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From: Secretary-General of the European Commission,
signed by Mr Jordi AYET PUIGARNAU, Director

date of receipt: 25 September 2015

To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of
the European Union

No. Cion doc.: C(2015) 6478 final - Annexes 1 to 7

Subject: ANNEXES to the COMMISSION DELEGATED REGULATION (EU) .../...
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

Delegations will find attached document C(2015) 6478 final - Annexes 1 to 7.

Encl.: C(2015) 6478 final - Annexes 1 to 7



Brussels, 25.9.2015
C(2015) 6478 final

ANNEXES 1 to 7

ANNEXES

to the

COMMISSION DELEGATED REGULATION (EU) .../...

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

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).

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-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 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)

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.

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

5.4. Linoleic acid

Minimum	Maximum
120 mg/100 kJ	300 mg/100 kJ
(500 mg/100 kcal)	(1200 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. Docosaheptaenoic 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.

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

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

⁽¹⁾ 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)⁽¹⁾	7,2	24	30	100
Zinc (mg)	0,18	0,3	0,75	1,25

⁽¹⁾ 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)⁽¹⁾	16,7	27,2	70	114
Vitamin D (µg)	0,48	0,72	2	3
Thiamin (µg)	9,6	72	40	300
Riboflavin (µg)	14,3	95,6	60	400
Niacin (mg)⁽²⁾	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)⁽³⁾	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)⁽⁴⁾	0,14	1,2	0,6	5

⁽¹⁾ Preformed vitamin A; RE = all *trans* retinol equivalent.
⁽²⁾ Preformed niacin.
⁽³⁾ Dietary folate equivalent: 1 µg DFE = 1 µg food folate = 0,6 µg folic acid from formula.
⁽⁴⁾ Based on vitamin E activity of RRR-α-tocopherol.

12. NUCLEOTIDES

The following nucleotides may be added:

	Maximum⁽¹⁾	
	(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

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

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

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, 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

Minimum	Maximum
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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.

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

4.4. **Linoleic acid**

Minimum	Maximum
120 mg/100 kJ	300 mg/100 kJ
(500 mg/100 kcal)	(1200 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**

Minimum	Maximum
1,1 g/100 kJ	-

(4,5 g/100 kcal)	-
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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
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)⁽¹⁾	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

⁽¹⁾ 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)⁽¹⁾	7,2	24	30	100
Zinc (mg)	0,18	0,3	0,75	1,25
⁽¹⁾ 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

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamin A (µg-RE)⁽¹⁾	16,7	27,2	70	114
Vitamin D (µg)	0,48	0,72	2	3
Thiamin (µg)	9,6	72	40	300
Riboflavin (µg)	14,3	95,6	60	400
Niacin (mg)⁽²⁾	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)⁽³⁾	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)⁽⁴⁾	0,14	1,2	0,6	5
⁽¹⁾ Preformed vitamin A; RE = all <i>trans</i> retinol equivalent. ⁽²⁾ Preformed niacin. ⁽³⁾ Dietary folate equivalent: 1 µg DFE = 1 µg food folate = 0,6 µg folic acid from formula. ⁽⁴⁾ Based on vitamin E activity of RRR-α-tocopherol.				

10. NUCLEOTIDES

The following nucleotides may be added:

	Maximum⁽¹⁾	
	(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

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

ANNEX III

INDISPENSABLE AND CONDITIONALLY INDISPENSABLE AMINO ACIDS IN BREAST MILK

For the purposes of point 2 of Annexes I and II, breast milk shall be used as reference protein as set out in Sections A and B of this Annex, respectively.

A. Infant formula and follow-on formula manufactured from cows' milk or goats' milk proteins and infant formula and follow-on formula manufactured from soya protein isolates, alone or in a mixture with cows' milk or goats' milk proteins

For the purposes of points 2.1. and 2.2. of Annexes I and II, the indispensable and conditionally indispensable amino acids in breast milk, expressed in mg per 100 kJ and 100 kcal, are the following:

	Per 100 kJ⁽¹⁾	Per 100 kcal
Cysteine	9	38
Histidine	10	40
Isoleucine	22	90
Leucine	40	166
Lysine	27	113
Methionine	5	23
Phenylalanine	20	83
Threonine	18	77
Tryptophan	8	32
Tyrosine	18	76
Valine	21	88

⁽¹⁾ 1 kJ = 0,239 kcal.

B. Infant formula and follow-on formula manufactured from protein hydrolysates

For the purposes of point 2.3. of Annexes I and II, the indispensable and conditionally indispensable amino acids in breast milk, expressed in mg per 100 kJ and 100 kcal, are the following:

	Per 100 kJ⁽¹⁾	Per 100 kcal
Arginine	16	69
Cysteine	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
⁽¹⁾ 1 kJ = 0,239 kcal.		

ANNEX IV

ACTIVE SUBSTANCES REFERRED TO IN ARTICLE 4(3)

Chemical name of the substance	Maximum residue level (mg/kg)
Cadusafos	0,006
Demeton-S-methyl/demeton-S-methyl sulfone/oxydemeton-methyl (individually or combined, expressed as demeton-S-methyl)	0,006
Ethoprophos	0,008
Fipronil (sum of fipronil and fipronil-desulfinyl, expressed as fipronil)	0,004
Propineb/propylenethiourea (sum of propineb and propylenethiourea)	0,006

ANNEX V

ACTIVE SUBSTANCES REFERRED TO IN ARTICLE 4(4)

Chemical name of the substance (residue definition)

Aldrin and dieldrin, expressed as dieldrin

Disulfoton (sum of disulfoton, disulfoton sulfoxide and disulfoton sulfone expressed as disulfoton)

Endrin

Fensulfothion (sum of fensulfothion, its oxygen analogue and their sulfones, expressed as fensulfothion)

Fentin, expressed as triphenyltin cation

Haloxypop (sum of haloxypop, its salts and esters including conjugates, expressed as haloxypop)

Heptachlor and *trans*-heptachlor epoxide, expressed as heptachlor

Hexachlorobenzene

Nitrofen

Omethoate

Terbufos (sum of terbufos, its sulfoxide and sulfone, expressed as terbufos)

ANNEX VI

NAMES REFERRED TO IN ARTICLE 5

Part A

Name referred to in Article 5(1)

The name of infant formula and follow-on formula other than infant formula and follow-on formula manufactured entirely from cows' milk or goats' milk proteins shall be respectively:

- in Bulgarian: ‘Храни за кърмачета’ and ‘Преходни храни’,
- in Spanish: ‘Preparado para lactantes’ and ‘Preparado de continuación’,
- in Czech: ‘Počáteční kojenecká výživa’ and ‘Pokračovací kojenecká výživa’,
- in Danish: ‘Modermælkserstatning’ and ‘Tilskudsblanding’,
- in German: ‘Säuglingsanfangsnahrung’ and ‘Folgenahrung’,
- in Estonian: ‘Imiku piimasegu’ and ‘Jätkupiimasegu’,
- in Greek: ‘Παρασκεύασμα για βρέφη’ and ‘Παρασκεύασμα δεύτερης βρεφικής ηλικίας’,
- in English: ‘Infant formula’ and ‘Follow-on formula’,
- in French: ‘Préparation pour nourrissons’ and ‘Préparation de suite’,
- in Croatian: ‘Početna hrana za dojenčad’ and ‘Prijelazna hrana za dojenčad’,
- in Italian: ‘Formula per lattanti’ and ‘Formula di proseguimento’,
- in Latvian: ‘Maisījums zīdaiņiem’ and ‘Papildu ēdināšanas maisījums zīdaiņiem’,
- in Lithuanian: ‘Pradinio maitinimo kūdikių mišiniai’ and ‘Tolesnio maitinimo kūdikių mišiniai’,
- in Hungarian: ‘Anyatej-helyettesítő tápszer’ and ‘Anyatej-kiegészítő tápszer’,
- in Maltese: ‘Formula tat-trabi’ and ‘Formula tal-prosegwiment’,
- in Dutch: ‘Volledige zuigelingenvoeding’ and ‘Opvolgzuigelingenvoeding’,
- in Polish: ‘Preparat do początkowego żywienia niemowląt’ and ‘Preparat do dalszego żywienia niemowląt’,
- in Portuguese: ‘Fórmula para lactentes’ and ‘Fórmula de transição’,
- in Romanian: ‘Formulă de început’ and ‘Formulă de continuare’,
- in Slovak: ‘Počiatočná dojčenská výživa’ and ‘Následná dojčenská výživa’.

- in Slovenian: ‘Začetna formula za dojenčke’ and ‘Nadaljevalna formula’,
- in Finnish: ‘Äidinmaidonkorvike’ and ‘Vieroitusvalmiste’,
- in Swedish: ‘Modersmjölksersättning’ and ‘Tillskottsnäring’.

Part B
Name referred to in Article 5(2)

The name of infant formula and follow-on formula manufactured entirely from cows’ milk or goats’ milk proteins shall be respectively:

- in Bulgarian: ‘Млека за кърмачета’ and ‘Преходни млека’,
- in Spanish: ‘Leche para lactantes’ and ‘Leche de continuación’,
- in Czech: ‘Počáteční mléčná kojenecká výživa’ and ‘Pokračovací mléčná kojenecká výživa’,
- in Danish: ‘Modermælkserstatning udelukkende baseret på mælk’ and ‘Tilskudsblanding udelukkende baseret på mælk’,
- in German: ‘Säuglingsmilchnahrung’ and ‘Folgemilch’,
- in Estonian: ‘Piimal põhinev imiku piimasegu’ and ‘Piimal põhinev jätkupiimasegu’,
- in Greek: ‘Γάλα για βρέφη’ and ‘Γάλα δεύτερης βρεφικής ηλικίας’,
- in English: ‘Infant milk’ and ‘Follow-on milk’,
- in French: ‘Lait pour nourrissons’ and ‘Lait de suite’,
- in Croatian: ‘Početna mliječna hrana za dojenčad’ and ‘Prijelazna mliječna hrana za dojenčad’,
- in Italian: ‘Latte per lattanti’ and ‘Latte di proseguimento’,
- in Latvian: ‘Piena maisījums zīdaiņiem’ and ‘Papildu ēdināšanas piena maisījums zīdaiņiem’,
- in Lithuanian: ‘Pradinio maitinimo kūdikių pieno mišiniai’ and ‘Tolesnio maitinimo kūdikių pieno mišiniai’,
- in Hungarian: ‘Tejalapú anyatej-helyettesítő tápszer’ and ‘Tejalapú anyatej-kiegészítő tápszer’,
- in Maltese: ‘Halib tat-trabi’ and ‘Halib tal-prosegwiment’,
- in Dutch: ‘Volledige zuigelingenvoeding op basis van melk’ or ‘Zuigelingenmelk’ and ‘Opvolgmelk’,
- in Polish: ‘Mleko początkowe’ and ‘Mleko następne’,

- in Portuguese: ‘Leite para lactentes’ and ‘Leite de transição’,
- in Romanian: ‘Lapte de început’ and ‘Lapte de continuare’,
- in Slovak: ‘Počiatočná dojčenská mliečna výživa’ and ‘Následná dojčenská mliečna výživa’,
- in Slovenian: ‘Začetno mleko za dojenčke’ and ‘Nadaljevalno mleko’,
- in Finnish: ‘Maitopohjainen äidinmaidonkorvike’ and ‘Maitopohjainen vieroitusvalmiste’,
- in Swedish: ‘Modersmjölksersättning uteslutande baserad på mjölk’ and ‘Tillskottsnäring uteslutande baserad på mjölk’.

ANNEX VII

REFERENCE INTAKES REFERRED TO IN ARTICLE 7(7)

Nutrient	Reference intake
Vitamin A	(µg) 400
Vitamin D	(µg) 7
Vitamin E	(mg TE) 5
Vitamin K	(µg) 12
Vitamin C	(mg) 45
Thiamin	(mg) 0,5
Riboflavin	(mg) 0,7
Niacin	(mg) 7
Vitamin B ₆	(mg) 0,7
Folate	(µg) 125
Vitamin B ₁₂	(µg) 0,8
Pantothenic acid	(mg) 3
Biotin	(µg) 10
Calcium	(mg) 550
Phosphorus	(mg) 550
Potassium	(mg) 1 000
Sodium	(mg) 400
Chloride	(mg) 500
Iron	(mg) 8
Zinc	(mg) 5
Iodine	(µg) 80
Selenium	(µg) 20
Copper	(mg) 0,5
Magnesium	(mg) 80
Manganese	(mg) 1,2