision S.I. 2019/651, reg. 72(6) by [S.I. 2020/1476 reg. 6\(7\)\(c\)\(i\)](#)
- Art. 9(2)(d) and word omitted in earlier amending provision S.I. 2019/651, reg. 72(6) by [S.I. 2020/1476 reg. 6\(7\)\(c\)\(ii\)](#)