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**Republic of Latvia**

**Cabinet**

**Regulation No. 370**

Adopted 26 May 2008

## **Regulations Regarding Infant Formulae and Follow-on Formulae for Infants**

*Issued pursuant to  
Section 4, Paragraph three of the  
Law On the Supervision of the Handling of Food  
and Section 7, Paragraph two of the  
Law On the Supervision of the Handling of Food*

### **I. General Provisions**

1. These Regulations prescribe the composition, labelling and advertising requirements for food products intended for infants from birth to 12 months of age (hereinafter - infants) - infant formulae and follow-on formulae for infants (hereinafter - formulae).

2. Due to the specific composition or special manufacturing process thereof, formulae shall be clearly separated from other types of food and shall be suitable for feeding healthy infants if it is not possible to feed them with breast milk.

3. In accordance with the purpose of use, formulae shall be divided into the following groups:

3.1. infant formulae, intended for the special diet of infants during the first few months of life and satisfying the nutritional requirements of such infants until commencement of the appropriate complementary feeding;

3.2. follow-on formulae for infants, intended for the nutritional diet of infants, upon introduction of the appropriate complementary feeding, and constituting the principal liquid element in a progressively diversified diet for these infants and children aged from one to three years (hereinafter - small children).

4. The appropriate formulae shall be allowed to be distributed in the European Economic Zone and exported to third countries in accordance to the requirements of these Regulations.

5. Formulae shall only be distributed in retail trade in pre-packaged form.

## II. Requirements for the Composition of a Formula

6. Formulae shall not contain any substances in such quantity as to endanger the health of infants and small children.

7. The manufacturer shall ensure that the composition of the product referred to in Sub-paragraph 3.1 of these Regulations shall comply with the requirements specified in Annex 1 of these Regulations. Infant formulae shall be manufactured from protein sources defined in Paragraph 2 of Annex 1 of these Regulations and other food ingredients, whose suitability for particular nutritional use by infants from birth has been established by generally accepted scientific data. Such suitability may be substantiated by systematically reviewing data regarding foreseeable benefits and safety considerations, as well as with appropriate studies, which shall be carried out according to expert guidance on the design and conduct of such studies.

8. The manufacturer shall ensure that the composition of the product referred to in Sub-paragraph 3.2 of these Regulations shall comply with the requirements specified in Annex 2 of these Regulations. Infant formulae shall be manufactured from the protein sources defined in Paragraph 2 of Annex 1 of these Regulations and other food ingredients, whose suitability for particular nutritional use by infants from birth has been established by generally accepted scientific data. Such suitability may be substantiated by systematically reviewing data regarding foreseeable benefits and safety considerations, as well as with appropriate studies which shall be carried out according to expert guidance on the design and conduct of such studies.

9. Only the substances referred to in Annex 3 to these Regulations shall be permitted to be added to formulae, in order to ensure that infants receive the necessary vitamins, mineral substances, amino acids and other nitrogen-containing substances and nutrients. Purity criteria shall be adopted for the substances referred to in Annex 3 to these Regulations, which are provided for by the regulatory enactments regarding the utilisation thereof in foodstuffs.

10. The levels for pesticide residues, specified in regulatory enactments regarding pesticide residues in products of plant and animal origin, in formulae shall not exceed 0.01 mg/kg, except the pesticides, the maximum permissible levels for residues of which have been specified in Annex 4 to these Regulations.

11. It is prohibited to use the pesticides specified in Annex 5 of these Regulations in the acquisition of agricultural products if these products are used in the production of formulae. It shall be considered that the pesticides referred to in Annex 5 to these Regulations have not been used, if:

11.1. the levels of residues of pesticides referred to in Annex 5, Table 1 of these Regulations do not exceed the analytical method quantitative determination limit of 0.003 mg/kg; or

11.2. the levels of residues of pesticides referred to in Annex 5, Table 2 of these Regulations do not exceed 0.003 mg/kg.

12. The permissible maximum levels of residues of pesticides in formulae, which have been produced for the feeding of infants, have been specified in Paragraph 10 and 11 of these Regulations.

13. When preparing formulae for use, only potable water shall be added thereto.

14. The utilisation of food additives in formulae shall be prescribed by the regulatory enactments regarding the use of food additives.

## III. Requirements for the Labelling of Formula

15. If the formula is produced from various proteins, the product label shall indicate the relevant formula trade name - "Infant Formula" or "Follow-on Formula for Infants".

16. If the formula is only produced from cows' milk proteins, the product label shall indicate the relevant formula trade name - "Infant Milk" or "Follow-on Milk for Infants".

17. When the formula is imported from another Member State of the European Union, the trade name of the product in Latvian shall correspond to the trade name of the product in one of the European Union Member State languages (Annex 6).

18. In addition to the information specified in the regulatory enactments regarding labelling of food products, the labelling of the formula shall specify:

18.1. the energy value of the product in kilojoules (kJ) and kilocalories (kcal), the content of proteins, carbohydrates and fats (expressed in numerical form) per 100 millilitres of the product ready for use;

18.2. the average quantity (expressed in numerical form) of each vitamin and each mineral substance referred to in Annexes 1 or 2 of these Regulations, and also the quantity of choline, inositol and carnitine (expressed in numerical

form), if they have been added, per 100 millilitres of the product ready for use;

18.3. product preparation, directions for storage and use and a warning regarding hazards to health, which may arise due to inappropriate preparation or storage of the product.

19. Labelling of a formula may include the average quantity of nutrients mentioned in Annex 3 (expressed in numerical form) per 100 ml of the product ready for use, which are not referred to in Annexes 1 or 2 to these Regulations.

20. The information provided in the labelling of a formula regarding the use of the product may not contain a recommendation to refuse breast-feeding. It is prohibited to use the words "humanised", "maternalised", "adjusted", "adapted" or other words in the labelling, which equate formulae to breast milk.

21. The product labelling referred to in Sub-paragraph 3.1 of these Regulations shall include the following:

21.1. information regarding the suitability of the product for feeding of infants from birth, if it is not possible to breast feed an infant.

21.2. the statement "Būtiska informācija" (Relevant Information), "Svarīga norāde" (Important Notice) or equivalent specification in bold print, followed by a statement:

21.2.1. regarding the superiority of breast feeding and breast milk as the best infant nutrition which protects infants from health impairments; and

21.2.2. that the product should be used only in accordance with the recommendation of a medical practitioner.

22. The labelling of the product referred to in Sub-paragraph 3.1 may not include pictures of children or other pictures or text idealising the use of the product. The label may include graphic representations which facilitate preparation of the product.

23. The product labelling referred to in Sub-paragraph 3.1 of these Regulations shall bear nutrition and health value annotations in accordance with the requirements referred to in Annex 7 to these Regulations.

24. The product labelling referred to in Sub-paragraph 3.2 of these Regulations shall specify that the product is only suitable for the nutrition of infants who are older than six months, that it is only part of a diversified diet and that is not to be utilised as an infant formula during the first six months of life, and that the decision to begin complementary feeding (including any exception in connection with nutrition up to six months of age), should only be made based on the advice of an independent person who has qualifications in medicine, nutrition or pharmacy, or the opinion of a specialist responsible for maternal and child care.

25. The additional labelling information referred to in Sub-paragraph 3.2 of these regulations, which is expressed in numerical form, may indicate information regarding the vitamin and mineral substances (expressed in terms of percentage of the reference value indicated therein) per 100 ml of the product prepared for use, set out in Annex 8 to these Regulations.

26. The products referred to in Sub-paragraph 3.1 of these Regulations and the products referred to in Sub-paragraph 3.2 of these Regulations shall be labelled in the language of the state, in which they shall be distributed, and in such a way that it would enable consumers to make a clear distinction between such products so as to avoid any risk of confusion between an infant formula and a follow-on formula for infants.

#### **IV. Requirements for Advertising a Formula and Informative Materials**

27. The requirements for labelling a formula, which are referred to by Paragraph 20, Sub-paragraph 21.2, Paragraphs 22, 23 and 26 of these Regulations, shall also apply to:

27.1. the presentation of the formula, packaging and the packaging materials utilised, as well as the way in which they are arranged and the setting in which they are displayed;

27.2. advertising of a formula.

28. Advertising of infant formulae shall be restricted to publications specialising in baby care and scientific publications in accordance with the requirements referred to in Paragraph 20, Sub-paragraph 21.2., Paragraphs 22, 23, 26 and Sub-paragraph 27.2 of these Regulations. Advertising may contain only scientifically valid information. The advertising shall not directly indicate or imply that bottle-feeding is equivalent or superior to breast feeding.

29. Formulae may not be advertised at the point of sale by giving out samples of the product directly to the consumers or in any other way promoting sales in retail trade (for example, with special show-cases, discount coupons, premiums, special sales, selling goods at reduced prices, selling in a package with other goods).

30. It is prohibited to distribute (either directly or indirectly) infant formulae or samples thereof for free or low-priced via the health care system, or to give them as gifts to pregnant women, mothers of infants and small children or members of their families.

31. The State agency "Public Health Agency" (hereinafter - Public Health Agency) shall provide those, for whom the referred to information is necessary, with objective and consistent written or audiovisual information regarding infant feeding. Public Health Agency shall ensure planning, presentation and dissemination of the referred to information, as well as control thereof. The information referred to shall cover the following issues:

31.1. the benefits and superiority of breast feeding over feeding with formulae;

31.2. maternal nutrition, preparing for breast-feeding and prolongation of breast feeding;

31.3. the possible negative effect on breast feeding, which may be caused by partial formula feeding;

31.4. the difficulty of resuming breast feeding after a pause; and

31.5. where necessary - information regarding the proper use of infant formulae shall contain information about their use, social and financial implications, regarding the health hazards of inappropriate foods or feeding methods, as well as of the improper use of a formula, that such formulae are only intended for infants for which formulae are necessary, and only for as long as that is necessary. It is prohibited to include in information any pictures which idealise the use of the referred to product.

32. The information regarding formulae, which the manufacturers and distributors provide to health care workers, shall be scientifically based.

33. Manufacturers and distributors may donate informative and educational supplementary aids or materials only on request, which the receiver of the donation shall submit to the Public Health Agency. The Public Health Agency shall evaluate the conformity of the respective supplementary aids or materials to the requirements referred to in Paragraph 35 of these Regulations and shall provide a written approval.

34. In order to coordinate donation of the informative and educational supplementary aids or materials, the manufacturer or distributor shall submit an application to the Public Health Agency, to which a description of the supplementary aids or materials or a copy thereof is attached.

35. The informative and educational supplementary aids or materials may bear the donating company's name or logo, but not its trademark, which has been patented for infant formula. Informative and educational supplementary aids or materials shall be distributed only through the mediation of the health care institutions.

36. Infant formulae may be supplied by donations or low-price sales to social care institutions for feeding infants, for whom these products are necessary, and only for as long as it is necessary.

37. For the implementation of the supervision of the principles and objectives of the International Code of Marketing of Breast-milk in relation to marketing, information and the responsibility of health care institutions, the Public Health Agency shall, once in every two years, perform monitoring of the code. The report on the monitoring results shall be submitted by the Public Health Agency to the Ministry of Health and the Ministry of Agriculture.

38. It shall be permissible to import and distribute an infant formula in Latvia, if the manufacturer, distributor or packer has previously submitted a written notification to the Food and Veterinary Service regarding its importation and distribution in the Republic of Latvia (Annex 9) and a sample of the relevant product's label.

39. The Food and Veterinary Service shall publish the list on the Internet home page thereof, where the infant formulae are indicated, for which the notification referred to in Paragraph 38 of these Regulations has been received. The following information shall be indicated in the list:

39.1. name, address and registration number of the manufacturer;

39.2. the name of the distributor, importer or packer, address and registration number;

39.3. the relevant name of the product.

40. If the Food and Veterinary Service determines that the infant formula does not meet the requirements of these Regulations, the relevant product shall be recognised as unfit for distribution and information regarding it shall be removed from the list referred to in Paragraph 39 of these Regulations.

## V. Closing Provisions

41. Cabinet Regulation No. 368 of 31 May 2005, Regulations Regarding the Mandatory Harmlessness Requirements for the Composition of Breast Milk Substitutes, as well as the Procedures for Labelling and Evaluation of

Advertising Thereof (*Latvijas Vēstnesis* [the Official Gazette of the Government of Latvia], 2005, Nos. 88, 210; 2007, No. 104), is repealed.

42. It shall be permissible to distribute until 31 December 2009 formulae, the composition and labelling of which do not comply with the requirements of these Regulations, if the requirements referred to in Cabinet Regulation No. 368 of 31 May 2005, Regulations Regarding the Mandatory Harmlessness Requirements for the Composition of Breast Milk Substitutes, as well as the Procedures for Labelling and Evaluation of Advertising thereof that were in force until the day of coming into force of these Regulations have been complied with. From 1 January 2010, it shall be prohibited to distribute formulae that do not comply with the requirements of these Regulations.

43. A distributor shall, until 1 July 2008, submit a written notification regarding infant formulae which have been manufactured or imported into Latvia up to the day of coming into force of these Regulations, together with a labelling sample for the relevant product.

## Informative Reference to European Union Directives

These Regulations contain legal norms arising from:

1) Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses;

2) Council Directive 92/52/ECC of 18 June 1992 on infant formulae and follow-on formulae intended for export to third countries;

3) Directive 96/84/EC of the European Parliament and Council of 19 December 1996 amending Directive 89/398/EEC on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses;

4) Directive 1999/41/EC of the European Parliament and Council of 7 June 1999 amending Directive 89/398/EEC on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses;

5) Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC.

Prime Minister I. Godmanis

Acting for the Minister for Agriculture -  
Minister for Education and Science T. Koņe

**Annex 1**  
Cabinet Regulation No. 370  
of 26 May 2008

### Infant Formulae (prescribed composition<sup>1</sup> requirements)

No. No.	Energy value and ingredients of formula, units of measurement	Minimum quantity	Maximum quantity
1	2	3	4
<b>1.</b>	<b>Energy value</b> , kJ/100 ml (kcal/100 ml)	250 (60)	295 (70)
<b>2.</b>	<b>Protein</b> <sup>2, 3,4.</sup>		
2.1.	in formula manufactured from cows' milk proteins, g/100 kJ (g/100 kcal)	0.45 (1.8) <sup>5</sup>	0,7 (3)
2.2.	in formula manufactured from protein hydrolysates, g/100 kJ (g/100 kcal)	0.45 (1.8) <sup>6, 7</sup>	0,7 (3)
2.3.	in formula manufactured from soy protein isolates, alone or in a mixture with cows' milk proteins, g/100 kJ (g/100 kcal)	0.56 (2.25) <sup>7</sup>	0.7 (3)
<b>3.</b>	<b>Taurine</b> , if added, mg/100 kJ (mg/100 kcal)	-	2.9 (12)
<b>4.</b>	<b>Choline</b> , mg/100 kJ (mg/100 kcal)	1.7 (7)	12 (50)
<b>5.</b>	<b>Lipids</b> , g/100 kJ (g/100 kcal) <sup>8.</sup>	1.05 (4.4)	1.4 (6.0)

5.1.	lauric acid and myristic acid	-	separately or as a whole 20% of the total fat content
5.2.	linoleic acid (in the form of glycerides (linoleates)), mg/100 kJ (mg/100 kcal)	70 (300)	285 (1200)
5.3.	alpha-linolenic acid, mg/100 kJ (mg/100 kcal)	12 (50)	-
5.4.	linoleic acid and alpha-linolenic acid ratio	5	15
5.5.	trans fatty acids	-	3 % of the total fat content
5.6.	erucic acid	-	1% of the total fat content
5.7.	long-chain polyunsaturated acids (LCP)) (C20, C22) may be added:		
5.7.1.	n-3 fatty acids	-	1% of the total fat content
5.7.2.	n-6 fatty acids	-	2% of the total fat content, arachidonic acid 1% of the total fat content
5.7.3.	eicosapentaenoic acid (20:5, n-3) content shall not exceed docosahexaenoic acid (22:6, n-3) content the docosahexaenoic acid (22:6, n-3) content shall not exceed the n-6 fatty acid content		
<b>6.</b>	<b>Phospholipids, g/l</b>		2
<b>7.</b>	<b>Inositol, mg/100 kJ (mg/100 kcal)</b>	1 (4)	10 (40)
<b>8.</b>	<b>Carbohydrates, g/100 kJ (g/100 kcal)<sup>10</sup>:</b>	2.2 (9)	3.4 (14)
8.1.	only lactose, maltose, sucrose, malto-dextrins, glucose syrup, dried glucose syrup, uncooked starch naturally free of gluten, gelatinised starch naturally free of gluten		
8.2.	lactose	1.1 (4.5) <sup>9</sup>	-
8.3.	sucrose, only for products which are produced from protein hydrolysates	-	20 % of the total carbohydrate content
8.4.	glucose, only for products which are produced from protein hydrolysates		0.5 (2)
8.5.	uncooked starch and/or gelatinised starch	-	2 g/100 ml and 30 % of the total carbohydrate content
<b>9.</b>	<b>Fructo-oligosaccharides and galacto- oligosaccharides<sup>10</sup>, g/100 ml</b>		0.8
<b>10.</b>	<b>Minerals:</b>		
10.1.	from cows' milk proteins or from protein hydrolysates in manufactured infant formula		
10.1.1.	sodium, mg/100 kJ (mg/100 kcal)	5 (20)	14 (60)
10.1.2.	potassium, mg/100 kJ (mg/100 kcal)	15 (60)	38 (160)
10.1.3.	chlorides, mg/100 kJ (mg/100 kcal)	12 (50)	38 (160)
10.1.4.	calcium, mg/100 kJ (mg/100 kcal)	12 (50)	33 (140)
10.1.5.	phosphorus, mg/100 kJ (mg/100 kcal)	6 (25)	22 (90)
10.1.6.	magnesium, mg/100 kJ (mg/100 kcal)	1.2 (5)	3.6 (15)
10.1.7.	iron, mg/100 kJ (mg/100 kcal)	0.07 (0.3)	0.3 (1.3)
10.1.8.	zinc, mg/100 kJ (mg/100 kcal)	0.12 (0.5)	0.36 (1.5)
10.1.9.	copper, µg /100 kJ (µg /100 kcal)	8.4 (35)	25 (100)
10.1.10.	iodine, µg/100 kJ (µg/100 kcal)	2.5 (10)	12 (50)
10.1.11.	selenium, µg /100 kJ (µg /100 kcal)	0.25 (1)	2.2 (9)
10.1.12.	manganese, µg /100 kJ (µg /100 kcal)	0.25 (1)	25 (100)
10.1.13.	fluoride, µg /100 kJ (µg /100 kcal)	-	25 (100)
10.1.14.	calcium and phosphorus ratio	1	2



10.2.	in a formula manufactured from soy protein isolates, alone or in a mixture with cows' milk proteins, mg/100 kJ (mg/100 kcal):		
10.2.1.	sodium, mg/100 kJ (mg/100 kcal)	5 (20)	14 (60)
10.2.2.	potassium, mg/100 kJ (mg/100 kcal)	15 (60)	38 (160)
10.2.3.	chlorides, mg/100 kJ (mg/100 kcal)	12 (50)	38 (160)
10.2.4.	calcium, mg/100 kJ (mg/100 kcal)	12 (50)	33 (140)
10.2.5.	phosphorus, mg/100 kJ (mg/100 kcal)	7.5 (30)	25(100)
10.2.6.	magnesium, mg/100 kJ (mg/100 kcal)	1.2 (5)	3.6 (15)
10.2.7.	iron, mg/100 kJ (mg/100 kcal)	0.12(0.45)	0.5 (2)
10.2.8.	zinc, mg/100 kJ (mg/100 kcal)	0.12 (0,5)	0.36 (1.5)
10.2.9.	copper, µg /100 kJ (µg /100 kcal)	8.4 (35)	25 (100)
10.2.10.	iodine, µg/100 kJ (µg/100 kcal)	2.5 (10)	12 (50)
10.2.11.	selenium, µg /100 kJ (µg /100 kcal)	0.25 (1)	2.2 (9)
10.2.12.	manganese, µg /100 kJ (µg /100 kcal)	0.25 (1)	25 (100)
10.2.13.	fluorides, µg /100 kJ (µg /100 kcal)	-	25 (100)
10.2.14.	calcium and phosphorus ratio	1.2	2.0
<b>11.</b>	<b>Vitamins:</b>		
11.1.	vitamin A, µg RE/100 kJ (µg RE/100 kcal) <sup>11</sup>	14 (60)	43 (180)
11.2.	vitamin D, µg/100 kJ (µg/100 kcal) <sup>12</sup>	0.25 (1)	0.65 (2.5)
11.3.	thiamin, µg/100 kJ (µg/100 kcal)	14 (60)	72 (300)
11.4.	riboflavin, µg/100 kJ (µg/100 kcal)	19 (80)	95 (400)
11.5.	niacin, µg /100 kJ (µg /100 kcal) <sup>13</sup>	72 (300)	375 (1500)
11.6.	pantothenic acid, µg/100 kJ (µg/100 kcal)	95 (400)	475 (2000)
11.7.	vitamin B <sub>6</sub> , µg/100 kJ (µg/100 kcal)	9 (35)	42 (175)
11.8.	biotin, µg/100 kJ (µg/100 kcal)	0.4 (1.5)	1.8 (7.5)
11.9.	folic acid, µg/100 kJ (µg/100 kcal)	2.5 (10)	12 (50)
11.10.	vitamin B <sub>12</sub> , µg/100 kJ (µg/100 kcal)	0.025 (0,1)	0.12 (0.5)
11.11.	vitamin C, µg/100 kJ (µg/100 kcal)	2.5 (10)	7.5 (30)
11.12.	vitamin K, µg/100 kJ (µg/100 kcal)	1 (4)	6 (25)
11.13.	Vitamin E (mg α-TE) <sup>14</sup>	0.5/g polyunsaturated acids expressed as linoleic acid, as corrected for the double bonds <sup>15</sup> , but not less than 0.1 mg/100 kJ (0.5 mg/100 kcal)	1.2 mg/100 kJ (5 mg/100 kcal)
12.	<b>Nucleotides</b> , total quantity, mg/100 kJ (mg/100 kcal), including:	-	1.2 (5)
12.1.	cytidine 5'-monophosphate, mg/100 kJ (mg/100 kcal)	-	0.60 (2.50)
12.2.	uridine 5'-monophosphate, mg/100 kJ (mg/100 kcal)	-	0.42 (1.75)
12.3.	adenosine 5'-monophosphate, mg/100 kJ (mg/100 kcal)	-	0.36 (1.50)
12.4.	guanosine 5'-monophosphate, mg/100 kJ (mg/100 kcal)	-	0.12 (0.50)
12.5.	inosine 5'-monophosphate, mg/100 kJ (mg/100 kcal)	-	0.24 (1,00)

<sup>1</sup> The formula is set out for usage in a finished product prepared according to the instructions of the manufacturer.

<sup>2</sup> Protein content = nitrogen content x 6.25.

<sup>3</sup> The addition of amino acids to the formula is permitted solely for the purpose of improving the nutritional value of the proteins, and only in the proportions necessary for this purpose.

<sup>4</sup> For a formula to have the energy value equal to breast milk, it shall contain an available quantity of each essential and non-essential amino acid which is not less than that contained in breast milk.

No.	Amino acids	mg/100 kJ (1 kJ = 0,239 kcal)	mg/100 kcal
1	2	3	4
1.	Cystine	9	38
2.	Histidine	10	40
3.	Isoleucine	22	90
4.	Leucine	40	166
5.	Lysine	27	113
6.	Methionine	5	23
7.	Phenylalanine	20	83
8.	Threonine	18	77
9.	Tryptophan	8	32
10.	Tyrosine	18	76
11.	Valine	21	88

For calculation purposes, the concentration of cystine and methionine may be added together, if the cystine/methionine ratio is not greater than 2, and the phenylalanine and tyrosine concentration can 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 for the particular nutritional use by infants is demonstrated through appropriate studies following generally accepted expert guidance on the design and conduct of such studies.

<sup>5</sup> If the infant formula is produced from cows' milk protein and its content is from 0.45 to 0.5 g/100 kJ (2 g/100 kcal), the suitability of the infant formula to nutritional use by infants shall be demonstrated through appropriate studies that are conducted, based on generally accepted guidance on the design and conduct of such studies.

<sup>6</sup> If the infant formula is produced from protein hydrolysates and its content is from 0.45 to 0.56 g/100 kJ (2.25 g/100 kcal), the suitability of the infant formula to nutritional use by infants shall be demonstrated through appropriate studies that shall be conducted, based on generally accepted guidance on the design and conduct of such studies, and the protein hydrolysates conform to these specifications.

1. Protein content (nitrogen content x 6.25):

minimum - 0.44 g/100 kJ (1.86 g/100 kcal), maximum - 0.7 g/100 kJ (3 g/100 kcal).

2. Protein source - demineralised sweet whey protein, derived from cows' milk after the enzymatic precipitation of caseins, utilising 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 an 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 - a two-stage hydrolysis process, in which trypsination is utilised with a heat-treatment stage (for 3 to 10 minutes at a temperature of 80-100°C) between two hydrolysis stages.

<sup>7</sup> The L-carnitine content shall be at least equal to 0.3 mg/100 kJ (1.2 mg/100 kcal).

<sup>8</sup> The use of sesame seed oil and cotton seed oil is prohibited.

<sup>9</sup> Shall not apply to a formula in which the content of soya proteins exceeds 50% of the total protein content.

<sup>10</sup> If the content contains 90% oligogalactosyl-lactose and 10% high molecular weight oligofructosyl sacchrose. Other combinations and maximum levels of fructo-oligosaccharides and galacto-oligosaccharides may be used in accordance with Paragraph 7 of these Regulations.

<sup>11</sup> RE - equivalent of all trans-retinols.

<sup>12</sup> In the form of cholecalciferol, of which 10 µg = 400 i.u. of vitamin D.

<sup>13</sup> Prefomed niacin.

<sup>14</sup>  $\beta$ -TE = d- $\alpha$ -tocopherol equivalent.

<sup>15</sup> 0.5 mg  $\alpha$ -TE/1 g linoleic acid (18:2 n-6); 0.75 mg  $\alpha$ -TE/1 g  $\alpha$ -linoleic acid (18:3 n-3); 1.0 mg  $\alpha$ -TE/1 g arachidonic acid (20:4 n-6); 1.25 mg  $\alpha$ -TE/1 g eicosapentaenoic acid (20:5 n-3); 1.5 mg  $\alpha$ -TE/1 g docosahexaenoic acid (22:6 n-3).

Acting for the Minister for Agriculture -  
Minister for Education and Science T. Koç

**Annex 2**  
Cabinet Regulation No. 370  
of 26 May 2008

## Follow-on Formulae for Infants



**(prescribed composition<sup>1</sup> requirements)**

No.	Energy value and ingredients of formula, units of measurement	Minimum quantity	Maximum quantity
1	2	3	4
<b>1.</b>	<b>Energy value</b> , kJ/100 ml (kcal/100 ml)	250 (60)	295 (70)
<b>2.</b>	<b>Proteins</b> <sup>2, 3, 4</sup> , g/100 kJ (g/100 kcal):		
2.1.	in a formula manufactured from cows' milk proteins, g/100 kJ (g/100 kcal)	0.45 (1.8)	0.8 (3.5)
2.2.	in a formula manufactured from protein hydrolysates, g/100 kJ (g/100 kcal):	0.56 (2.25)	0.8 (3.5)
2.3.	in a formula manufactured from soy protein isolates, alone or in a mixture with cows' milk proteins, g/100 kJ (g/100 kcal)	0.56 (2.25)	0.8 (3.5)
<b>3.</b>	calcium, mg/100 kJ (mg/100 kcal)		2.9 (12)
<b>4.</b>	<b>Lipids</b> , g/100 kJ (g/100 kcal) <sup>6</sup> :	0.96 (4.0)	1.4 (6.0)
4.1.	lauric acid and myristic acid	-	separately or as a whole 20% of the total fat content
4.2.	linoleic acid (in the form of glycerides, i.e. linoleates)	70 (300) <sup>9</sup>	285 (1200)
4.3.	alpha-linolenic acid, mg/100 kJ (mg/100 kcal)	12 (50)	
4.4.	linoleic/alpha-linolenic acid ratio	5	15
4.5.	trans fatty acids	-	3 % of the total fat content
4.6.	erucic acid	-	1% of the total fat content
4.7.	long-chain polyunsaturated fatty acids (LCP) (C20, C22) may be added:		
4.7.1.	n-3 fatty acids	-	1% of the total fat content
4.7.2.	n-6 fatty acids	-	2% of the total fat content, arachidonic acid 1% of the total fat content
4.7.3.	the eicosapentaenoic acid (20:5 n-3) content shall not exceed the docosahexaenoic acid (22:6 n-3) content; the docosahexaenoic acid (22:6 n-3) content shall not exceed the n-6 fatty acid content		
<b>5.</b>	<b>Phospholipids</b> , g/l		2
<b>6.</b>	<b>Carbohydrates</b> , g/100 kJ (g/100 kcal) <sup>7</sup> :	2.2 (9)	3.4 (14)
6.1.	lactose	1.1 (4.5) <sup>8</sup>	-
6.2.	sucrose, fructose, honey <sup>9</sup>	-	separately or as a whole 20% of the total carbohydrate content
6.3.	glucose, only for a product which has been produced from protein hydrolysates		0.5 (2)
<b>7.</b>	<b>Fructo-oligosaccharides and galacto-oligosaccharides</b> <sup>10</sup> , g/100 ml		0.8
<b>8.</b>	Minerals:		
8.1.	from cows' milk proteins or from protein hydrolysates in manufactured formula		
8.1.1.	sodium, mg/100 kJ (mg/100 kcal)	5 (20)	14 (60)
8.1.2.	potassium, mg/100 kJ (mg/100 kcal)	15 (60)	38 (160)
8.1.3.	chlorides, mg/100 kJ (mg/100 kcal)	12 (50)	38 (160)
8.1.4.	calcium, mg/100 kJ (mg/100 kcal)	12 (50)	33 (140)
8.1.5.	phosphorus, mg/100 kJ (mg/100 kcal)	6 (25)	22 (90)

8.1.6.	magnesium, mg/100 kJ (mg/100 kcal)	1.2 (5)	3.6 (15)
8.1.7.	iron, mg/100 kJ (mg/100 kcal)	0.14 (0.6)	0.5 (2)
8.1.8.	zinc, mg/100 kJ (mg/100 kcal)	0.12 (0.5)	0.36 (1.5)
8.1.9.	copper, µg /100 kJ (µg /100 kcal)	8.4 (35)	25 (100)
8.1.10.	iodine, µg/100 kJ (µg/100 kcal)	2.5 (10)	12 (50)
8.1.11.	selenium, µg /100 kJ (µg /100 kcal)	0.25 (1)	2.2 (9)
8.1.12.	manganese, µg /100 kJ (µg /100 kcal)	0.25 (1)	25 (100)
8.1.13.	fluorides, µg /100 kJ (µg /100 kcal)	-	25 (100)
8.1.14.	Calcium/phosphorus ratio	1	2
8.2.	in a formula manufactured only from soy protein isolates or mixed with cows' milk proteins		
8.2.1.	sodium, mg/100 kJ (mg/100 kcal)	5 (20)	14 (60)
8.2.2.	potassium, mg/100 kJ (mg/100 kcal)	15 (60)	38 (160)
8.2.3.	chlorides, mg/100 kJ (mg/100 kcal)	12 (50)	38 (160)
8.2.4.	calcium, mg/100 kJ (mg/100 kcal)	12 (50)	33 (140)
8.2.5.	phosphorus, mg/100 kJ (mg/100 kcal)	7.5 (30)	25 (100)
8.2.6.	magnesium, mg/100 kJ (mg/100 kcal)	1.2 (5)	3.6 (15)
8.2.7.	iron, mg/100 kJ (mg/100 kcal)	0.22 (0.9)	0.65 (2.5)
8.2.8.	zinc, mg/100 kJ (mg/100 kcal)	0.12 (0.5)	0.36 (1.5)
8.2.9.	copper, µg/100 kJ (µg/100 kcal)	8.4 (35)	25 (100)
8.2.10.	iodine, µg/100 kJ (µg/100 kcal)	2.5 (10)	12 (50)
8.2.11.	selenium, µg /100 kJ (µg /100 kcal)	0.25 (1)	2.2 (9)
8.2.12.	manganese, µg /100 kJ (µg /100 kcal)	0.25 (1)	25 (100)
8.2.13.	fluorides, µg /100 kJ (µg /100 kcal)	-	25 (100)
8.2.14.	calcium/phosphorus ratio	1	2
9.	Vitamins:		
9.1.	vitamin A, µg RE/100 kJ (µg RE/100 kcal) <sup>11</sup>	14 (60)	43 (180)
9.2.	vitamin D, µg/100 kJ (µg/100 kcal) <sup>12</sup>	0.25 (1)	0.75 (3)
9.3.	thiamin, µg/100 kJ (µg/100 kcal)	14 (60)	72 (300)
9.4.	riboflavin, µg/100 kJ (µg/100 kcal)	19 (80)	95 (400)
9.5.	niacin, µg /100 kJ (µg /100 kcal) <sup>13</sup>	72 (300)	375 (1500)
9.6.	pantothenic acid, µg/100 kJ (µg/100 kcal)	95 (400)	475 (2000)
9.7.	vitamin B <sub>6</sub> , µg/100 kJ (µg/100 kcal)	9 (35)	42 (175)
9.8.	biotin, µg/100 kJ (µg/100 kcal)	0.4 (1.5)	1.8 (7.5)
9.9.	folic acid, µg /100 kJ (µg /100 kcal)	2.5 (10)	12 (50)
9.10.	vitamin B <sub>12</sub> , µg/100 kJ (µg/100 kcal)	0.025 (0.1)	0.12 (0.5)
9.11.	vitamin C, µg/100 kJ (µg/100 kcal)	2.5 (10)	7.5 (30)
9.12.	vitamin K, µg/100 kJ (µg/100 kcal)	1 (4)	6 (25)
9.13.	vitamin E, mg α-TE <sup>14</sup>	0.5/g polyunsaturated acids expressed as linoleic acid as corrected for the double bonds <sup>15</sup> , but not less than 0.1 mg/100 kJ (0.5 mg/100 kcal)	1.2 mg/100 kJ (5 mg/100 kcal)
10.	<b>Nucleotides</b> , total quantity that may be added, mg/100 kJ (mg/100 kcal), including:	-	1.2 (5)
10.1.	cytidine 5'-monophosphate, mg/100 kJ (mg/100 kcal)	-	0.60 (2.50)
10.2.	uridine 5'-monophosphate, mg/100 kJ (mg/100 kcal)	-	0.42 (1.75)
10.3.	adenosine 5'-monophosphate, mg/100 kJ (mg/100 kcal)	-	0.36 (1.50)
10.4.	guanosine 5'-monophosphate, mg/100 kJ (mg/100 kcal)	-	0.12 (0.50)

10.5.	inosine 5'-monophosphate, mg/100 kJ (mg/100 kcal)	-	0.24 (1.00)
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Notes.

- <sup>1</sup>The formulae is set out for usage in a finished product prepared according to the instructions of the manufacturer.  
<sup>2</sup> Protein content = nitrogen content x 6.25.  
<sup>3</sup> The addition of amino acids to the formula is permitted solely for the purpose of improving the nutritional value of the proteins, and only in the proportions necessary for this purpose.  
<sup>4</sup> If the formula is made of soy proteins alone or together with cows' milk proteins, other proteins are not permitted to be added.  
<sup>5</sup> For a formula to have the energy value equal to breast milk, it shall contain an available quantity of each essential and non-essential amino acid which is not less than that contained in breast milk proteins.

**The content of essential and semi-essential amino acids in breast milk:**

No.	Amino acids	mg/100 kJ (1 kJ = 0.239 kcal)	mg/100 kcal
1	2	3	4
1.	Cystine	9	38
2.	Histidine	10	40
3.	Isoleucine	22	90
4.	Leucine	40	166
5.	Lysine	27	113
6.	Methionine	5	23
7.	Phenylalanine	20	83
8.	Threonine	18	77
9.	Tryptophan	8	32
10.	Tyrosine	18	76
11.	Valine	21	88

For calculation purposes, the concentration of cystine and methionine may be added together, if the cystine/methionine ratio is not greater than 2, and the phenylalanine and tyrosine concentration can 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 for the particular nutritional use by infants is demonstrated through appropriate studies following generally accepted expert guidance on the design and conduct of such studies.

- <sup>6</sup> The use of sesame seed oil and cotton seed oil is prohibited.  
<sup>7</sup> It is not permitted to use ingredients containing gluten.  
<sup>8</sup> Shall not apply to a formula in which the content of soy protein isolates exceeds 50% of the total protein content.  
<sup>9</sup> The honey is processed in order to destroy *Clostridium botulinum* spores.  
<sup>10</sup> If the content contains 90% oligogalactosyl-lactose and 10% high molecular weight oligofructosyl saccharose. Other combinations and maximum levels of fructo-oligosaccharides and galacto-oligosaccharides may be used in accordance with Paragraph 8 of these Regulations.  
<sup>11</sup> RE = equivalent of all trans-retinols.  
<sup>12</sup> In the form of cholecalciferol, of which 10 µg = 400 i.u. of vitamin D.  
<sup>13</sup> Previously prepared niacin.  
<sup>14</sup> α-TE = d- α-tocopherol equivalent.  
<sup>15</sup> 0.5 mg α-TE/1 g linoleic acid (18:2 n-6); 0.75 mg α-TE/1 g α-linoleic acid (18:3 n-3); 1.0 mg α-TE/1 g arachidonic acid (20:4 n-6); 1.25 mg α-TE/1 g eicosapentaenoic acid (20:5 n-3); 1.5 mg α-TE/1 g docosahexaenoic acid (22:6 n-3).

Acting for the Minister for Agriculture -  
Minister for Education and Science T. Koçer

**Annex 3**  
Cabinet Regulation No. 370  
of 26 May 2008

**Substances, which are Permitted to be Added to Formulae**

No.	Substance	Permitted forms of the substance
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1	2	3
1.	Vitamins:	
1.1.	vitamin A	retinyl acetate retinyl palmitate retinol
1.2.	vitamin D	vitamin D <sub>2</sub> (ergocalciferol) vitamin D <sub>3</sub> (cholecalciferol)
1.3.	vitamin B <sub>1</sub>	thiamin hydrochloride thiamin mononitrate
1.4.	vitamin B <sub>2</sub>	riboflavin sodium riboflavin-5'-phosphate
1.5.	niacin	nicotinamide nicotinic acid
1.6.	vitamin B <sub>6</sub>	pyridoxine hydrochloride pyridoxine- 5'-phosphate
1.7.	pantothenic acid	calcium D-pantothenate sodium D-pantothenate dexpantenol
1.8.	folate	folic acid
1.9.	vitamin B <sub>12</sub>	cyanocobalamin hydroxocobalamin
1.10.	biotin	D-biotin
1.11.	vitamin C	L-ascorbic acid sodium L-ascorbate calcium L-ascorbate 6-palmityl-L-ascorbic acid (ascorbyl palmitate) potassium ascorbate
1.12.	vitamin K	phylloquinone (phytomenadione)
1.13.	vitamin E	D-alpha-tocopherol DL-alpha-tocopherol D-alpha-tocopherol acetate DL-alpha-tocopherol acetate
2.	Minerals:	
2.1.	calcium (Ca)	calcium carbonate calcium chloride calcium citrates calcium gluconate calcium glycerophosphate calcium lactate calcium hydroxide calcium phosphates
2.2.	magnesium (Mg)	magnesium carbonate magnesium chloride magnesium oxide magnesium phosphates magnesium sulphate magnesium gluconate magnesium hydroxide magnesium citrates
2.3.	iron (Fe)	ferrous citrate ferrous gluconate ferrous lactate ferrous sulphate ferric ammonium citrate ferrous fumarate ferric diphosphate (ferric pyrophosphate) ferrous bisglycinate
2.4.	Copper (Cu)	cupric citrate cupric gluconate cupric sulphate copper lysine complex cupric carbonate

2.5.	iodine (J)	potassium iodide sodium iodide potassium iodate
2.6.	zinc (Zn)	zinc acetate zinc chloride zinc lactate zinc sulphate zinc citrate zinc gluconate zinc oxide
2.7.	manganese (Mn)	manganese carbonate manganese chloride manganese citrate manganese gluconate manganese sulphate
2.8.	sodium (Na)	sodium bicarbonate sodium chloride sodium citrate sodium gluconate sodium carbonate sodium lactate sodium phosphates sodium hydroxide
2.9.	potassium (K)	potassium bicarbonate potassium carbonate potassium chloride potassium citrates potassium gluconate potassium lactate potassium phosphates potassium hydroxide
2.10.	selenium (Se)	sodium selenate sodium selenite
3.	<b>Amino acids and other nitrogen compounds:</b>	
3.1.	L-arginine and its hydrochloride	
3.2.	L-cystine and its hydrochloride	
3.3.	L-histidine and its hydrochloride	
3.4.	L-isoleucine and its hydrochloride	
3.5.	L-leucine and its hydrochloride	
3.6.	L-lysine and its hydrochloride	
3.7.	L-cysteine and its hydrochloride	
3.8.	L-methionine	
3.9.	L-phenylalanine	
3.10.	L-threonine	
3.11.	L-tryptophan	
3.12.	L-tyrosine	
3.13.	L-valine	
3.14.	L-carnitine and its hydrochloride	
3.15.	L-carnitine-L-tartrate	
3.16.	taurine	
3.17.	cytidine -5'-monophosphate and its sodium salt	
3.18.	uridine -5'-monophosphate and its sodium salt	
3.19.	adenosine -5'-monophosphate and its sodium salt	
3.20.	guanosine -5'-monophosphate and its sodium salt	
3.21.	inosine -5'-monophosphate and its sodium salt	
4.	Other nutrients:	
4.1.	choline	
4.2.	choline chloride	
4.3.	choline citrate	

4.4.	choline bitartrate	
4.5.	inositol	

Acting for the Minister for Agriculture -  
Minister for Education and Science T. Koe

**Annex 4**  
Cabinet Regulation No. 370  
of 26 May 2008

### Maximum Permissible Level for Pesticides or Their Metabolic Residues in Formulae

No.	Name of pesticide (pesticide metabolite)	Maximum permissible residue limit (mg/kg)
1.	Cadusafos	0.006
2.	Demeton-S-methyl/demeton-S-methylsulfone/oxydemeton-methyl (individually or combined, expressed as demeton-S-methyl)	0.006
3.	Ethoprophos	0.008
4.	Fipronil (sum of fipronil and fipronil-desulfinyl, expressed as fipronil)	0.004
5.	Propineb/propylenethiourea (sum of propineb and propylenethiourea)	0.006

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**Annex 5**  
Cabinet Regulation No. 370  
of 26 May 2008

### Pesticides which are Prohibited to be Used in the Acquisition of Agricultural Products if these Products are Used in Manufacturing of Formulae, and the Residues thereof

Table 1

No.	Name of pesticide (name of pesticide residue)
1.	Disulfoton (sum of disulfoton, disulfoton sulphoxide and disulfoton sulfone, expressed as disulfoton))
2.	Fensulfothion (sum of fensulfothion, fensulfothion oxygen analogue and fensulfothion sulphones, expressed as fensulfothion)
3.	Fentin, expressed as triphenyltin cation
4.	Haloxifop (sum of haloxifop, its salts and esters including conjugates, expressed as haloxifop)
5.	Heptachlor and trans-heptachlor epoxide, expressed as heptachlor
6.	Hexachlorobenzene
7.	Nitrofen
8.	Omethoate
9.	Terbufos (sum of terbufos, its sulfoxide and sulfone, expressed as terbufos)

Table 2

No.	Name of pesticide
1.	Aldrin and dieldrin, expressed as dieldrin
2.	Endrin

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## Trade Names of Formulae in Latvian and European Union Languages

Trade names of formulae substitutes made of various proteins in Latvian and European Union languages:

No.	Language	Trade name	
1.1.	Latvian	Mākslīgais maisījums zīdaiņiem	Mākslīgais papildu ēdināšanas maisījums zīdaiņiem
1.2.	English	Infant formula	Follow-on formula
1.3.	Danish	Modernmælkserstatning	Tilskudsblanding
1.4.	German	Säuglingsanfangsnahrung	Folgenahrung
1.5.	Greek	Παρασκευάσμα για βρέφη	Παρασκευάσμα δεύτερης βρεφικής ηλικίας
1.6.	Spanish	Preparado para lactantes	Preparado de continuación
1.7.	French	Préparation pour nourrissons	Préparation de suite
1.8.	Italian	Alimento per lattanti	Alimento di proseguimento
1.9.	Dutch	Volledige zuigelingenvoeding	Opvolgzuigelingenvoeding
1.10.	Portuguese	Fórmula para lactentes	Fórmula de transição
1.11.	Finnish	Äidinmaidonkorvike	Vieroitusvalmiste
1.12.	Swedish	Modersmjölksersättning	Tillskottsnäring
1.13.	Czech	Počáteční kojenecká výživa	Pokračovací kojenecká výživa
1.14.	Estonian	Imiku piimasegu	Jätukupiimasegu
1.15.	Lithuanian	Mišinys kūdikiams iki papildomo maitinimo įvedimo	Mišinys kūdikiams, įvedus papildomą maitinimą
1.16.	Hungarian	Anyatej-helyettesítő tápszer	Anyatej-kiegészítő tápszer
1.17.	Maltese	Formula tat-trabi	Formula tal-prosegwiment
1.18.	Polish	Preparat do początkowego żywienia niemowląt	Preparat do dalszego żywienia niemowląt
1.19.	Slovenian	Začetna formula za dojenčke	Nadaljevalna formula za dojenčke
1.20.	Slovak	Počiatočná dojčenská výživa	Následná dojčenská výživa
1.21.	Bulgarian	Храни за кърмачета	Преходни храни
1.22.	Romanian	Preparate pentru sugari	Preparate pentru copii de vârstă mică

Trade names of formulae made of cows' milk proteins in Latvian and European Union languages:

No.	Language	Trade name	
2.1.	Latvian	Mākslīgais piena maisījums zīdaiņiem	Mākslīgais papildu ēdināšanas piena maisījums zīdaiņiem
2.2.	English	Infant milk	Follow-on milk
2.3.	Danish	Modernmælkserstatning udelukkende baseret på mælk	Tilskudsblanding udelukkende baseret på mælk
2.4.	German	Säuglingsmilchnahrung	Folgemilch
2.5.	Greek	Γάλα για βρέφη	Γάλα δεύτερης βρεφικής ηλικίας
2.6.	Spanish	Leche para lactantes	Leche de continuación
2.7.	French	Lait pour nourrissons	Lait de suite
2.8.	Italian	Latte per lattanti	Latte di proseguimento
2.9.	Dutch	Volledige zuigelingenvoeding op basis van melk/Zuigelingenmelk	Opvolgmelk
2.10.	Portuguese	Leite para lactentes	Leite de transição
2.11.	Finnish	Maitopohjainen äidinmaidonkorvike	Maitopohjainen vieroitusvalmiste
2.12.	Swedish	Modersmjölksersättning uteslutande baserad på mjölk	Tillskottsnäring uteslutande baserad på mjölk
2.13.	Czech	Počáteční mléčná kojenecká výživa	Pokračovací mléčná kojenecká výživa

2.14.	Estonian	Piimal põhinev imiku piimasegu	Piimal põhinev jätkupiimasegu
2.15.	Lithuanian	Pieno mišinys kūdikiams iki papildomo maitinimo įvedimo	Pieno mišinys kūdikiams, įvedus papildomą maitinimą
2.16.	Hungarian	Tejalapú anyatej-helyettesítő tápszer	Tejalapú anyatej-kiegészítő tápszer
2.17.	Maltese	Ħalib tat-trabi	Ħalib tal-prosegwiment
2.18.	Polish	Mleko początkowe	Mleko następne
2.19.	Slovenian	Začetno mleko za dojenčke	Nadaljevalno mleko za dojenčke
2.20.	Slovak	Počiatočná dojčenská mliečna výživa	Následná dojčenská mliečna výživa
2.21.	Bulgarian	Млека за кърмачета	Преходни млека
2.22.	Romanian	Lapte pentru sugari	Lapte pentru copii de varsta mica

Acting for the Minister for Agriculture -  
Minister for Education and Science T. Koçe

**Annex 7**  
Cabinet Regulation No.370  
of 26 May 2008

## Infant Formulae - Nutritional Values and Health References and Utilisation Procedures

No.	References	Conditions of utilisation
1	2	3
1.	References which are related to nutritional value:	
1.1.	only contains lactose	Lactose shall be the only carbohydrate present in the composition
1.2.	does not contain lactose	The lactose content shall not be greater than 2.5 mg/100 kJ (10 mg/100 kcal)
1.3.	long chain polyunsaturated fatty acid (LCP) has been added or an equivalent reference as regards the addition of docosahexaenoic acid	The docosahexaenoic acid content shall not be less than 0.2% of the total fatty acid content
1.4.	a reference to the option of the addition of such ingredients:	
1.4.1.	taurine	By choice added in such amount, that would be in conformity with the particular intended utilisation for infants and in accordance with the conditions prescribed in Annex 1
1.4.2.	fructo-oligosaccharides and galacto-oligosaccharides	
1.4.3.	nucleotides	
2.	References, relating to the health of the product, including the reduction of disease risk references:	
2.1.	reduced allergy risk to cows' milk proteins. The labelling may contain a reference regarding a reduced allergen content and regarding a reduced allergen antigen properties	<p>a) objective and scientifically verified data must be available, attesting to the referred to properties</p> <p>b) the formula meets the requirements of Annex 1, Sub-paragraph 2.2 and the amount of immunoreactive protein that has been determined by generally accepted methods is less than 1% of nitrogen-containing substances in the formula</p> <p>c) the labelling shall indicate that the product must not be consumed by infants allergic to the intact proteins from which the product is made, unless generally accepted clinical tests provide proof of the product's tolerance in more than 90% of infants (confidence interval 95%), hypersensitive to proteins from which the formula is made</p> <p>d) infant formula, which is administered orally to experimental animals, should not induce sensitisation to the intact proteins from which the formula has been derived.</p>

### Reference Number for Nutrient Labelling for Follow-on Formulae for Infants

No.	Nutrient	Reference value
1.	vitamin A	400 µg
2.	vitamin D	7 µg
3.	vitamin E	5 mg TE
4.	vitamin K	12 µg
5.	vitamin C	45 mg
6.	Thiamin	0.5 mg
7.	Riboflavin	0.7 mg
8.	Niacin	7 mg
9.	vitamin B6	0.7 mg
10.	Folate	125 µg
11.	vitamin B <sub>12</sub>	0.8 µg
12.	Pantothenic acid	3 mg
13.	Biotin	10 µg
14.	Calcium	550 mg
15.	Phosphorus	550 mg
16.	Potassium	1,000 mg
17.	Sodium	400 mg
18.	Chlorine	500 mg
19.	Iron	8 mg
20.	Zinc	5 mg
21.	Iodine	80 µg
22.	Selenium	20 µg
23.	Copper	0.5 mg
24.	Magnesium	80 mg
25.	Manganese	1.2 mg

### Notice Regarding Infant Formulae, Which are Imported and Distributed in the Republic of Latvia

#### I. Information Regarding the Submitter

Name of product		
Producer	firm (name)	
	state	
	address	

registration number

## II. Information Regarding the Submitter of the Notice

Mark the appropriate square

Producer

Packer

Importer

Company (name)	
State	
Legal address	
Registration number in the Commercial Register	
Registration (recognition) certificate number of the food undertaking issued by the Food and Veterinary Service	
Contact person	
Contact telephone	
E-mail address	

## III. Certification by the Submitter

I have got acquainted with the regulatory enactments prescribing the requirements for importing, distribution, composition and labelling of infant formulae in the Republic of Latvia. I certify that the provided information is true.

\_\_\_\_\_

(position, telephone number)

\_\_\_\_\_

(signature and full name)\*

\_\_\_\_\_

(date)

Place for a seal

\* The referred to details "signature", "date", and "place for a seal" of the document shall not be filled in if the document is prepared in accordance with the regulatory enactments regarding drawing up of electronic documents.

Acting for the Minister for Agriculture -  
Minister for Education and Science T. Koķe

\_\_\_\_\_

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