

ANNEX I

COMPOSITIONAL REQUIREMENTS REFERRED TO IN ARTICLE 2(1)

1. ENERGY

Minimum	Maximum
250 kJ/100 ml	293 kJ/100 ml
(60 kcal/100 ml)	(70 kcal/100 ml)

2. PROTEINS

(Protein content = nitrogen content × 6,25)

2.1. Infant formula manufactured from cows' milk or goats' milk proteins

Minimum	Maximum
0,43 g/100 kJ	0,6 g/100 kJ
(1,8 g/100 kcal)	(2,5 g/100 kcal)

For an equal energy value, infant formula manufactured from cows' milk or goats' milk proteins must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein as set out in Section A of Annex III. Nevertheless, for calculation purposes, the concentration of methionine and cysteine may be added together if the methionine:cysteine ratio is not greater than 2, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2. The ratio of methionine:cysteine and of tyrosine:phenylalanine may be greater than 2, provided that the suitability of the product concerned for infants is demonstrated in accordance with Article 3(3).

The L-carnitine content shall be at least equal to 0,3 mg/100 kJ (1,2 mg/100 kcal).

2.2. Infant formula manufactured from soya protein isolates, alone or in a mixture with cows' milk or goats' milk proteins

Minimum	Maximum
0,54 g/100 kJ	0,67 g/100 kJ
(2,25 g/100 kcal)	(2,8 g/100 kcal)

Only protein isolates from soya shall be used in manufacturing this infant formula.

For an equal energy value, infant formula manufactured from soya protein isolates, alone or in a mixture with cows' milk or goats' milk proteins, must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein as set out in Section A of Annex III. Nevertheless, for calculation purposes, the concentration of methionine and cysteine may be added together if the methionine:cysteine ratio is not greater than 2, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2. The ratio of methionine:cysteine and of tyrosine:phenylalanine may be greater than 2, provided that the suitability of the product concerned for infants is demonstrated in accordance with Article 3(3).

Changes to legislation: There are currently no known outstanding effects for the Commission Delegated Regulation (EU) 2016/127, ANNEX I. (See end of Document for details)

The L-carnitine content shall be at least equal to 0,3 mg/100 kJ (1,2 mg/100 kcal).

2.3. Infant formula manufactured from protein hydrolysates

Minimum	Maximum
0,44 g/100 kJ	0,67 g/100 kJ
(1,86 g/100 kcal)	(2,8 g/100 kcal)

2.3.1. Protein source

Demineralised sweet whey protein derived from cows' milk after enzymatic precipitation of caseins using chymosin, consisting of:

- (a) 63 % caseino-glycomacropptide free whey protein isolate with a minimum protein content of 95 % of dry matter and protein denaturation of less than 70 % and a maximum ash content of 3 %; and
- (b) 37 % sweet whey protein concentrate with a minimum protein content of 87 % of dry matter and protein denaturation of less than 70 % and a maximum ash content of 3,5 %.

2.3.2. Protein processing

Two-stage hydrolysis process using a trypsin preparation with a heat-treatment step (from 3 to 10 minutes at 80 to 100 °C) between the two hydrolysis steps.

2.3.3. Indispensable and conditionally indispensable amino acids and L-carnitine

For an equal energy value, infant formula manufactured from protein hydrolysates must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein as set out in Section B of Annex III. Nevertheless, for calculation purposes, the concentration of methionine and cysteine may be added together if the methionine:cysteine ratio is not greater than 2, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2. The ratio of methionine:cysteine and of tyrosine:phenylalanine may be greater than 2, provided that the suitability of the product concerned for infants is demonstrated in accordance with Article 3(3).

The L-carnitine content shall be at least equal to 0,3 mg/100 kJ (1,2 mg/100 kcal).

- 2.4. In all cases, amino acids may be added to infant formula solely for the purpose of improving the nutritional value of the proteins, and only in the proportions necessary for that purpose.

3. TAURINE

If added to infant formula, the amount of taurine shall not be greater than 2,9 mg/100 kJ (12 mg/100 kcal).

4. CHOLINE

Minimum	Maximum
6,0 mg/100 kJ	12 mg/100 kJ
(25 mg/100 kcal)	(50 mg/100 kcal)

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5. LIPIDS

Minimum	Maximum
1,1 g/100 kJ	1,4 g/100 kJ
(4,4 g/100 kcal)	(6,0 g/100 kcal)

5.1. The use of the following substances shall be prohibited:

- sesame seed oil,
- cotton seed oil.

5.2. The *trans* fatty acid content shall not exceed 3 % of the total fat content.

[^{F1}5.3. The erucic acid content shall not exceed 0,4 % of the total fat content.]

Textual Amendments

F1 Substituted by [Commission Delegated Regulation \(EU\) 2019/828 of 14 March 2019 amending Delegated Regulation \(EU\) 2016/127 with regard to vitamin D requirements for infant formula and erucic acid requirements for infant formula and follow-on formula \(Text with EEA relevance\)](#).

5.4. Linoleic acid

Minimum	Maximum
120 mg/100 kJ	300 mg/100 kJ
(500 mg/100 kcal)	(1 200 mg/100 kcal)

5.5. Alpha-linolenic acid

Minimum	Maximum
12 mg/100 kJ	24 mg/100 kJ
(50 mg/100 kcal)	(100 mg/100 kcal)

5.6. Docosahexaenoic acid

Minimum	Maximum
4,8 mg/100 kJ	12 mg/100 kJ
(20 mg/100 kcal)	(50 mg/100 kcal)

5.7. Other long-chain (20 and 22 carbon atoms) polyunsaturated fatty acids may be added. In that case the content of long-chain polyunsaturated fatty acids shall not exceed 2 % of the total fat content for n-6 long-chain polyunsaturated fatty acids (1 % of the total fat content for arachidonic acid (20:4 n-6)).

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

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6. PHOSPHOLIPIDS

The amount of phospholipids in infant formula shall not be greater than 2 g/l.

7. INOSITOL

Minimum	Maximum
0,96 mg/100 kJ	9,6 mg/100 kJ
(4 mg/100 kcal)	(40 mg/100 kcal)

8. CARBOHYDRATES

Minimum	Maximum
2,2 g/100 kJ	3,3 g/100 kJ
(9 g/100 kcal)	(14 g/100 kcal)

8.1. Only the following carbohydrates may be used:

- lactose,
- maltose,
- sucrose,
- glucose,
- glucose syrup or dried glucose syrup,
- malto-dextrins,
- pre-cooked starch (naturally free of gluten),
- gelatinised starch (naturally free of gluten).

8.2. Lactose

Minimum	Maximum
1,1 g/100 kJ	—
(4,5 g/100 kcal)	—

Those minimum levels shall not apply to infant formula:

- in which soya protein isolates represent more than 50 % of the total protein content, or
- bearing the statement 'lactose free' in accordance with Article 9(2).

8.3. Sucrose

Sucrose may only be added to infant formula manufactured from protein hydrolysates. If added, the sucrose content shall not exceed 20 % of the total carbohydrate content.

8.4. Glucose

Glucose may only be added to infant formula manufactured from protein hydrolysates. If added, the glucose content shall not exceed 0,5 g/100 kJ (2 g/100 kcal).

8.5. Glucose syrup or dried glucose syrup

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Glucose syrup or dried glucose syrup may be added to infant formula manufactured from cows' milk or goats' milk proteins or infant formula manufactured from soya protein isolates (alone or in a mixture with cows' milk or goats' milk proteins) only if its dextrose equivalent does not exceed 32. If glucose syrup or dried glucose syrup is added to these products, the glucose content resulting from glucose syrup or dried glucose syrup shall not exceed 0,2 g/100 kJ (0,84 g/100 kcal).

The maximum glucose amounts laid down in point 8.4 shall apply if glucose syrup or dried glucose syrup is added to infant formula manufactured from protein hydrolysates.

8.6. Pre-cooked starch and/or gelatinised starch

Minimum	Maximum
—	2 g/100 ml, and 30 % of the total carbohydrate content

9. FRUCTO-OLIGOSACCHARIDES AND GALACTO-OLIGOSACCHARIDES

Fructo-oligosaccharides and galacto-oligosaccharides may be added to infant formula. In that case their content shall not exceed: 0,8 g/100 ml in a combination of 90 % oligogalactosyl-lactose and 10 % high molecular weight oligofructosyl-saccharose.

Other combinations and maximum levels of fructo-oligosaccharides and galacto-oligosaccharides may be used, provided that their suitability for infants is demonstrated in accordance with Article 3(3).

10. MINERAL SUBSTANCES

10.1. Infant formula manufactured from cows' milk or goats' milk proteins or protein hydrolysates

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Sodium (mg)	6	14,3	25	60
Potassium (mg)	19,1	38,2	80	160
Chloride (mg)	14,3	38,2	60	160
Calcium (mg)	12	33,5	50	140
Phosphorus (mg)^a	6	21,5	25	90
Magnesium (mg)	1,2	3,6	5	15
Iron (mg)	0,07	0,31	0,3	1,3
Zinc (mg)	0,12	0,24	0,5	1
Copper (µg)	14,3	24	60	100
Iodine (µg)	3,6	6,9	15	29
Selenium (µg)	0,72	2	3	8,6

^a Total phosphorus.

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Manganese (µg)	0,24	24	1	100
Molybdenum (µg)	—	3,3	—	14
Fluoride (µg)	—	24	—	100

a Total phosphorus.

The calcium:available phosphorus molar ratio shall not be less than 1 nor greater than 2. The amount of available phosphorus shall be calculated as 80 % of total phosphorus for infant formula manufactured from cow's milk protein, goats' milk protein or protein hydrolysates.

10.2. Infant formula manufactured from soya protein isolates, alone or in a mixture with cows' milk or goats' milk proteins

All requirements of point 10.1 shall apply, except for those concerning iron, phosphorus and zinc, which shall be as follows:

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Iron (mg)	0,11	0,48	0,45	2
Phosphorus (mg)^a	7,2	24	30	100
Zinc (mg)	0,18	0,3	0,75	1,25

a Total phosphorus.

The calcium:available phosphorus molar ratio shall not be less than 1 nor greater than 2. The amount of available phosphorus shall be calculated as 70 % of total phosphorus for infant formula manufactured from soya protein isolates.

11. VITAMINS

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamin A (µg-RE)^a	16,7	27,2	70	114
[^{F1}Vitamin D (µg)]	0,48	0,6	2	2,5]
Thiamine (µg)	9,6	72	40	300
Riboflavin (µg)	14,3	95,6	60	400
Niacin (mg)^b	0,1	0,36	0,4	1,5
Pantothenic acid (mg)	0,1	0,48	0,4	2

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 formula.

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

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Vitamin B₆ (µg)	4,8	41,8	20	175
Biotin (µg)	0,24	1,8	1	7,5
Folate (µg-DFE)^c	3,6	11,4	15	47,6
Vitamin B₁₂ (µg)	0,02	0,12	0,1	0,5
Vitamin C (mg)	0,96	7,2	4	30
Vitamin K (µg)	0,24	6	1	25
Vitamin E (mg α-tocopherol)^d	0,14	1,2	0,6	5

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 formula.

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

12. NUCLEOTIDES

The following nucleotides may be added:

	Maximum^a	
	(mg/100 kJ)	(mg/100 kcal)
cytidine 5'-monophosphate	0,60	2,50
uridine 5'-monophosphate	0,42	1,75
adenosine 5'-monophosphate	0,36	1,50
guanosine 5'-monophosphate	0,12	0,50
inosine 5'-monophosphate	0,24	1,00

a The total concentration of nucleotides shall not exceed 1,2 mg/100 kJ (5 mg/100 kcal).

Changes to legislation:

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