

ANNEX II

COMPOSITIONAL REQUIREMENTS REFERRED TO IN ARTICLE 2(2)

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. Follow-on formula manufactured from cows' milk or goats' milk proteins

[^{F1} Minimum	Maximum
0,38 g/100 kJ	0,6 g/100 kJ
(1,6 g/100 kcal)	(2,5 g/100 kcal)]

Textual Amendments

- F1** Substituted by [Commission Delegated Regulation \(EU\) 2018/561 of 29 January 2018 amending Delegated Regulation \(EU\) 2016/127 with regard to protein requirements for follow-on formula \(Text with EEA relevance\)](#).

For an equal energy value, follow-on 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 and the concentration of phenylalanine and tyrosine may be added together.

2.2. Follow-on 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 follow-on formula.

For an equal energy value, follow-on 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 and the concentration of phenylalanine and tyrosine may be added together.

2.3. Follow-on formula manufactured from protein hydrolysates

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

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-glycomacropeptide 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

For an equal energy value, follow-on 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 and the concentration of phenylalanine and tyrosine may be added together.

- 2.4. In all cases, amino acids may be added to follow-on 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 follow-on formula, the amount of taurine shall not be greater than 2,9 mg/100 kJ (12 mg/100 kcal).

4. LIPIDS

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

- 4.1. The use of the following substances shall be prohibited:

- sesame seed oil,
- cotton seed oil.

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

- [^{F2}4.3. The erucic acid content shall not exceed 0,4 % of the total fat content.]

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

Textual Amendments

- F2** 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).

4.4. Linoleic acid

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

4.5. Alpha-linolenic acid

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

4.6. Docosahexaenoic acid

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

- 4.7. 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.

5. PHOSPHOLIPIDS

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

6. CARBOHYDRATES

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

- 6.1. The use of ingredients containing gluten shall be prohibited.

- 6.2. Lactose

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

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

Those minimum levels shall not apply to follow-on 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).

6.3. Sucrose, fructose, honey

Minimum	Maximum
—	separately or as a whole: 20 % of the total carbohydrate content

Honey shall be treated to destroy spores of *Clostridium botulinum*.

6.4. Glucose

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

6.5. Glucose syrup or dried glucose syrup

Glucose syrup or dried glucose syrup may be added to follow-on formula manufactured from cows' milk or goats' milk proteins or follow-on 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 6.4 shall apply if glucose syrup or dried glucose syrup is added to follow-on formula manufactured from protein hydrolysates.

7. FRUCTO-OLIGOSACCHARIDES AND GALACTO-OLIGOSACCHARIDES

Fructo-oligosaccharides and galacto-oligosaccharides may be added to follow-on 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).

8. MINERAL SUBSTANCES

8.1. Follow-on 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

a Total phosphorus.

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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)	0,14	0,48	0,6	2
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
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 follow-on formula manufactured from cow's milk protein, goats' milk protein or protein hydrolysates.

8.2. Follow-on formula manufactured from soya protein isolates, alone or in a mixture with cows' milk or goats' milk proteins

All requirements of point 8.1 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)	0,22	0,6	0,9	2,5
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 follow-on formula manufactured from soya protein isolates.

9. VITAMINS

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

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamin A (µg-RE)^a	16,7	27,2	70	114
Vitamin D (µg)	0,48	0,72	2	3
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
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.

10. 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:

There are currently no known outstanding effects for the Commission Delegated Regulation
(EU) 2016/127, ANNEX II.