L.N. 304 of 2007

FOOD SAFETY ACT
(CAP. 449)

Infant Formulae and Follow-on Formulae, 2007

IN exercise of the powers conferred by article 10 of the Food Safety Act, the Minister of Health, the Elderly and Community Care has made the following regulations:-

Title.

1. The title of these regulations is the Infant Formulae and Follow-on Formulae Regulations, 2007.

Commencement and scope.

2. (1) These regulations implement the provisions of Commission Directive 2006/141/EC of 22nd December, 2006, and they shall enter into force on 31st December, 2007.

(2) The provisions shall apply in such a way as to:

(a) permit trade in products complying with this regulation by the 1st January, 2008 at the latest,

(b) without prejudice to paragraph 13, prohibit, with effect from 31st December, 2009 trade in products which do not comply with this regulation.

Applicability.

3. These regulations concern compositional and labelling requirements for infant formulae and follow-on formulae intended for use by infants in good health.

Definitions.

4. (1) For the purpose of these regulations, the definitions 'claim', 'nutrition claim', 'health claim' and 'reduction of disease risk claim' in Article 2(2)(1), (4), (5) and (6) of Regulation (EC) No 1924/2006 shall apply.

(2) The following definitions shall also apply:

(a) 'infants' means children under the age of 12 months;

(b) 'young children' means children aged between one and three years;

(c) 'infant formulae' means foodstuffs intended for particular nutritional use by infants during the first months of life and satisfying by themselves the nutritional requirements of such

infants until the introduction of appropriate complementary feeding;

(d) 'follow-on formulae' means foodstuffs intended for particular nutritional use by infants when appropriate complementary feeding is introduced and constituting the principal liquid element in a progressively diversified diet of such infants;

(e) 'pesticide residue' means the residue in infant formulae and follow-on formulae of a plant protection product, as defined in point 1 of Article 2 of Directive 91/414/EEC, including its metabolites and products resulting from its degradation or reaction.

Sale of infant formulae and follow-on formulae.

5. (1) Infant formulae and follow-on formulae may be marketed within the Community only if they comply with these regulations.

(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.

Manufacture of infant formulae and follow-on formulae.

6. (1) Infant formulae shall be manufactured from protein sources defined in point 2 of the First Schedule and other food ingredients, as the case may be, whose suitability for particular nutritional use by infants from birth has been established by generally accepted scientific data.

(2) Follow-on formulae shall be manufactured from protein sources defined in point 2 of the Second Schedule and other food ingredients, as the case may be, whose suitability for particular nutritional use by infants aged over six months has been established by generally accepted scientific data.

(3) Such suitability, as mentioned in paragraphs 6(1) and 6(2), shall be demonstrated 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.

(4) The prohibitions and limitations on the use of food ingredients in infant formulae and follow-on formulae set out in the First and Second Schedules shall be observed.

Compositional Criteria.

7. (1) Infant formulae shall comply with the compositional criteria set out in the First Schedule taking into account the specifications of the Fifth Schedule.

In the case of infant formulae manufactured from cows' milk proteins defined in point 2.1 of the First Schedule with a protein content between the minimum and 0,5 g/100 kJ (2 g/100 kcal), the suitability of the infant formula for the particular nutritional use by infants shall be demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

In the case of infant formulae manufactured from protein hydrolysates defined in point 2.2 of the First Schedule with a protein content between the minimum and 0,56 g/100 kJ (2,25g/100 kcal), the suitability of the infant formula for the particular nutritional use by infants shall be demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies and shall be in accordance with the appropriate specifications set out in the Sixth Schedule.

(2) Follow-on formulae shall comply with the compositional criteria set out in the Second Schedule taking into account the specifications set out in the Fifth Schedule.

(3) In order to make infant formulae and follow-on formulae ready for use, nothing more shall be required, as the case may be, than the addition of water.

(4) Only the substances listed in the Third Schedule may be used in the manufacture of infant formulae and follow-on formulae in order to satisfy the requirements on:

(a) mineral substances;

(b) vitamins;

(c) amino acids and other nitrogen compounds;

(d) other substances having a particular nutritional purpose.

(5) Infant formulae and follow-on formulae shall not contain any substance in such quantity as to endanger the health of infants and young children.

(6) Purity criteria for substances, concerning the use of substances listed in the Third Schedule, in the manufacture of foodstuffs for purposes other than those covered by this Regulation, shall apply.

(7) For those substances for which no purity criteria have been provided for in Community legislation, generally acceptable purity criteria recommended by international bodies shall apply until the adoption of such criteria at Community level.

However, national rules setting stricter purity criteria than those recommended by international bodies may be maintained.

(8) Infant formulae and follow-on formulae shall not contain residues of individual pesticides at levels exceeding 0,01 mg/kg of the product as proposed ready for consumption or as reconstituted according to the instructions of the manufacturer. Analytical methods for determining the levels of pesticide residues shall be generally acceptable standardised methods.

(9) The pesticides listed in the Eight Schedule shall not be used in agricultural products intended for the production of infant formulae and follow-on formulae.

However, for the purpose of controls:

(a) pesticides listed in Table 1 of the Eighth Schedule are considered not to have been used if their residues do not exceed a level of 0,003 mg/kg. This level, which is considered to be the limit of quantification of the analytical methods, shall be kept under regular review in the light of technical progress;

(b) pesticides listed in Table 2 of the Eighth Schedule are considered not to have been used if their residues do not exceed a level of 0,003 mg/kg. This level shall be kept under regular review in the light of data on environmental contamination.

(10) By way of derogation from paragraph 7(8), for the pesticides listed in the Ninth Schedule, the maximum residue levels specified therein shall apply.

(11) The levels referred to in paragraphs 7(9) and 7(10) shall apply to the products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers.

Monitoring of infant formulae.

8. (1) To facilitate the efficient official monitoring of infant formulae, when a food business operator places an infant formula on the market he shall notify the Food Safety Commission by forwarding a model of the label used for the product.

(2) The competent authorities for the purposes of this paragraph are those referred to in paragraphs 19(13) to 19(18) of the Regulation of 2004 concerning the Labelling, Presentation and Advertising of Foodstuffs, Regulations, 2004.

L.N. 483 of 2004.

Labelling and Presentation of infant formulae and follow-on formulae.

9. (1) (a) Except as provided for in paragraph 9(2), the name under which infant formulae and follow-on formulae are sold shall be, respectively:

(i) *in English*: 'infant formula' and 'follow-on formula'

(ii) *in Maltese*: 'formula tat-trabi' and 'formula tal-prosegwiment'

(b) The name under which the products covered by regulation 4(2) (c) and (d) are sold shall be, respectively:

"infant formula" and "follow-on formula".

However, the name of products manufactured entirely from cows' milk proteins, shall be respectively:

"infant milk" and "follow-on milk".

(c) Without prejudice to paragraph (b) above, the list provided for in the Tenth Schedule specifies the names under which the products covered by regulation 4(2) (c) and (d) are sold in all the European Community languages.

(2) The name under which infant formulae and follow-on formulae manufactured entirely from cows' milk proteins are sold, shall be respectively:

(i) *in English*: 'infant milk' and 'follow-on milk'

(ii) *in Maltese*: 'ħalib tat-trabi' and 'ħalib tal-prosegwiment'

(3) The labelling shall bear, in addition to those provided for in paragraph 5(1) of the Labelling, Presentation and Advertising of Foodstuffs Regulations, 2004, the following mandatory particulars in Maltese and, or English:

(a) in the case of infant formulae, a statement to the effect that the product is suitable for particular nutritional use by infants from birth when they are not breast fed;

(b) in the case of follow-on formulae, a statement to the effect that the product is suitable only for particular nutritional use by 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;

(c) in the case of infant formulae and follow-on formulae, the available energy value, expressed in kJ and kcal, and the content of proteins, carbohydrates and lipids, expressed in numerical form, per 100 ml of the product ready for use;

(d) in the case of infant formulae and follow-on formulae, the average quantity of each mineral substance and of each vitamin mentioned in the First and Second Schedules respectively, and where applicable of choline, inositol and carnitine, expressed in numerical form, per 100 ml of the product ready for use;

(e) in the case of infant formulae and follow-on formulae, instructions for appropriate preparation, storage and disposal of the product and a warning against the health hazards of inappropriate preparation and storage.

(4) The labelling may bear the following particulars:

(a) for infant formulae and follow-on formulae the average quantity of nutrients mentioned in the Third Schedule when such declaration is not covered by paragraph (3)(d) of this regulation, expressed in numerical form, per 100 ml of the product ready for use;

(b) for follow-on formulae in addition to numerical information, information on vitamins and minerals included in the Seventh Schedule, expressed as a percentage of the reference values given therein, per 100 ml of the product ready for use.

(5) The labelling of infant formulae and follow-on formulae shall be designed to provide the necessary information about the

appropriate use of the products so as not to discourage breast feeding. The use of the terms 'humanised', 'maternalised', 'adapted', or similar terms shall be prohibited.

(6) The labelling of infant formulae shall, in addition, bear the following mandatory particulars, preceded by the words 'Important Notice' or their equivalent:

(a) statement concerning the superiority of breast feeding;

(b) 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.

(7) The labelling of infant formulae shall not include pictures of infants, nor shall it include other pictures or text which may idealise the use of the product. It may, however, have graphic representations for easy identification of the product and for illustrating methods of preparation.

(8) The labelling of infant formulae may bear nutrition and health claims only in the cases listed in the Fourth Schedule and in accordance with the conditions set out therein.

(9) Infant formulae and follow-on formulae shall be labelled in such a way that it enables consumers to make a clear distinction between such products so as to avoid any risk of confusion between infant formulae and follow-on formulae.

(10) The requirements, prohibitions and restrictions referred to in paragraphs 10(5) to 10(9) shall also apply to:

(a) the presentation of the products concerned, in particular their shape, appearance or packaging, the packaging materials used, the way in which they are arranged and the setting in which they are displayed;

(b) advertising.

Advertising of infant formulae.

10. (1) Advertising of infant formulae shall be restricted to publications specialising in baby care and scientific publications. Such advertisements for infant formulae shall be subject to the conditions laid down in paragraphs 9(5) to 9(9) and paragraph 9(10)(b) and 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 formulae 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.

Providing consistent information on infant formulae and follow-on formulae.

11. (1) Objective and consistent information shall be provided on infant and young child feeding for use by families and those involved in the field of infant and young child nutrition covering the planning, provision, design and dissemination of information and their control.

(2) Informational and educational materials, whether written or audiovisual, 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;

(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 formulae.

When such materials contain information about the use of infant formulae, 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 formulae. Such material shall not use any pictures which may idealise the use of infant formulae.

(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 formulae and shall be distributed only through the health care system.

(4) Donations or low-price sales of supplies of infant formulae 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 formulae and only for as long as required by such infants.

Dietary foods for special medical purposes intended specifically for infants. L.N. 309 of 2001.

12. The new requirements set out in paragraphs 7(1) and 7(2) of these regulations shall not apply mandatorily to dietary foods for special medical purposes intended specifically for infants, as referred to in point 4 of the Schedule to the Dietary Foods for Special Medical Purposes until 1st January 2012.

Repeals L.N. 208 of 2002.

13. The Infant Formulae and Follow-on Formulae Regulations, 2002 are hereby repealed and any reference to those regulations shall be construed as a reference to these regulations.

FIRST SCHEDULE

ESSENTIAL COMPOSITION OF INFANT FORMULAE WHEN RECONSTITUTED AS INSTRUCTED BY THE MANUFACTURER

The values set out in this Schedule 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	295 kJ/100 ml
(60 kcal/100 ml)	(70 kcal/100 ml)

2. PROTEINS

(Protein content = nitrogen content × 6,25)

2.1 **Infant formulae manufactured from cows' milk proteins**

Minimum ([1])	Maximum
0,45 g/100 kJ	0,7 g/100 kJ
(1,8 g/100 kcal)	(3 g/100 kcal)

([1]) Infant formulae manufactured from cows' milk protein with a protein content between the minimum and 0,5 g/100 kJ (2 g/100 kcal) shall be in accordance with the second subparagraph of paragraph 7(1).

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 the Fifth Schedule). 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.

2.2 **Infant formulae manufactured from protein hydrolysates**

Minimum ([1])	Maximum
0,45 g/100 kJ	0,7 g/100 kJ
(1,8 g/100 kcal)	(3 g/100 kcal)

([1]) Infant formulae manufactured from protein hydrolysates with a protein content between the minimum and 0,56 g/100 kJ (2,25 g/100 kcal) shall be in accordance with the third subparagraph of Article 7(1).

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 the Fifth Schedule). 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).

2.3 **Infant formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins**

Minimum	Maximum
0,56 g/100 kJ	0,7 g/100 kJ
(2,25 g/100 kcal)	(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 the Fifth Schedule). 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).

2.4 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	12 mg/100 kJ
(7 mg/100 kcal)	(50 mg/100 kcal)

5. LIPIDS

Minimum	Maximum
1,05 g/100 kJ	1,4 g/100 kJ
(4,4 g/100 kcal)	(6,0 g/100 kcal)

5.1 The use of the following substances shall be prohibited:

— sesame seed oil,

— cotton seed oil.

5.2 **Lauric acid and myristic acid**

Minimum	Maximum
-	separately or as a whole: 20 % of the total fat content

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

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

5.5 **Linoleic acid (in the form of glycerides = linoleates)**

Minimum	Maximum
70 mg/100 kJ	285 mg/100 kJ
(300 mg/100 kcal)	(1 200 mg/100 kcal)

5.6 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.

5.7 Long-chain (20 and 22 carbon atoms) polyunsaturated fatty acids (LCP) 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))

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

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

6. PHOSPHOLIPIDS

The amount of phospholipids in infant formulae shall not be greater than 2 g/l.

7. INOSITOL

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

8. CARBOHYDRATES

Minimum	Maximum
2,2 g/100 kJ	3,4 g/100 kJ
(9 g/100 kcal)	(14 g/100 kcal)

8.1 Only the following carbohydrates may be used:

— lactose,

— maltose,

— sucrose,

— glucose,

— malto-dextrins,

— glucose syrup or dried glucose syrup,

— pre-cooked starch
— gelatinised starch
} naturally free of gluten.

8.2 **Lactose**

Minimum	Maximum
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.

8.3 **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.

8.4 **Glucose**

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

8.5 **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 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-oligosaccharides may be used in accordance with paragraph 6.

10. MINERAL SUBSTANCES

10.1 **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	25	90
Magnesium (mg)	1,2	3,6	5	15
Iron (mg)	0,07	0,3	0,3	1,3
Zinc (mg)	0,12	0,36	0,5	1,5
Copper (µg)	8,4	25	35	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.

10.2 **Infant formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins**

All requirements of point 10.1 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) ([1])	14	43	60	180
Vitamin D (µg) ([2])	0,25	0,65	1	2,5
Thiamin (µg)	14	72	60	300
Riboflavin (µg)	19	95	80	400
Niacin (µg) ([3])	72	375	300	1 500
Pantothenic acid (µg)	95	475	400	2 000
Vitamin B6 (µg)	9	42	35	175
Biotin (µg)	0,4	1,8	1,5	7,5
Folic Acid (µg)	2,5	12	10	50
Vitamin B12 (µg)	0,025	0,12	0,1	0,5
Vitamin C (mg)	2,5	7,5	10	30
Vitamin K (µg)	1	6	4	25
Vitamin E (mg α-TE) ([4])	0,5/g of polyunsaturated fatty acids expressed as linoleic acid as corrected for the double bonds ([5]) 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 ([5]) but in no case less than 0,5 mg per 100 available kcal	5

([1]) RE = all trans retinol equivalent.
([2]) In the form of cholecalciferol, of which 10 µg = 400 i.u. of vitamin D.
([3]) Preformed niacin.
([4]) α-TE = d-α-tocopherol equivalent.
([5]) 0,5 mg α-TE/1 g linoleic acid (18:2 n-6); 0,75 mg α-TE/1 g α-linolenic 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).

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).

SECOND SCHEDULE

ESSENTIAL COMPOSITION OF FOLLOW-ON FORMULAE WHEN RECONSTITUTED AS INSTRUCTED BY THE MANUFACTURER

The values set out in this Schedule 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	295 kJ/100 ml
(60 kcal/100 ml)	(70 kcal/100 ml)

2. PROTEINS

(Protein content = nitrogen content × 6,25)

2.1 **Follow-on formulae manufactured from cows' milk proteins**

Minimum	Maximum
0,45 g/100 kJ	0,8 g/100 kJ
(1,8 g/100 kcal)	(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 the Fifth Schedule). 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.

2.2 **Follow-on formulae manufactured from protein hydrolysates**

Minimum	Maximum
0,56 g/100 kJ	0,8 g/100 kJ
(2,25 g/100 kcal)	(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 the Fifth Schedule). 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.

2.3 **Follow-on formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk Proteins**

Minimum	Maximum
0,56 g/100 kJ	0,8 g/100 kJ
(2,25 g/100 kcal)	(3,5 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 the Fifth Schedule). 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.

2.4 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	1,4 g/100 kJ
(4,0 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 **Lauric acid and myristic acid**

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

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

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

4.5 **Linoleic acid (in the form of glycerides = linoleates)**

Minimum	Maximum
70 mg/100 kJ (300 mg/100 kcal)	285 mg/100 kJ (1 200 mg/100 kcal)

4.6 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.

4.7 Long-chain (20 and 22 carbon atoms) polyunsaturated fatty acids (LCP) 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))

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

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

5. PHOSPHOLIPIDS

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

6. CARBOHYDRATES

Minimum	Maximum
2,2 g/100 kJ (9 g/100 kcal)	3,4 g/100 kJ (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)	—

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

6.3 **Sucrose, fructose, honey**

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

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

6.4 **Glucose**

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

7. FRUCTO-OLIGOSACCHARIDES AND GALACTO-OLIGOSACCHARIDES

Fructo-oligosaccharides and galacto-oligosaccharides may be added to follow-on 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-oligosaccharides may be used in accordance with paragraph 7(2).

8. MINERAL SUBSTANCES

8.1 **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	25	90
Magnesium (mg)	1,2	3,6	5	15
Iron (mg)	0,14	0,5	0,6	2
Zinc (mg)	0,12	0,36	0,5	1,5
Copper (µg)	8,4	25	35	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 in follow-on formulae shall not be less than 1,0 nor greater than 2,0.

8.2 **Follow-on formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk Proteins**

All requirements of point 8.1 shall apply, except for those concerning iron, and phosphorus, which shall be as follows:

	Per 100 kJ		Per 100 kcal	
	Maximum	Minimum	Maximum	Minimum
Iron (mg)	0,22	0,65	0,9	2,5
Phosphorus (mg)	7,5	25	30	100

9. VITAMINS

	Per 100 kJ		Per 100 kcal	
	Maximum	Minimum	Maximum	Minimum
Vitamin A (µg-RE) ([1])	14	43	60	180
Vitamin D (µg) ([2])	0,25	0,75	1	3
Thiamin (µg)	14	72	60	300
Riboflavin (µg)	19	95	80	400
Niacin (µg) ([3])	72	375	300	1 500
Pantothenic acid (µg)	95	475	400	2 000
Vitamin B6 (µg)	9	42	35	175
Biotin (µg)	0,4	1,8	1,5	7,5
Folic Acid (µg)	2,5	12	10	50
Vitamin B12 (µg)	0,025	0,12	0,1	0,5
Vitamin C (mg)	2,5	7,5	10	30
Vitamin K (µg)	1	6	4	25
Vitamin E (mg α-TE) ([4])	0,5/g polyunsaturated fatty acids expressed as linoleic acid as corrected for the double bonds ([5]) but in no case less than 0,1 mg per 100 available kJ	1,2	0,5/g polyunsaturated fatty acids expressed as linoleic acid as corrected for the double bonds ([5]) but in no case less than 0,5 mg per 100 available kcal	5

([1]) RE = all *trans* retinol equivalent.

([2]) In the form of cholecalciferol, of which10 µg = 400 i.u. of vitamin D.

([3]) Preformed niacin.

([4]) α-TE = d-α-tocopherol equivalent.

([5]) 0,5 mg α-TE/1 g linoleic acid (18:2 n-6); 0,75 mg α-TE/1 g α-linolenic 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).

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).

THIRD SCHEDULE

NUTRITIONAL SUBSTANCES

1. **Vitamins**

Vitamin	Vitamin formulation
Vitamin A	Retinyl acetate Retinyl palmitate Retinol
Vitamin D	Vitamin D2 (ergocalciferol) Vitamin D3 (cholecalciferol)
Vitamin B1	Thiamin hydrochloride Thiamin mononitrate
Vitamin B2	Riboflavin Riboflavin-5′-phosphate, sodium
Niacin	Nicotinamide Nicotinic acid
Vitamin B6	Pyridoxine hydrochloride Pyridoxine-5′-phosphate
Folate	Folic acid
Pantothenic acid	D-pantothenate, calcium D-pantothenate, sodium Dexpanthenol
Vitamin B12	Cyanocobalamin Hydroxocobalamin
Biotin	D-biotin
Vitamin C	L-ascorbic acid Sodium L-ascorbate Calcium L-ascorbate 6-palmityl-L-ascorbic acid (ascorbyl palmitate) Potassium ascorbate
Vitamin E	D-alpha tocopherol DL-alpha tocopherol D-alpha tocopherol acetate 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-cystine 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′
Uridine 5′
Adenosine 5′
Guanosine 5′
Inosine 5′

4. **Other nutritional substances**

Choline
Choline chloride
Choline citrate
Choline bitartrate
Inositol

FOURTH SCHEDULE

NUTRITION AND HEALTH CLAIMS FOR INFANT FORMULAE AND CONDITIONS WARRANTING A CORRESPONDING CLAIM

1. NUTRITION CLAIMS

Nutrition claim related to	Conditions warranting the nutrition claim
1.1 Lactose only	Lactose is the only carbohydrate present.
1.2 Lactose free	Lactose content is not greater than 2,5 mg/100 kJ (10 mg/100 kcal).
1.3 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.
1.4 Nutrition claims on the addition of the following optional ingredients:	
1.4.1 taurine 1.4.2 fructo-oligosaccharides and galacto-oligosaccharides 1.4.3 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 the First Schedule .

2. HEALTH CLAIMS (INCLUDING REDUCTION OF DISEASE RISK CLAIMS)

Nutrition claim related to	Conditions warranting the health claim
2.1 Reduction of risk to allergy to milk proteins. This health claim may include terms referring to reduced allergen or reduced antigen properties.	(a) Objective and scientifically verified data as proof to the claimed properties must be available; (b) The infant formulae shall satisfy the provisions set out in point 2.2 of the First Schedule 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; (c) The label shall indicate that the product must not be consumed by infants allergic to the 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; (d) The infant formulae administered orally must not induce sensitisation, in animals, to the intact proteins from which the infant formulae are manufactured.

FIFTH SCHEDULE

INDISPENSABLE AND CONDITIONALLY INDISPENSABLE AMINO ACIDS IN BREAST MILK

For the purpose of this Directive, 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
Cystine	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.

SIXTH SCHEDULE

Specification for the protein content and source and the processing of protein used in the manufacture of infant formulae with a protein content 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 × 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 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 %.

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.

SEVENTH SCHEDULE

REFERENCE VALUES FOR NUTRITION LABELLING FOR FOODS INTENDED FOR INFANTS AND YOUNG CHILDREN

Nutrient	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) 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

EIGHTH SCHEDULE

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
Haloxyfop (sum of haloxyfop, its salts and esters including conjugates, expressed as haloxyfop)
Heptachlor and *trans*-heptachlor epoxide, expressed as heptachlor
Hexachlorobenzene
Nitrofen
Omethoate
Terbufos (sum of terbufos, its sulfoxide and sulfone, expressed as terbufos)

Table 2

Chemical name of the substance
Aldrin and dieldrin, expressed as dieldrin
Endrin

NINTH SCHEDULE

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 and propylenethiourea)	0,006

TENTH SCHEDULE

Names under which products covered by Regulation 4(2) (c) and (d) are sold in all the European Community Languages:

— *in English*: 'infant formula' and 'follow-on formula',
— *in Danish*: 'Modermælkserstatning' and 'Tilskudsblanding',
— *in German*: 'Säuglingsanfangsnahrung' and 'Folgenahrung',
— *in Greek*: 'Παρασκεύασμα για βρέφη' and 'Παρασκεύασμα δεύτερης βρεφικής ηλικίας',
— *in Spanish*: 'Preparado para lactantes' and 'Preparado de continuación',
— *in French*: 'Préparation pour nourrissons' and 'Préparation de suite',
— *in Italian*: 'Alimento per lattanti' and 'Alimento di proseguimento',
—*in Dutch*: 'Volledige zuigelingenvoeding' and 'Opvolgzuigelingenvoeding',
— *in Portuguese*: 'Fórmula para lactentes' and 'Fórmula de transição',
— *in Finnish*: 'Äidinmaidonkorvike' and 'Vieroitusvalmiste',
— *in Swedish*: 'Modersmjölksersättning' and 'Tillskottsnäring',
— *in Czech*: 'počáteční kojenecká výživa' and 'pokračovací kojenecká výživa',
— *in Estonian*: 'imiku piimasegu' and 'jätkupiimasegu',
— *in Latvian*: 'Mākslīgais maisījums zīdaiņiem' un 'Mākslīgais papildu ēdināšanas maisījums zīdaiņiem',
— *in Lithuanian*: 'mišinys kūdikiams iki papildomo maitinimo įvedimo' and 'mišinys kūdikiams, įvedus papildomą maitinimą',
— *in Hungarian*: 'anyatej-helyettesítő tápszer' and 'anyatejkiegészítő tápszer',
—*in Maltese*: 'formula tat-trabi' and 'formula tal-prosegwiment',
— *in Polish*: 'preparat do początkowego żywienia niemowląt' and 'preparat do dalszego żywienia niemowląt',
— *in Slovenian*: 'začetna formula za dojenčke' and 'nadaljevalna formula za dojenčke',
— *in Slovak*: 'počiatočná dojčenská výživa' and 'následná dojčenská výživa'.
— *in Bulgarian*: 'храни за кърмачета' and 'преходни храни',
— *in Romanian*: 'preparate pentru sugari' and 'preparate pentru copii de vârstă mică'.

Names under which products manufactured entirely from cows' milk proteins are sold in all the European Community languages:

— *in English*: 'infant milk' and 'follow-on milk',
— *in Danish*: 'Modermælkserstatning udelukkende baseret påmælk' and 'Tilskudsblanding udelukkende baseret på mælk',
— *in German*: 'Säuglingsmilchnahrung' and 'Folgemilch',
— *in Greek*: 'Γάλα για βρέφη' and 'Γάλα δεύτερης βρεφικής ηλικίας',
— *in Spanish*: 'Leche para lactantes' and 'Leche de continuación',
— *in French*: 'Lait pour nourrissons' and 'Lait de suite',
— *in Italian*: 'Latte per lattanti' and 'Latte di proseguimento',
— *in Dutch*: 'Volledige zuigelingenvoeding op basis van melk' or 'Zuigelingenmelk' and 'Opvolgmelk',
— *in Portuguese*: 'Leite para lactentes' and 'Leite de transição',
— *in Finnish*: 'Maitopohjainen äidinmaidonkorvike' and 'Maitopohjainen vieroitusvalmiste',
— *in Swedish*: 'Modersmjölksersättning uteslutande baserad på mjölk' and 'Tillskottsnäring uteslutande baserad på mjölk',
— *in Czech*: 'počáteční mléčná kojenecká výživa' and 'pokračovací mléčná kojenecká výživa',
— *in Estonian*: 'Piimal põhinev imiku piimasegu' and 'Piimal põhinev jätkupiimasegu',
— *in Latvian*: 'Mākslīgais piena maisījums zīdaiņiem' un 'Mākslīgais papildu ēdināšanas piena maisījums zīdaiņiem',
— *in Lithuanian*: 'pieno mišinys kūdikiams iki papildomo maitinimo įvedimo' and 'pieno mišinys kūdikiams įvedus papildomą maitinimą',
— *in Hungarian*: 'tejalapú anyatej-helyettesítő tápszer' and 'tejalapú anyatej-kiegészítő tápszer',
— *in Maltese*: 'ħalib tat-trabi' and 'ħalib tal-prosegwiment',
— *in Polish*: 'mleko początkowe' and 'mleko następne',
— *in Slovenian*: 'začetno mleko za dojenčke' and 'nadaljevalno mleko za dojenčke',
— *in Slovak*: 'počiatočná dojčenská mliečna výživa' and 'následná dojčenská mliečna výživa',
— *in Bulgarian*: 'млека за кърмачета' and 'преходни млека',
— *in Romanian*: 'lapte pentru sugari' and 'lapte pentru copii de vârstă mică'.

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