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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

(Text with EEA relevance)

(OJ L 25, 2.2.2016, p. 1)

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		Official Journal		
		No	page	date
►**M1**	Commission Delegated Regulation (EU) 2018/561 of 29 January 2018	L 94	1	12.4.2018
►**M2**	Commission Delegated Regulation (EU) 2019/828 of 14 March 2019	L 137	12	23.5.2019
►**M3**	Commission Delegated Regulation (EU) 2021/572 of 20 January 2021	L 120	4	8.4.2021
►**M4**	Commission Delegated Regulation (EU) 2021/1041 of 16 April 2021	L 225	4	25.6.2021

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COMMISSION DELEGATED REGULATION (EU) 2016/127

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(Text with EEA relevance)

Article 1

Placing on the market

1. Infant formula and follow-on formula may only be placed on the market if they comply with this Regulation.

2. No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life until the introduction of appropriate complementary feeding.

Article 2

Compositional requirements

1. Infant formula shall comply with the compositional requirements set out in Annex I taking into account the values for the indispensable and conditionally indispensable amino acids set out in Annex III.

2. Follow-on formula shall comply with the compositional requirements set out in Annex II taking into account the values for the indispensable and conditionally indispensable amino acids set out in Annex III.

3. The values set out in Annexes I and II shall apply to the infant formula and follow-on formula ready for use, marketed as such or after preparation in accordance with the manufacturer's instructions. For such preparation nothing more than the addition of water shall be required.

Article 3

Suitability of ingredients

1. Infant formula shall be manufactured from protein sources as set out in point 2 of Annex I and other food ingredients, as the case may be, whose suitability for infants from birth has been established by generally accepted scientific data.

2. Follow-on formula shall be manufactured from protein sources as set out in point 2 of Annex II and other food ingredients, as the case may be, whose suitability for infants aged over six months has been established by generally accepted scientific data.

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3. The suitability referred to in paragraphs 1 and 2 shall be demonstrated by the food business operator through a systematic review of the available data relating to the expected benefits and to safety considerations as well as, where necessary, appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

Article 4

Requirements on pesticides

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1. For the purposes of this Article, ‘residue’ means pesticide residue as referred to in point (c) Article 3(2) of Regulation (EC) No 396/2005.

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2. Infant formula and follow-on formula shall not contain residues at levels exceeding 0,01 mg/kg per active substance.

Those levels shall be determined by generally accepted standardised analytical methods.

3. By way of derogation from paragraph 2, for the active substances listed in Annex IV, the maximum residue levels specified in that Annex shall apply.

4. Infant formula and follow-on formula shall only be produced from agricultural products for the production of which plant protection products containing the active substances listed in Annex V have not been used.

However, for the purpose of checks, plant protection products containing the active substances listed in Annex V are considered not to have been used if their residues do not exceed a level of 0,003 mg/kg.

5. The levels referred to in paragraphs 2, 3 and 4 shall apply to the infant formula and follow-on formula ready for use, marketed as such or after preparation in accordance with the manufacturer's instructions.

Article 5

Name of the food

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 as set out in Part A of Annex VI.

2. The name of infant formula and follow-on formula manufactured entirely from cows' milk or goats' milk proteins shall be as set out in Part B of Annex VI.

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Article 6

Specific requirements on food information

1. Unless otherwise provided in this Regulation, infant formula and follow-on formula shall comply with Regulation (EU) No 1169/2011.

2. In addition to the mandatory particulars listed in Article 9(1) of Regulation (EU) No 1169/2011, the following shall be additional mandatory particulars for infant formula:

(a) a statement that the product is suitable for infants from birth when they are not breast fed;

(b) instructions for appropriate preparation, storage and disposal of the product and a warning against the health hazards of inappropriate preparation and storage;

(c) a statement concerning the superiority of breast feeding and a statement recommending that the product be used only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care. The particulars referred to in this point shall be preceded by the words ‘important notice’ or their equivalent and shall be given also in the presentation and advertising of infant formula.

3. In addition to the mandatory particulars listed in Article 9(1) of Regulation (EU) No 1169/2011, the following shall be additional mandatory particulars for follow-on formula:

(a) a statement that the product is suitable only for infants over the age of six months, that it should form only part of a diversified diet, that it is not to be used as a substitute for breast milk during the first six months of life and that the decision to begin complementary feeding, including any exception to six months of age, should be made only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care, based on the individual infant's specific growth and development needs;

(b) instructions for appropriate preparation, storage and disposal of the product and a warning against the health hazards of inappropriate preparation and storage.

4. Article 13(2) and (3) of Regulation (EU) No 1169/2011 shall also apply to the additional mandatory particulars referred to in paragraphs 2 and 3 of this Article.

5. All mandatory particulars for infant formula and follow-on formula shall appear in a language easily understood by the consumers.

6. The labelling, presentation and advertising of infant formula and follow-on formula shall provide the necessary information about the appropriate use of the products, so as not to discourage breast feeding.

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The labelling, presentation and advertising of infant formula and follow-on formula shall not use the terms ‘humanised’, ‘maternalised’, ‘adapted’, or terms similar to them.

The labelling, presentation and advertising of infant formula and follow-on formula shall be designed in such a way that it avoids any risk of confusion between infant formula and follow-on formula and enables consumers to make a clear distinction between them, in particular as to the text, images and colours used.

Article 7

Specific requirements on the nutrition declaration

1. In addition to the information referred to in Article 30(1) of Regulation (EU) No 1169/2011, the mandatory nutrition declaration for infant formula and follow-on formula shall include the amount of each mineral substance and of each vitamin listed in Annex I or Annex II to this Regulation respectively and present in the product, with the exception of molybdenum.

The mandatory nutrition declaration for infant formula shall also include the amount of choline, inositol and carnitine.

By way of derogation from Article 30(1) of Regulation (EU) No 1169/2011, the mandatory nutrition declaration for infant formula and follow-on formula shall not include the amount of salt.

2. In addition to the information referred to in Article 30(2)(a) to (e) of Regulation (EU) No 1169/2011, the content of the mandatory nutrition declaration for infant formula and follow-on formula may be supplemented with one or more of the following:

(a) the amounts of components of protein, carbohydrate or fat;

(b) the whey protein/casein ratio;

(c) the amount of any of the substances listed in Annex I or Annex II to this Regulation or in the Annex to Regulation (EU) No 609/2013, where the indication of any of those substances is not covered by paragraph 1;

(d) the amount of any of the substances added to the product pursuant to Article 3.

3. By way of derogation from Article 30(3) of Regulation (EU) No 1169/2011, the information included in the mandatory nutrition declaration for infant formula and follow-on formula shall not be repeated on the labelling.

4. The nutrition declaration shall be mandatory for all infant formula and follow-on formula, irrespective of the size of the largest surface of the packaging or container.

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5. Articles 31 to 35 of Regulation (EU) No 1169/2011 shall apply to all the nutrients included in the nutrition declaration for infant formula and follow-on formula.

6. By way of derogation from Articles 31(3), 32(2) and 33(1) of Regulation (EU) No 1169/2011, the energy value and the amounts of nutrients of infant formula and follow-on formula shall be expressed per 100 ml of the food ready for use after preparation in accordance with the manufacturer's instructions. Where appropriate, the information may in addition refer to 100 g of the food as sold.

7. By way of derogation from Article 32(3) and (4) of Regulation (EU) No 1169/2011, the energy value and the amount of nutrients of infant formula and follow-on formula shall not be expressed as a percentage of the reference intakes set out in Annex XIII to that Regulation.

In addition to the form of expression referred to in paragraph 6, in the case of follow-on formula, the declaration on vitamins and minerals in respect of the vitamins and minerals listed in Annex VII to this Regulation may be expressed as a percentage of the reference intakes set out in that Annex in relation to per 100 ml of the food ready for use after preparation in accordance with the manufacturer's instructions.

8. The particulars included in the nutrition declaration for infant formula and follow-on formula that are not listed in Annex XV to Regulation (EU) No 1169/2011 shall be presented after the most relevant entry of that Annex they belong to or are components of.

Particulars not listed in Annex XV to Regulation (EU) No 1169/2011 that do not belong to or are not components of any of the entries of that Annex shall be presented in the nutrition declaration after the last entry of that Annex.

Article 8

Nutrition and health claims for infant formula

Nutrition and health claims shall not be made on infant formula.

Article 9

Statements related to lactose and docosahexaenoic acid (DHA)

1. The statement ‘lactose only’ may be used for infant formula and follow-on formula provided that lactose is the only carbohydrate present in the product.

2. The statement ‘lactose free’ may be used for infant formula and follow-on formula provided that the lactose content in the product is not greater than 2,5 mg/100 kJ (10 mg/100 kcal).

When the statement ‘lactose free’ is used for infant formula and follow-on formula manufactured from protein sources other than soya protein isolates, it shall be accompanied by the statement ‘not suitable

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for
infants with galactosaemia', which shall be indicated with the same font size and prominence as the statement 'lactose free' and in close proximity to it.

3. The statement 'contains Docosahexaenoic acid (as required by the legislation for all infant formula)' or 'contains DHA (as required by the legislation for all infant formula)' may only be used for infant formula placed on the market before 22 February 2025.

Article 10

Requirements for promotional and commercial practices for infant formula

1. Advertising of infant formula shall be restricted to publications specialising in baby care and scientific publications.

Member States may further restrict or prohibit such advertising. Such advertising shall contain only information of a scientific and factual nature. Such information shall not imply or create a belief that bottle-feeding is equivalent or superior to breast feeding.

2. There shall be no point-of-sale advertising, giving of samples or any other promotional device to induce sales of infant formula directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales.

3. Manufacturers and distributors of infant formula shall not provide, to the general public or to pregnant women, mothers or members of their families, free or low-priced products, samples or any other promotional gifts, either directly or indirectly via the health care system or health workers.

4. Donations or low-price sales of supplies of infant formula to institutions or organisations, whether for use in the institutions or for distribution outside them, shall only be used by or distributed for infants who have to be fed on infant formula and only for as long as required by such infants.

Article 11

Requirements on information relating to infant and young child feeding

1. Member States shall take measures ensuring that objective and consistent information is provided on infant and young child feeding for use by families and those involved in the field of infant and young child nutrition, and covering the planning, provision, design and dissemination of information and their control.

2. Informational and educational materials, whether written or audio-visual, dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children, shall include clear information on all the following points:

(a) the benefits and superiority of breast feeding;

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(b) maternal nutrition and the preparation for and maintenance of breast feeding;

(c) the possible negative effect on breast feeding of introducing partial bottle feeding;

(d) the difficulty of reversing the decision not to breast feed;

(e) where needed, the proper use of infant formula.

Where such materials contain information about the use of infant formula, they shall include the social and financial implications of its use, the health hazards of inappropriate foods or feeding methods, and, in particular, the health hazards of improper use of infant formula. Such material shall not use any pictures which may idealise the use of infant formula.

3. Donations of informational or educational equipment or materials by manufacturers or distributors shall be made only on request and with the written approval of the appropriate national authority or within guidelines given by that authority for this purpose. Such equipment or materials may bear the donating company's name or logo, but shall not refer to a proprietary brand of infant formula and shall be distributed only through the health care system.

Article 12

Notification

1. When infant formula is placed on the market, the food business operator shall notify the competent authority of each Member State where the product concerned is being marketed of the information appearing on the label, by sending to it a model of the label used for the product, and of any other information the competent authority may reasonably request to establish compliance with this Regulation.

2. When follow-on formula manufactured from protein hydrolysates or follow-on formula containing other substances than those listed in Annex II are placed on the market, the food business operator shall notify the competent authority of each Member State where the product concerned is being marketed of the information appearing on the label, by sending to it a model of the label used for the product, and of any other information the competent authority may reasonably request to establish compliance with this Regulation, unless a Member State exempts the food business operator from that obligation under a national system that guarantees an efficient official monitoring of the product concerned.

Article 13

Directive 2006/141/EC

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In accordance with Article 20(4) of Regulation (EU) No 609/2013, Directive 2006/141/EC is repealed with effect from 22 February 2020. However, Directive 2006/141/EC shall continue to apply until 21 February 2022 to infant formula and follow-on formula manufactured from protein hydrolysates

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References to Directive 2006/141/EC in other acts shall be construed as references to this Regulation in accordance with the scheme set out in the first paragraph.

Article 14

Entry into force and application

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

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It shall apply from 22 February 2020, except in respect of infant formula and follow-on formula manufactured from protein hydrolysates, to which it shall apply from 22 February 2022.

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For the purposes of the second subparagraph of Article 21(1) of Regulation (EU) No 609/2013, in respect of infant formula and follow-on formula manufactured from protein hydrolysates the later date referred to in the second paragraph of this Article shall be considered as the date of application.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

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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).

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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)

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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.

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5.3. The erucic acid content shall not exceed 0,4 % of the total fat content.

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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.

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)

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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.

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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.

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11. VITAMINS

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamin A (µg-RE) (1)	16,7	27,2	70	114
▼M2 Vitamin D (µg)	0,48	0,6	2	2,5
▼B Thiamine (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 B_6 (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 B_{12} (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).

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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

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Minimum	Maximum
0,38 g/100 kJ	0,6 g/100 kJ
(1,6 g/100 kcal)	(2,5 g/100 kcal)

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

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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.

▼M2

4.3. The erucic acid content shall not exceed 0,4 % of the total fat content.

▼B

4.4. Linoleic acid

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

▼B

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)	—

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*.

▼B

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.

▼B

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
Thiamine (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 B_6 (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 B_{12} (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.

▼B

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).

▼B

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

▼B

	Per 100 kJ (1)	Per 100 kcal
Phenylalanine	15	62
Threonine	19	80
Tryptophan	7	30
Tyrosine	14	59
Valine	19	80

(1) 1 kJ = 0,239 kcal.

▼M4

ANNEX IV

ACTIVE SUBSTANCES REFERRED TO IN ARTICLE 4(3)

Chemical name of the parent compound of the substance ([1])	Maximum residue level (mg/kg)
Cadusafos	0,006
Demeton-S-methyl Demeton-S-methyl sulfone Oxydemeton-methyl	0,006
Ethoprophos	0,008
Fipronil	0,004
Propineb	0,006

([1]) The most updated residue definition applies as set out in the relevant Annexes II, III, IV or V to Regulation (EC) No 396/2005 (the residue definition is mentioned in brackets behind the parent compound of the substance).

▼M4

ANNEX V

ACTIVE SUBSTANCES REFERRED TO IN ARTICLE 4(4)

Chemical name of the parent compound of the substance [1]
Aldrin
Dieldrin
Disulfoton
Endrin
Fensulfothion
Fentin
Haloxyfop
Heptachlor
Hexachlorobenzene
Nitrofen
Omethoate
Terbufos.

[1] The most updated residue definition applies as set out in the relevant Annexes II, III, IV or V to Regulation (EC) No 396/2005 (the residue definition is mentioned in brackets behind the parent compound of the substance).

▼B

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’.

▼B

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: ‘Ħalib tat-trabi’ and ‘Ħalib 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’.

▼B

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
Thiamine	(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