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Republic of Moldova

GOVERNMENT

RESOLUTION No. 338
of May 11, 2011

**on the approval of Sanitary Regulations on infant formulae
and follow-on formulae of nutrition
for infants and young children**

Published: May 17, 2011, in the Official Gazette (Monitorul Oficial) No. 82, Art. No : 390

By virtue of Art. 6 of the Law No. 10-XVI of February 3, 2009, on the state supervision of public health (the Official Gazette of the Republic of Moldova, 2009, No. 67, Art. 183), Art. 9 of the Law No. 78-XV of March 18, 2004, on foodstuffs (the Official Gazette of the Republic of Moldova, 2004, No. 83-87, Art. 431), as well as in order to ensure a higher level of protection of the population's health, the Government herewith RESOLVES:

1. To approve the Sanitary Regulations on infant formulae and follow-on formulae of nutrition for infants and young children (as attached).
2. This resolution shall come into effect in a term of 3 months as of its publication in the Official Gazette of the Republic of Moldova.
3. The Ministry of Health shall be vested with the control over the fulfilment of this resolution.

PRIME-MINISTER

Vladimir FILAT

Minister of health

**Countersigned:
Andrei Usatii**

No. 338. Chisinau, May 11, 2011.

Approved by virtue of
Government Resolution No. 338
of May 11, 2011

SANITARY REGULATIONS
on infant formulae and follow-on formulae
of nutrition for infants and young children

The Sanitary Regulations on infant formulae and follow-on formulae of nutrition for infants and young children (hereinafter referred to as the Regulations) have been brought in line with the Commission Directive 2006/141/CE of December 22, 2006, published in the Official Journal of the European Communities (OJEC) No. L 401 of December 30, 2006, and with the amendment of the Commission Directive 1999/21/CE.

I. General provisions

1. These Regulations apply to infant formulae and follow-on formulae of nutrition for infants and young children, marketed as foodstuffs and presented as such, however, without prejudice to the provisions of the national legislation regarding foodstuffs.

2. The following definitions shall be used in these Regulations:

infants – children with an age of under twelve months;

young children – children with an age between one year and three years;

infant formulae – foodstuffs intended for the special nutrition of infants in the first months of life and satisfying on their own the nutritional needs of those infants until the introduction of appropriate additional food;

follow-on formulae – foodstuffs intended for the special nutrition of infants when appropriate additional food is introduced; such formulae make up the main liquid element in the increasingly diversified diet of the children.

3. Infant formulae and follow-on formulae can be sold in the territory of the Republic of Moldova only compliant with these Regulations. No other foodstuffs, except the infant formulae, may be sold or otherwise presented as adequate to fulfil on their own the infants' nutritional requirements, in the first months of life, up to the introduction of appropriate additional food.

The supervision and control over the compliance with these Regulations shall be carried out by the Ministry of Health (National Centre for Public Health).

II. Requirements to the composition of infant formulae and
follow-on formulae of nutrition for infants and young children

4. Infant formulae and follow-on formulae may not contain any substance in an amount that would endanger the health of infants and young children.

5. Infant formulae must be manufactured from the protein sources defined in Art. 2 of the Annex 1 to these Regulations and be adequate for the special nutrition of infants from birth onwards.

6. Follow-on formulae must be manufactured from the protein sources defined in Art. 2 of the Annex 1 to these Regulations and be adequate for the special nutrition of children

with the age of over six months.

7. Only the substances listed in Annex 3 to these Regulations may be used to manufacture infant formulae and follow-on formulae, in order to comply with the requirements as to:

- a) mineral substances;
- b) vitamins;
- c) amino-acids and other nitrogen based compounds;
- d) other substances for a specific nutritional aim.

The purity criteria provided for in the national legislation on the use of the substances listed in Annex 3 to these Regulations apply for the manufacture of foodstuffs intended for other purposes than the ones these Regulations deal with.

8. In order to facilitate the efficient official monitoring of infant formulae, the manufacturers dealing in the foodstuffs sector and intending to place an infant formula in the national market shall notify the Ministry of Health (National Centre for Public Health) in advance, by submitting a sample of the label used for the product at issue.

9. Infant formulae and follow-on formulae may not contain any residues of different pesticides in amounts larger than 0.01 mg/kg of the product recommended for use as such or to be reconstituted as instructed by the manufacturer. The level of pesticide residues shall be determined with the help of standard analytical methods. The pesticides listed in Annex 8 to these Regulations may not be used for the agricultural products intended for the manufacture of infant formulae and follow-on formulae.

For the purposes of control:

- a) the pesticides listed in Table 1 of Annex 4 to these Regulations shall be considered as not used, if their residue content does not exceed 0.003 mg/kg.
- b) the pesticides listed in Table 2 in Annex 4 to these Regulations shall be considered as not used, if their residue content does not exceed 0.003 mg/kg.
- c) in derogation of paragraph 1 of this article, the maximum residue content as set out in the relevant Annex shall apply for the pesticides listed in Annex 5 to these Regulations.

The contents specified under the letters b) and c) of this article shall apply to the products recommended for use as such or to be reconstituted as instructed by the manufacturer.

III. Labelling of infant formulae and follow-on formulae of nutrition for infants and young children

10. In addition to the provisions of paragraph (1) chapter IV of the Norms of labelling of foodstuffs, approved by virtue of Government Resolution No. 996 of August 20, 2003, "On the approval of Norms of labelling of foodstuffs and Norms of labelling of household chemicals", the labelling shall contain the following compulsory claims:

- a) in case of infant formulae – a claim specifying that the product is adequate for the special nutrition of infants, from birth onwards, if they are not breastfed;
- b) in case of follow-on formulae – a claim specifying that the product is adequate only for the special nutrition of infants with the age of over six months.
- c) in case of infant formulae and follow-on formulae – a claim stating the available energy value, expressed in kJ and kcal, as well as the protein contents, in compliance with Annex 6, carbohydrates and lipids, in number terms, per 100 ml of the product ready for use;
- d) in case of infant formulae and all follow-on formulae – a claim stating the average

amount of every mineral substance set out in Annex 1 and, accordingly, in Annex 2 to these Regulations, as well as the amount of choline, inositol and carnitine, in number terms, per 100 ml of the product ready for use;

- e) in case of infant formulae and all follow-on formulae – instructions for the proper preparation, conservation and elimination of the product, as well as a warning as to the health risks resulting from improper preparation and conservation.
Infant formulae and follow-on formulae shall be sold under the name “food for infants” and “food for young children”.

11. The labelling may contain the following claims:

- a) in case of infant formulae and all follow-on formulae – a claim stating the average amount of nutrients set out in Annex 3 to these Regulations, provided that such claim is not specified in paragraph 10 letter d) of the Regulations, in number terms, per 100 ml of the product ready for use;
- b) in case of follow-on formulae – a claim specifying, in addition to the numerical information, information on the vitamins and mineral substances included in Annex 7 to these Regulations, expressed as a percentage of the reference values set out therein, per 100 ml of the product ready for use.

12. The labelling of infant formulae and follow-on formulae shall be conceived in a way that shall provide the necessary information on the appropriate use of the products, so as not to discourage breastfeeding.

The use of such terms as “humanized”, “maternalized” and “adapted” or similar terms shall be prohibited.

13. The labelling of infant formulae shall also contain a compulsory notice regarding the superiority of breastfeeding, preceded by the expression “Important notice”.

14. The labelling of infant formulae may not contain images of infants, nor other images or texts that might idealize the use of the product. Nevertheless, the labelling may contain graphic images facilitating product identification and illustrating the method of preparation.

15. The labelling of infant formulae may contain claims as to nutritional values and health only under the circumstances set out in Annex 8 to these Regulations and in compliance with the terms stipulated therein.

16. Infant formulae and follow-on formulae shall be labelled in a way that would enable the users to make a clear distinction between those products, so as to avoid any risk of confusion between the infant formulae and follow-on formulae.

17. The informational and educational aids, either written or audiovisual, regarding the nutrition of infants and intended for pregnant women and mothers of infants and young children, shall contain clear information on all aspects listed hereinafter:

- a) the advantages and superiority of breastfeeding, in compliance with Annex 9;
- b) mother’s nutrition, her training aimed at starting and continuing breastfeeding;
- c) the possible negative effect of the introduction of partial bottle feeding on the breastfeeding;
- d) difficulty to reverse the decision not to breastfeed;
- e) correct use of infant formulae, as the case may be.

In the event that the abovementioned aids contain information on the use of infant formulae, they should also deal with the social and financial implications of such use, the health risks of foodstuffs or of some improper methods of feeding and particularly, the health risks caused by

an improper use of infant formulae. Those aids may not contain any images suggesting the use of infant formulae as an ideal solution.

18. The requirements stipulated in these Regulations do not apply to dietetic foodstuffs for infants for special medical purposes.

IV. Final provisions

19. On the date of coming into effect of this Resolution the Ministry of Health shall abrogate the current Sanitary Norms of nutritional labelling, the labelling of special dietetic foodstuffs, the labelling of genetically modified products or products derived from genetically modified organisms, in the part dealing with “infants formulae” and “follow-on formulae”, “milk for infants” and “follow-on milk”.

[Annex 1](#)

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Annex 1
to Sanitary Regulations
on infant formulae and follow-on formulae
of nutrition for infants and young children

Essential composition of infant formulae

The values set out in this Annex refer to the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer.

1. Energy

Minimum	Maximum
250 kJ/100 ml (60 kcal/100 ml)	295 kJ/100 ml (70 kcal/100 ml)

2. Proteins

(Protein content = nitrogen content × 6.25)

a) Infant formulae manufactured from cows' milk proteins

Minimum	Maximum
0.45 g/100 kJ (1.8 g/100 kcal)	0.7 g/100 kJ (3 g/100 kcal)

For an equal energy value, the infant formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex 5). Nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together if the methionine:cystine 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:cystine may be greater than 2 but shall not be greater than 3 provided that the suitability of the product for the particular nutritional use by infants is demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

b) Infant formulae manufactured from protein hydrolysates

Minimum	Maximum
0.45 g/100 kJ (1.8 g/100 kcal)	0.7 g/100 kJ (3 g/100 kcal)

For an equal energy value, the infant formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least

equal to that contained in the reference protein (breast milk, as defined in Annex 5). Nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together if the methionine:cystine 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:cystine may be greater than 2 but shall not be greater than 3 provided that the suitability of the product for the particular nutritional use by infants is demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

The L-carnitine content shall be at least equal to 0.3 mg/100 kJ (1.2 mg/100 kcal).

c) Infant formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk protein

Minimum	Maximum
0.56 g/100 kJ (2.25 g/100 kcal)	0.7 g/100 kJ (3 g/100 kcal)

Only protein isolates from soya shall be used in manufacturing these infant formulae.

For an equal energy value the infant formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex 5). Nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together if the methionine:cystine 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:cystine may be greater than 2 but shall not be greater than 3 provided that the suitability of the product for the particular nutritional use by infants is demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

The L-carnitine content shall be at least equal to 0.3 mg/100 kJ (1.2 mg/100 kcal).

In all cases, amino acids may be added to infant formulae 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 formulae, the amount of taurine shall not be greater than 2.9 mg/100 kJ (12 mg/100 kcal).

4. Choline

Minimum	Maximum
1.7 mg/100 kJ (7 mg/100 kcal)	12 mg/100 kJ (50 mg/100 kcal)

5. Lipids

Minimum	Maximum
1.05 g/100 kJ (4.4 g/100 kcal)	1.4 g/100 kJ (6.0 g/100 kcal)

a) The use of the following substances shall be prohibited:

sesame seed oil;

cotton seed oil;

b) Lauric acid and myristic acid

maximum – separately or as a whole: 20% of the total fat content;

c) The trans fatty acid content shall not exceed 3% of the total fat content;

d) The erucic acid content shall not exceed 1% of the total fat content;

e) Linoleic acid (in the form of glycerides = linoleates)

Minimum	Maximum
70 mg/100 kJ (300 mg/100 kcal)	285 mg/100 kJ (1200 mg/100 kcal)

f) The alpha-linolenic acid content shall not be less than 12 mg/100 kJ (50 mg/100 kcal).

The linoleic : alpha-linolenic acid ratio shall not be less than 5 nor greater than 15.

g) Long chain polyunsaturated fatty acids (LCP) of 20 and 22 carbon atoms may be added; in that case their content shall not exceed:

1% of the total fat content for n-3 LCP, and

2% of the total fat content for n-6 LCP [1% of the total fat content for arachidonic acid (20:4 n-6)];

h) The eicosapentaenoic acid (20:5 n-3) content shall not exceed the content of docosahexaenoic acid (22:6 n-3);

i) The docosahexaenoic acid (22:6 n-3) content shall not exceed that of LCP n-6.

6. Phospholipids

The amount of phospholipids in infant formulae shall not exceed 2 g/l.

7. Inositol

Minimum	Maximum
1 mg/100 kJ (4 mg/100 kcal)	10 mg/100 kJ (40 mg/100 kcal)

8. Carbohydrates

Minimum	Maximum
2.2 g/100 kJ (9 g/100 kcal)	3.4 g/100 kJ (14 g/100 kcal)

a) Only the following carbohydrates may be used:

lactose;
maltose;
sucrose;
glucose;
malto-dextrins;
glucose syrup, dried glucose syrup;
pre-cooked starch – naturally free of gluten;
gelatinized starch;

b) Lactose

minimum - 1.1 g/100 kJ (4.5 g/100 kcal).

This provision shall not apply to infant formulae in which soya protein isolates represent more than 50% of the total protein content;

c) Sucrose

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

d) Glucose

Glucose may only be added to infant formulae manufactured from protein hydrolysates. If added, the glucose contents shall not exceed 0.5 g/100 kJ (2 g/100 kcal);

e) Pre-cooked starch and/or gelatinized starch

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 formulae. 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-oligozaharides may be used in accordance with section 5 of the Regulations.

10. Mineral substances

a) Infant formulae manufactured from cows' milk proteins or protein hydrolysates

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Sodium (mg)	5	14	20	60
Potassium (mg)	15	38	60	160
Chloride (mg)	12	38	50	160
Calcium (mg)	12	33	50	140
Phosphorus (mg)	6	22	5	90
Magnesium (mg)	1.2	3.6	0.3	15
Iron (mg)	0.07	0.3	0.5	1.3
Zinc (mg)	0.12	0.36	35	1.5
Copper (µg)	8.4	25	10	100
Iodine (µg)	2.5	12	10	50
Selenium (µg)	0.25	2.2	1	9
Manganese (µg)	0.25	25	1	100
Fluoride (µg)	-	25	-	100

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

b) Infant formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins.

All requirements of subparagraph a) of this section shall apply, except for those concerning iron and phosphorus, which shall be as follows:

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Iron (mg)	0.12	0.5	0.45	2
Phosphorus (mg)	7.5	25	30	100

11. Vitamins

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamin A (µg-RE)	14	43	60	180
Vitamin D (µg)	0.25	0.65	1	0.25
	14	72	60	300

Thiamin (µg)	19	95	80	400
Riboflavin (µg)	72	375	300	1500
Niacin (µg)	95	475	400	2000
Pantothenic acid (µg)	9	42	35	175
Vitamin B6 (µg)	0.4	1.8	1.5	7.5
Biotin (µg)	2.5	12	10	50
Folic acid (µg)	0.025	0.12	0.1	0.5
Vitamin B12 (µg)	2.5	7.5	10	30
Vitamin C (mg)	1	6	4	25
Vitamin K (µg)	0.5/g of polyunsaturated fatty acids expressed as linoleic acid as corrected for the double bonds but in no case less than 0.1 mg per 100 available kJ	1.2	0.5/g of polyunsaturated fatty acids linoleic acid expressed as corrected double bonds but in no case less than 0.5 mg per 100 available kcal	5

12. Nucleotides

The following nucleotides may be added:

	Maximum	
	(mg/100 kJ)	(mg/100 kcal)
Cytidine 5'-monophosphate	0.6	2.5
Uridine 5'-monophosphate	0.42	1.75
Adenosine 5'-monophosphate	0.36	1.5
Guanosine 5'-monophosphate	0.12	0.5
Inosine 5'-monophosphate	0.24	1

Annex 2
to Sanitary Regulations
on infant formulae and follow-on formulae
of nutrition for infants and young children

Essential composition of follow-on formulae

The values set out in this Annex refer to the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer.

1. Energy

Minimum	Maximum
250 kJ/100 ml (60 kcal/100 ml)	295 kJ/100 ml (70 kcal/100 ml)

2. Proteins

(Protein content = nitrogen content × 6.25)

a) Follow-on formulae manufactured from cows' milk proteins

Minimum	Maximum
0.45 g/100 kJ (1.8 g/100 kcal)	0.7 g/100 kJ (3 g/100 kcal)

For an equal energy value, the infant formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex 5). Nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together if the methionine:cystine 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:cystine may be greater than 2 but shall not be greater than 3 provided that the suitability of the product for the particular nutritional use by infants is demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

b) Follow-on formulae manufactured from protein hydrolysates

Minimum	Maximum
0.56 g/100 kJ (2.25 g/100 kcal)	0.8 g/100 kJ (3.5 g/100 kcal)

For an equal energy value, the follow-on formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex 5). Nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together if the methionine:cystine ratio is not greater than 3, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2.

c) Follow-on formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk protein.

Minimum	Maximum
0.56 g/100 kJ (2.25 g/100 kcal)	0.7 g/100 kJ (3 g/100 kcal)

Only protein isolates from soya shall be used in manufacturing these formulae.

For an equal energy value the follow-on formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex 5). Nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together if the methionine:cystine ratio is not greater than 3, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2.

In all cases, amino acids may be added to follow-on formulae 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 formulae, the amount of taurine shall not be greater than 2.9 mg/100 kJ (12 mg/100 kcal).

4. Lipids

Minimum	Maximum
0.96 g/100 kJ (4.0 g/100 kcal)	1.4 g/100 kJ (6.0 g/100 kcal)

a) The use of the following substances shall be prohibited:

sesame seed oil;

cotton seed oil;

b) Lauric acid and myristic acid

maximum - separately or as a whole: 20% of the total fat content;

- c) The trans fatty acid content shall not exceed 3% of the total fat content;
- d) The erucic acid content shall not exceed 1% of the total fat content;
- e) Linoleic acid (in the form of glycerides = linoleates)

Minimum	Maximum
70 mg/100 kJ (300 mg/100 kcal)	285 mg/100 kJ (1200 mg/100 kcal)

f) The alpha-linolenic acid content shall not be less than 12 mg/100 kJ (50 mg/100 kcal).

The linoleic : alpha-linolenic acid ratio shall not be less than 5 nor greater than 15.

g) Long chain polyunsaturated fatty acids (LCP) of 20 and 22 carbon atoms may be added; in that case their content shall not exceed:

1% of the total fat content for n-3 LCP, and

2% of the total fat content for n-6 LCP [1% of the total fat content for arachidonic acid (20:4 n-6)];

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

i) The docosahexaenoic (22:6 n-3) acid content shall not exceed that of n-6 LCP.

5. Phospholipids

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

6. Inositol

Minimum	Maximum
1 mg/100 kJ (4 mg/100 kcal)	10 mg/100 kJ (40 mg/100 kcal)

7. Carbohydrates

Minimum	Maximum
2.2 g/100 kJ (9 g/100 kcal)	3.4 g/100 kJ (14 g/100 kcal)

a) Only the following carbohydrates may be used:

lactose;

maltose;

sucrose;

glucose;

malto-dextrins;

glucose syrup, dried glucose syrup;
pre-cooked starch – naturally free of gluten;
gelatinized starch;

b) Lactose

minimum - 1.1 g/100 kJ (4.5 g/100 kcal).

This provision shall not apply to follow-on formulae in which soya protein isolates represent more than 50% of the total protein content.

c) Sucrose

Sucrose may only be added to follow-on formulae manufactured from protein hydrolysates. If added, the sucrose content shall not exceed 20% of the total carbohydrate content;

d) Glucose

Glucose may only be added to follow-on formulae manufactured from protein hydrolysates. If added, the glucose contents shall not exceed 0.5 g/100 kJ (2 g/100 kcal);

8. Fructo-oligosaccharides and galacto-oligosaccharides

Fructo-oligosaccharides and galacto-oligozaharides may be added to follow-on formulae. In this 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 contents of fructo-oligosaccharides and galacto-oligozaharides may be used in accordance with paragraph 5 of the Regulations.

9. Mineral substances

a) Follow-on formulae manufactured from cows' milk proteins or protein hydrolysates

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Sodium (mg)	5	14	20	60
Potassium (mg)	15	38	60	160
Chloride (mg)	12	38	50	160
Calcium (mg)	12	33	50	140
Phosphorus (mg)	6	22	5	90
Magnesium (mg)	1.2	3.6	0.3	15
Iron (mg)	0.07	0.3	0.5	1.3
Zinc (mg)	0.12	0.36	35	1.5
Copper (µg)	8.4	25	10	100
Iodine (µg)	2.5	12	10	50

Selenium (µg)	0.25	2.2	1	9
Manganese (µg)	0.25	25	1	100
Fluoride (µg)	-	25	-	100

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

b) Follow-on formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins.

All requirements of subparagraph a) of this section shall apply, except for those concerning iron and phosphorus, which shall be as follows:

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Iron (mg)	0.12	0.5	0.45	2
Phosphorus (mg)	7.5	25	30	100

10. Vitamins

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamin A(µg-RE)	14	43	60	180
Vitamin D (µg)	0.25	0.65	1	0.25
Thiamin (µg)	14	72	60	300
Riboflavin (µg)	19	95	80	400
Niacin (µg)	72	375	300	1500
Pantothenic acid (µg)	95	475	400	2000
Vitamin B6 (µg)	9	42	35	175
Vitamin B6 (µg)	0.4	1.8	1.5	7.5
Biotin (µg)	2.5	12	10	50
Folic acid (µg)	0.025	0.12	0.1	0.5
Vitamin B12 (µg)	2.5	7.5	10	30
Vitamin C (mg)	1	6	4	25
Vitamin K (µg)	0.5/g	0.5/g of	0.5/g of	5
Vitamin E (mg α-TE)	0.5/g of polyunsaturated fatty acids expressed as linoleic acid as corrected for the double bonds but in no case less than 0.1 mg per 100 available kJ	1.2	0.5/g of polyunsaturated fatty acids expressed as linoleic acid as corrected for the double bonds but in no case less than 0.5 mg per 100 available kcal	

11. Nucleotides

The following nucleotides may be added:

	Maximum	
	(mg/100 kJ)	(mg/100 kcal)
Cytidine 5'-monophosphate	0.6	2.5
Uridine 5'-monophosphate	0.42	1.75
Adenosine 5'-monophosphate	0.36	1.5
Guanosine 5'-monophosphate	0.12	0.5
Inosine 5'-monophosphate	0.24	1

Annex 3
to Sanitary Regulations
on infant formulae and follow-on formulae
of nutrition for infants and young children

Nutritional substances

1. Vitamins

Vitamins	Vitamin Formulation
Vitamin A	a) Retinyl acetate b) Retinyl palmitate c) Retinol
Vitamin D	a) Vitamin D2 (ergocalciferol) b) Vitamin D3 (cholecalciferol)
Vitamin B1	a) Thiamin hydrochloride b) Thiamin mononitrate
Vitamin B2	a) Riboflavin b) Riboflavin-5'-phosphate, sodium
Niacin	a) Nicotinamide b) Nicotinic acid
Vitamin B6	a) Pyridoxine hydrochloride b) Pyridoxine-5'-phosphate
Folate	Folic acid
Pantothenic acid	a) D-pantothenate, calcium b) D-pantothenate, sodium c) Dexpanthenol
Vitamin B12	a) Cyanocobalamin b) Hydroxocobalamin
Biotin	D-Biotin
Vitamin C	a) L-ascorbic acid b) Sodium L-ascorbate c) Calcium L-ascorbate d) 6-palmitoyl-L-ascorbic acid (ascorbyl palmitate) e) Potassium ascorbate
Vitamin E	a) D-alpha-tocopherol b) DL-alpha-tocopherol

	c) D-alpha tocopherol acetate d) DL-alpha tocopherol acetate
Vitamin K	Phylloquinone (Phytomenadione)

2. Mineral substances

Mineral substances	Permitted salts
Calcium (Ca)	Calcium carbonate Calcium chloride Calcium salts of citric acid Calcium gluconate Calcium glycerophosphate Calcium lactate Calcium salts of orthophosphoric acid Calcium hydroxide
Magnesium (Mg)	Magnesium carbonate Magnesium chloride Magnesium oxide Magnesium salts of orthophosphoric acid Magnesium sulphate Magnesium gluconate Magnesium hydroxide Magnesium salts of citric acid
Iron (Fe)	Ferrous citrate Ferrous gluconate Ferrous lactate Ferrous sulphate Ferric ammonium citrate Ferrous fumarate Ferric diphosphate (Ferric pyrophosphate) Ferrous bisglycinate
Copper (Cu)	Cupric citrate Cupric gluconate Cupric sulphate Copper-lysine complex Cupric carbonate
Iodine (I)	Potassium iodide Sodium iodide

	Potassium iodate
Zinc (Zn)	Zinc acetate Zinc chloride Zinc lactate Zinc sulphate Zinc citrate Zinc gluconate Zinc oxide
Manganese (Mn)	Manganese carbonate Manganese chloride Manganese citrate Manganese sulphate Manganese gluconate
Sodium (Na)	Sodium bicarbonate Sodium chloride Sodium citrate Sodium gluconate Sodium carbonate Sodium lactate Sodium salts of orthophosphoric acid Sodium hydroxide
Potassium (K)	Potassium bicarbonate Potassium carbonate Potassium chloride Potassium salts of citric acid Potassium gluconate Potassium lactate Potassium salts of orthophosphoric acid Potassium hydroxide
Selenium (Se)	Sodium selenate Sodium selenite

3. Amino acids and other nitrogen compounds

L-cysteine and its hydrochloride
L-histidine and its hydrochloride
L-isoleucine and its hydrochloride
L-leucine and its hydrochloride
L-lysine and its hydrochloride
L-cysteine and its hydrochloride
L-methionine

L-phenylalanine
L-threonine
L-tryptophan
L-tyrosine
L-valine
L-carnitine and its hydrochloride
L-carnitine-L-tartrate
Taurine
Cytidine 5'-monophosphate and its sodium salt
Uridine 5'-monophosphate and its sodium salt
Adenosine 5'-monophosphate and its sodium salt
Guanosine 5'-monophosphate and its sodium salt
Inosine 5'-monophosphate and its sodium salt

4. Other nutrients

Choline
Choline chloride
Choline citrate
Choline bitartrate
Inositol

Annex 4
to Sanitary Regulations
on infant formulae and follow-on formulae
of nutrition for infants and young children

**Pesticides which shall not be used in agricultural production intended for the
production of infant formulae and follow-on formulae**

Table 1

Chemical name of the substance (residue definition)

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

Table 2

Chemical name of the substance

Aldrin and dieldrin, expressed as dieldrin
Endrin

Annex 5
to Sanitary Regulations
on infant formulae and follow-on formulae
of nutrition for infants and young children

**Specific maximum residue levels of pesticides or metabolites of pesticides
in infant formulae and follow-on formulae**

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 propylenethiourea)	0.006

Annex 6
to Sanitary Regulations
on infant formulae and follow-on formulae
of nutrition for infants and young children

**Specification for the protein content and source
and the processing of the protein used in the manufacture of infant formulae
with a protein content of less than 0.56 g/100 kJ (2.25 g/100 kcal)
manufactured from hydrolysates of whey proteins
derived from cows' milk protein**

1. Protein Content

Protein content = nitrogen content \times 6.25

Minimum | Maximum |

0.44 g/100 kJ | 0.7 g/100 kJ |

(1.86 g/100 kcal) | (3 g/100 kcal) |

2. Protein Source

Demineralised sweet whey protein derived from cows' milk after enzymatic precipitation of casein 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%.

3. 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.

Annex 7
to Sanitary Regulations
on infant formulae and follow-on formulae
of nutrition for infants and young children

**Reference values for nutrition labelling for foods intended
for infants and young children**

Nutrient	Unit of measure	Labelling reference value
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 B6	mg	0.7
Folate	µg	125
Vitamin B12	µg	0.8
Pantothenic acid	mg	3
Biotin	µg	10
Calcium	mg	550
Phosphorus	mg	550
Potassium	mg	1000
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	µg	1.2

Annex 8
to Sanitary Regulations
on infant formulae and follow-on formulae
of nutrition for infants and young children

**Nutrition and health claims for infant formulae and conditions
warranting nutrition claim**

a) Nutrition claims

Nutrition claim	Conditions warranting nutrition claim
Lactose only Lactose free	Lactose is the only carbohydrate present. Lactose content is not greater than 2.5 mg/100 kJ (10 mg/100 kcal)
Added LCP or an equivalent nutrition claim related to the addition of docosahexaenoic acid	The docosahexaenoic acid content is not less than 0.2% of the total fatty acid content

nutrition claims on the addition of the following optional ingredients:
taurine;
fructo-oligosaccharides and galacto-oligosaccharides;
nucleotides voluntarily added at a level that would be appropriate for the intended particular use by infants and in accordance with the conditions set out in Annex 1.

b) Health claims (including reduction of disease risk claims)

Health claim	Conditions warranting health claim
Reduction of risk to allergy to milk proteins. This health claim may include terms referring to reduced allergen or reduced antigen properties	Objective and scientifically verified data as proof to the claimed properties must be available The infant formulae shall satisfy the provisions set out in point b) of Annex 1 and the amount of immunoreactive protein measured with methods generally acceptable as appropriate shall be less than 1% of nitrogen containing substances in the formulae The label shall indicate that the product must not be consumed by infants allergic to the

	<p>intact proteins from which it is manufactured unless generally accepted clinical tests provide proof of the infant formulae's tolerance in more than 90% of infants (confidence interval 95%) hypersensitive to proteins from which the hydrolysate is manufactured</p> <p>The infant formulae administered orally must not induce sensitisation, in animals, to the intact proteins from which the infant formulae are manufactured</p>
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Annex 9
to Sanitary Regulations
on infant formulae and follow-on formulae
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AMINO ACIDS IN BREAST MILK

Name	Permitted limit, mg (per 100 kJ)*	Permitted limit, mg (per 100 kcal)
Cystine	9	38
Histidine	10	40
Isoleucine	22	90
Leucine	40	166
Lysine	27	113
Methionine	5	23
Phenilalanine	20	83
Threonine	18	77
Tryptophan	8	32
Tyrosine	18	76
Valine	21	88

*1 kJ equals 0.239 kcal.