►**B**

COMMISSION DIRECTIVE
of 14 May 1991
on infant formulae and follow-on formulae

(91/321/EEC)

(OJ L 175, 4.7.1991, p. 35)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Directive 96/4/EC of 16 February 1996	L 49	12	28.2.1996
►**M2**	Commission Directive 1999/50/EC of 25 May 1999	L 139	29	2.6.1999
►**M3**	Commission Directive 2003/14/EC of 10 February 2003	L 41	37	14.2.2003

Amended by:

►**A1**	Act of Accession of Austria, Sweden and Finland	C 241	21	29.8.1994
	(adapted by Council Decision 95/1/EC, Euratom, ECSC)	L 1	1	1.1.1995

▼B

COMMISSION DIRECTIVE

of 14 May 1991

on infant formulae and follow-on formulae

(91/321/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs for particular nutritional uses ([1]), and in particular Article 4 thereof,

Whereas the essential composition of the products in question must satisfy the nutritional requirements of infants in good health as established by generally accepted scientific data;

Whereas on the basis of these data the essential composition of infant formulae and follow-on formulae manufactured from cows' milk proteins and soya proteins alone or in a mixture can already be defined; whereas the same is not true for preparations based wholly or partly on other sources of protein; whereas for this reason specific rules for such products, if necessary, will therefore have to be adopted at a later date;

Whereas this Directive reflects current knowledge about these products; whereas any modification, to allow innovation based on scientific and technical progress, will be decided by the procedure laid down in Article 13 of Directive 89/398/EEC;

Whereas because of the persons for which these products are intended it will be necessary to lay down microbiological criteria and maximum levels for contaminants; whereas given the complexity of the subject these will have to be adopted at a later stage;

Whereas infant formula is the only processed foodstuff which wholly satisfies the nutritional requirements of infants during the first four to six months of life; whereas in order to safeguard the health of such infants it is necessary to ensure that the only products marketed as suitable for such use during the period would be infant formulae;

Whereas pursuant to Article 7 (1) of Directive 89/398/EEC the products covered by this Directive are subject to the general rules laid down by Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer ([2]), as last amended by Directive 89/395/EEC ([3]); whereas this Directive adopts and expands upon the additions and exceptions to those general rules, where it is appropriate, in order to promote and protect breast-feeding;

Whereas, in particular, the nature and destination of the products covered by this Directive require nutritional labelling for the energy value and principal nutrients they contain; whereas, on the other hand, the method of use must be specified in conformity with Article 3 (1) (8) and Article 10 (2) of Directive 79/112/EEC, in order to prevent inappropriate uses likely to be detrimental to the health of infants;

Whereas, pursuant to Article 2 (2) of Directive 79/112/EEC, and in order to supply objective and scientifically verified information, it is necessary to define the conditions under which claims about the particular composition of an infant formula are authorized;

Whereas, in an effort to provide better protection for the health of infants, the rules of composition, labelling and advertising laid down in this Directive should be in conformity with the principles and the

([1]) OJ No L 186, 30. 6. 1989, p. 27.
([2]) OJ No L 33, 8. 2. 1979, p. 1.
([3]) OJ No L 186, 30. 6. 1989, p. 17.

▼B

aims of the International Code of Marketing of Breast-Milk Substitutes adopted by the 34th World Health Assembly, bearing in mind the particular legal and factual situations existing in the Community;

Whereas given the important role which information on infant feeding plays in choosing, by pregnant women and mothers of infants, the type of nourishment provided to their children, it is necessary for Member States to take appropriate measures in order that this information ensures an adequate use of the products in question and is not counter to the promotion of breast-feeding;

Whereas this Directive does not concern the conditions of sale of publications specializing in baby care and of scientific publications;

Whereas the Scientific Committee for Food, in accordance with Article 4 of Directive 89/398/EEC, has been consulted on the provisions liable to affect public health;

Whereas issues relating to products intended for export to third countries should be dealt with in a coherent and homogeneous manner in a separate measure;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive is a specific Directive within the meaning of Article 4 of Directive 89/398/EEC and lays down compositional and labelling requirements for infant formulae and follow-on formulae intended for use by infants in good health in the Community. It also provides for Member States to give effect to principles and aims of the International Code of Marketing of Breast-Milk Substitutes dealing with marketing, information and responsibilities of health authorities.

2. For the purposes of this Directive,

(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 four to six months of life and satisfying by themselves the nutritional requirements of this category of persons;

(d) 'follow-on formulae' means foodstuffs intended for particular nutritional use by infants aged over four months and constituting the principal liquid element in a progressively diversified diet of this category of persons;

▼M2

(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 Council Directive 91/414/EEC ([1]), including its metabolites and products resulting from its degradation or reaction.

▼B

Article 2

Member States shall ensure that the products referred to in Article 1 (2) (c) and (d) may be marketed within the Community only if they conform to the definitions and rules laid down in this Directive. 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 four to six months of life.

([1]) OJ L 230, 19.8.1991, p. 1.

▼B

Article 3

1. Infant formulae shall be manufactured from protein sources defined in the Annexes 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 the Annexes and other food ingredients as the case may be whose suitability for particular nutritional use by infants aged over four months has been established by generally accepted scientific data.

3. The prohibitions and limitations on the use of food ingredients laid down in Annexes I and II shall be observed.

Article 4

1. Infant formulae must comply with the compositional criteria specified in Annex I.

2. Follow-on formulae must comply with the compositional criteria specified in Annex II.

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.

Article 5

1. Only the substances listed in Annex III may be used in the manufacture of infant formulae and follow-on formulae in order to satisfy the requirements on:

— mineral substances,

— vitamins,

— amino acids and other nitrogen compounds,

— other substances having a particular nutritional purpose.

The purity criteria for these substances shall be stipulated at a later stage.

2. The provisions relating to the use of additives in the manufacture of infant formulae and follow-on formulae shall be laid down in a Council directive.

▼M2

Article 6

▼M3

1. Infant formulae and follow-on formulae shall not contain any substance in such quantity as to endanger the health of infants and young children. Necessary maximum levels for substances other than those referred to in paragraphs 2 and 3 shall be established without delay.

▼M2

2. 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.

▼M3

3. (a) Those pesticides listed in Annex IX shall not be used in agricultural products intended for the production of infant formulae and follow-on formulae. However, for the purpose of control:

(i) pesticides listed in Table 1 of Annex IX 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;

▼M3

(ii) pesticides listed in Table 2 of Annex IX 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.

(b) By derogation of paragraph 2, for the pesticides listed in Annex X, the maximum residue levels specified therein shall apply.

For pesticides listed in Annex X, where a decision concerning the non-inclusion of an active substance in Annex I to Directive 91/414/EEC is taken, Annex IX and Annex X to this Directive shall be amended accordingly.

(c) The levels referred to in subparagraphs (a) and (b) shall apply to the products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers.

▼M2

4. Microbiological criteria shall be established as necessary.

▼B

Article 7

1. The name under which the products covered by Article 1 (2) are sold shall be, respectively:

— 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’,

▼A1

— in Finnish:
‘Äidinmaidonkorvike’ and ‘Vieroitusvalmiste’,

— in Swedish:
‘Modersmjölksersättning’ and ‘Tillskottsnäring’.

▼B

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

— in English:
‘Infant milk’ and ‘follow-on milk’,

— in Danish:
‘Modermælkserstatning udelukkende baseret på mælk’ 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’,

▼B

— 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’,

▼A1

— in Finnish:

‘Maitopohjainen äidinmaidonkorvike’ and ‘Maitopohjainen vieroitusvalmiste’,

— in Swedish:

‘Modersmjölksersättning uteslutande baserad på mjölk’ and ‘Tillskottsnäring uteslutande baserad på mjölk’.

▼B

2. The labelling shall bear, in addition to those provided for in Article 3 of Directive 79/112/EEC, the following mandatory particulars:

(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 infant formulae that do not contain added iron, a statement to the effect that, when the product is given to infants over the age of four months, their total iron requirements must be met from other additional sources;

(c) 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 four months, that it should form only part of a diversified diet and that it is not to be used as a substitute for breast milk during the first four months of life;

▼M1

(d) 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;

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

▼B

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

▼M1

2a. The labelling may bear:

(a) the average quantity of nutrients mentioned in Annex III when such declaration is not covered by the provisions of paragraph 2 (e) of this Article, 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 Annex VIII, expressed as a percentage of the reference values given therein, per 100 ml of the product ready for use, provided that the quantities present are at least equal to 15 per cent of the reference values;

▼B

3. The labelling of infant formulae and follow-on formulae shall be designed to provide the necessary information about the appropriate

▼B

use of the products so as not to discourage breast-feeding. The use of the terms ‘humanized’, ‘maternalized’, or similar terms shall be prohibited. The term ‘adapted’ may only be used in conformity with paragraph 6 and Annex IV, point 1.

4. The labelling of infant formulae shall in addition bear the following mandatory particulars, preceded by the words ‘Important Notice’ or their equivalent:

(a) 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.

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

6. The labelling may bear claims concerning the special composition of an infant formula only in the cases listed in Annex IV and in accordance with the conditions laid down therein.

7. The requirements, prohibitions and restrictions referred to in paragraphs 3 to 6 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.

Article 8

1. Advertising of infant formulae shall be restricted to publications specializing in baby care and scientific publications. Member States may further restrict or prohibit such advertising. Such advertisements for infant formulae shall be subject to the conditions laid down in Article 7 (3), (4), (5), (6) and (7) (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.

Article 9

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

2. Member States shall ensure that 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

(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, whether manufactured industrially or home-prepared.

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 idealize the use of infant formulae.

3. Member States shall ensure that 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. Member States shall ensure that donations or low-price sales of supplies of infant formulae to institutions or organizations, 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.

Article 10

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive. They shall immediately inform the Commission thereof. Those provisions shall be applied in such a way as to:

— permit trade in products complying with this Directive, by 1 December 1992,

— prohibit trade in products which do not comply with this Directive, with effect from 1 June 1994.

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Article 11

This Directive is addressed to the Member States.

▼B

ANNEX I

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

NB: The values refer to the product ready for use

1. **Energy**

Minimum	Maximum
250 kJ	315 kJ
(60 kcal/100 ml)	(75 kcal/100 ml)

▼M1

2. **Protein**

(Protein content = nitrogen content × 6,38) for cows' milk proteins.

(Protein content = nitrogen content × 6,25) for soya protein isolates and protein partial hydrolysates.

The 'chemical index' shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein and the quantity of each corresponding amino acid of the reference protein.

2.1. *Formulae manufactured from cows' milk proteins*

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

For an equal energy value, the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex V); nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together.

2.2. *Formulae manufactured from protein partial hydrolysates*

Minimum	Maximum
0,56 g/100 kJ	0,7 g/100 kJ
(2,25 g/100 kcal)	(3 g/100 kcal)

For an equal energy value, the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex V); nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together.

The protein efficiency ratio (PER) and the net protein utilization (NPU) must be at least equal to those of casein.

The taurine content shall be equal to at least 10 μmoles/100 kJ (42 μmoles/100 kcal) and the L-carnitine content shall be equal to at least 1,8 μmoles/100 kJ (7,5 μmoles/100 kcal).

▼B

2.3. *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
(2,56 g/100 kcal)	(3 g/100 kcal)

Only soya protein isolates must be used in manufacturing these formulae.

The chemical index shall be equal to at least 80 % of that of the reference protein (breast milk, as defined in Annex VI).

For an equal energy value the formula must contain an available quantity of methionine at least equal to that contained in the reference protein (breast milk, as defined in Annex V).

▼B

The L-carnitine content shall be at least equal to 1,8 µmoles/100 kJ (7,5 µmoles/100 kcal).

2.4. *In all cases*, the addition of amino acids is permitted solely for the purpose of improving the nutritional value of the proteins, and only in the proportions necessary for that purpose.

3. **Lipids**

►M1 Minimum ◄	Maximum
►M1 1,05 g/100 kJ ◄	1,5 g/100 kJ
►M1 (4,4 g/100 kcal) ◄	(6,5 g/100 kcal)

3.1. The use of the following substances is prohibited:

— sesame seed oil,

— cotton seed oil,

▼M1

—————

▼B

3.2. *Lauric acid*

Minimum	Maximum
—	15 % of the total fat content

3.3. *Myristic acid*

Minimum	Maximum
—	15 % of the total fat content

3.4. *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)

▼M1

3.5. 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.

3.6. The trans fatty acid content shall not exceed 4 % of the total fat content.

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

3.8. 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)

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

▼B

4. **Carbohydrates**

Minimum	Maximum
1,7 g/100 kJ	3,4 g/100 kJ
(7 g/100 kcal)	(14 g/100 kcal)

4.1. Only the following carbohydrates may be used:

— lactose,

— maltose,

— sucrose,

▼B

— malto-dextrins,
— glucose syrup or dried glucose syrup,
— pre-cooked starch
— gelatinized starch
} naturally free of gluten

4.2. *Lactose*

Minimum	Maximum
0,85 g/100 kJ	—
(3,5 g/100 kcal)	—

This provision does not apply to formulae in which soya proteins represent more than 50 % of the total protein content.

4.3. *Sucrose*

Minimum	Maximum
—	20 % of the total carbohydrate content

4.4. *Pre-cooked starch and/or gelatinized starch*

Minimum	Maximum
—	2 g/100 ml, and 30 % of the total carbohydrate content

5. **Mineral substances**

5.1. *Formulae manufactured from cows' milk proteins*

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimun	Maximum
Sodium (mg)	5	14	20	60
Potassium (mg)	15	35	60	145
Chloride (mg)	12	29	50	125
Calcium (mg)	12	—	50	—
Phosphorus (mg)	6	22	25	90
Magnesium (mg)	1,2	3,6	5	15
Iron (mg) (1)	0,12	0,36	0,5	1,5
Zinc (mg)	0,12	0,36	0,5	1,5
Copper (µg)	4,8	19	20	80
Iodine (µg)	1,2	—	5	—
▼M1				
Selenium (2) µg	—	0,7	—	3

▼B

(1) Limit applicable to formulae with added iron.

▼M1

(2) Limit applicable to formulae with added selenium.

▼B

The calcium/phosphorus ratio shall not be less than 1,2 nor greater than 2,0.

5.2. *Formulae manufactured from soya proteins, alone or in a mixture with cows' milk proteins*

All requirements of paragraph 5.1. are applicable except those concerning iron and zinc, which are as follows:

▼B

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Iron (mg)	0,25	0,5	1	2
Zinc (mg)	0,18	0,6	0,75	2,4

6. **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)	10	—	40	—
Riboflavin (µg)	14	—	60	—
▼M1 Niacin (mg-NE)	0,2	—	0,8	—
▼B Pantothenic acid (µg)	70	—	300	—
Vitamin B_6 (µg)	9	—	35	—
Biotin (µg)	0,4	—	1,5	—
Folic Acid (µg)	1	—	4	—
Vitamin B_{12} (µg)	0,025	—	0,1	—
Vitamin C (µg)	1,9	—	8	—
Vitamin K (µg)	1	—	4	—
Vitamin E (mg α-TE) (3)	0,5/g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0,1 mg per 100 available kJ	—	0,5/g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0,5 mg per 100 available kcal	—

(1) RE = all trans retinol equivalent.
(2) In the form of cholecalciferol, of which 10 µg = 400 i.u. of vitamin D.
(3) α-TE = d-α- tocopherol equivalent.

▼M1

7. 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 exeed 1,2 mg/100 kJ (5 mg/100 kcal).

▼B

ANNEX II

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

NB: The values refer to the product ready for use

1. **Energy**

Minimum	Maximum
250 kJ/100 ml (60 kcal/100 ml)	335 kJ/100 ml (80 kcal/100 ml)

2. **Proteins**

(Protein content = nitrogen content × 6,38) for cows' milk proteins.

(Protein content = nitrogen content × 6,25) for soya protein isolates.

Minimum	Maximum
0,5 g/100 kJ (2,25 g/100 kcal)	1 g/100 kJ (4,5 g/100 kcal)

The chemical index of the proteins present shall be at least equal to 80 % of that of the reference protein (casein ►M1 or breast milk ◄ as defined in Annex VI).

The 'chemical index' shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein and the quantity of each corresponding amino acid of the reference protein.

For follow-on formulae manufactured from soya proteins, alone or in a mixture with cows' milk proteins, only protein isolates from soya may be used.

Amino acids may be added to follow-on formulae for the purpose of improving the nutritional value of the proteins, in the proportions necessary for that purpose.

►M1 For an equal energy value, these formulae must contain an available quantity of methionine at least equal to that contained in breast milk as defined in Annex V. ◄

3. **Lipids**

Minimum	Maximum
0,8 g/100 kJ (3,3 g/100 kcal)	1,5 g/100 kJ (6,5 g/100 kcal)

3.1. The use of the following substances is prohibited:

— sesame seed oil,

— cotton seed oil,

▼M1

———————

▼B

3.2. *Lauric acid*

Minimum	Maximum
—	15 % of the total fat content

3.3. *Myristic acid*

Minimum	Maximum
—	15 % of the total fat content

▼B

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

Minimum	Maximum
70 mg/100 kJ (300 mg/100 kcal): this limit applies only to follow-on formulae containing vegetable oils	—

▼M1

3.5. The trans fatty acid content shall not exceed 4 % of the total fat content.

3.6. The eruic acid content shal not exceed 1 % of the total fat content.

▼B

4. **Carbohydrates**

Minimum	Maximum
1,7 g/100 kJ (7 g/100 kcal)	3,4 g/100 kJ (14 g/100 kcal)

4.1. The use of ingredients containing gluten is prohibited.

4.2. *Lactose*

Minimum	Maximum
0,45 g/100 kJ (1,8 g/100 kcal)	—

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

4.3. *Sucrose, fructose, honey*

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

5. **Mineral substances**

5.1.

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Iron (mg)	0,25	0,5	1	2
Iodine (μg)	1,2	—	5	—

5.2. *Zinc*

5.2.1. Follow-on formulae manufactured entirely from cows' milk

Minimum	Maximum
0,12 mg/100 kJ (0,5 mg/100 kcal)	—

5.2.2. Follow-on formulae containing soya protein isolates, or mixed with cows' milk

Minimum	Maximum
0,18 mg/100 kJ (0,75 mg/100 kcal)	—

▼B

5.3. *Other mineral substances*

The concentrations are at least equal to those normally found in cows' milk, reduced, where appropriate, in the same ratio as the protein concentration of the follow-on formulae to that of cows' milk. The typical composition of cows' milk is given, for guidance, in Annex VIII.

5.4. The calcium/phosphorus ratio shall not exceed 2,0.

6. **Vitamins**

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamin A (µg-ER) (1)	14	43	60	180
Vitamin D (µg) (2)	0,25	0,75	1	3
Vitamin C (µg)	1,9	—	8	—
Vitamin E (mg α-TE) (3)	0,5/g polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0,1 mg per 100 available kJ	—	0,5/g polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0,5 mg per 100 available kcal	—

(1) RE = all trans retinol equivalent.
(2) In the form of cholecalciferol, of which10 µg = 400 u.i. of vitamin D.
(3) α-TE = d-α-tocopherol equivalent.

▼M1

7. The following nucleotides may be added:

	Maximum (1)	
	(mg/100 kJ)	(mg/100 kcal)
cytidine 5′-monophosphate	0,60	2,50
uridine 5′-monophosphate	0,42	1,75
adenosine 5′-monophosphate	0,36	1,50
guanosine 5′-monophosphate	0,12	0,50
inosine 5′-monophosphate	0,24	1,00

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

▼B

ANNEX III

NUTRITIONAL SUBSTANCES

1. **Vitamins**

Vitamin	Vitamin formulation
Vitamin A	Retinyl acetate Retinyl palmitate Beta-carotene Retinol
Vitamin D	Vitamin D_2 (ergocalciferol) Vitamin D_3 (cholecalciferol)
Vitamin B_1	Thalmin hydrochloride Thalmin mononitrate
Vitamin B_2	Riboflavin Riboflavin-5′-phosphate, sodium
Niacin	Nicotinamide Nicotinic acid
Vitamin B_6	Pyridoxine hydrochloride Pyridoxine-5′-phosphate
Folate	Folic acid
Pantothenic acid	D-pantothenate, calcium D-pantothenate, sodium Dexpanthenol
Vitamin B_{12}	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

▼B

Mineral substances	Permitted salts
	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)
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

▼B

Mineral substances	Permitted salts
	Potassium lactate
	Potassium salts of orthophosphoric acid
	Potassium hydroxide
▼M1 Selenium	Sodium selenate
	Sodium selenite

▼B

3. **Amino acids and other nitrogen compounds**

L-arginine and its hydrochloride
L-cystine and its hydrochloride
L-histidine and its hydrochloride
L-isoleucine and its hydrochloride
L-leucine and its hydrochloride
L-cysteine 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
Taurine

▼M1

cytidine 5′- monophosphate and its sodium salt
uridine 5′- monophosphate and its sodium salt
adenosine 5′- monophosphate and its sodium salt
guanosine 5′- monophosphate and its sodium salt
inosine 5′- monophosphate and its sodium salt.

▼B

4. **Others**

Choline
Choline chloride
Choline citrate
Choline bitartrate
Inositol

▼B

ANNEX IV

COMPOSITIONAL CRITERIA FOR INFANT FORMULAE, WARRANTING A CORRESPONDING CLAIM

Claim related to	Conditions warranting the claim
1. Adapted protein	The protein content is lower than 0,6 g/100 kJ (2,5 g/100 kcal) and the whey protein/casein ratio is not less than 1,0.
2. Low sodium	The sodium content is lower than 9 mg/100 kJ (39 mg/100 kcal).
3. Sucrose free	No sucrose is present.
4. Lactose only	Lactose is the only carbohydrate present.
5. Lactose free	No lactose is present ([1]).
6. Iron enriched	Iron is added.
▼M1	
7. Reduction of risk to allergy to milk proteins. This claim may include terms referring to reduced allergen of reduced antigen properties.	(a) The formulae shall satisfy the provisions laid down in Section 2.2 of Annex I and the amount of immunoreactive protein measured with methods gererally acceptable as appropriate shall be less than 1 % of nitrogen containing substances in the formulae; (b) The label shall indicate that the product must not be consumed by infants allergic to the intact proteins from which it is made unless generally accepted clinical tests provide proof of the formulae's tolerance in more than 90 % of infants (confidence interval 95 %) hypersensitive to proteins from which the hydrolysate is made; (c) The formulae administered orally should not induce sensitization, in animals, to the intact proteins from which the formulae are derived; (d) Objective and scientifically verified data as proof to the claimed properties must be available.

▼B

([1]) When determined by a method the detection limits of which will be established at a later stage.

▼B

ANNEX V

ESSENTIAL AND SEMI-ESSENTIAL AMINO ACIDS IN BREAST MILK

For the purpose of this report, the essential and semi-essential amino acids in breast milk, expressed in mg per 100 kJ and 100 kcal, are the following:

	Per 100 kJ [1]	Per 100 kcal
Arginine	16	69
Cystine	6	24
Histidine	11	45
Isoleucine	17	72
Leucine	37	156
Lysine	29	122
Methionine	7	29
Phenylalanine	15	62
Threonine	19	80
Tryptophan	7	30
Tyrosine	14	59
Valine	19	80

[1] 1 kJ = 0,239 kcal.

▼B

ANNEX VI

Amino acid composition of casein and breast milk protein

The amino acid composition of casein and breast milk protein:

(g/100 g of protein)

	Casein (1)	Breast milk (1)
Arginine	3,7	3,8
Cystine	0,3	1,3
Histidine	2,9	2,5
Isoleucine	5,4	4,0
Leucine	9,5	8,5
Lysine	8,1	6,7
Methionine	2,8	1,6
Phenylalanine	5,2	3,4
Threonine	4,7	4,4
Tryptophan	1,6	1,7
Tyrosine	5,8	3,2
Valine	6,7	4,5

(1) Amino acid content of foods and biological data on protein. *FAO Nutritional Studies, No 24, Rome 1970, items 375 and 383*.

▼B

ANNEX VII

The mineral elements in cows' milk

As a reference, the contents of mineral elements in cows' milk expressed per 100 g of solids-non-fat and per g of proteins are the following:

	Per 100 g SNF (1)	Per g of proteins
Sodium (mg)	550	15
Potassium (mg)	1 680	43
Chloride (mg)	1 050	28
Calcium (mg)	1 350	35
Phosphorus (mg)	1 070	28
Magnesium (mg)	135	3,5
Copper (µg)	225	6
Iodine	NS (2)	NS

(1) SNF: 'solids no fats'.
(2) NS: non-specified, varies widely according to season and stock farming conditions.

▼M1

ANNEX VIII

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

Nutrient	Labelling reference value
Vitamin A	(µg) 400
Vitamin D	(µg) 10
Vitamin C	(mg) 25
Thiamin	(mg) 0,5
Riboflavin	(mg) 0,8
Niacin equivalents	(mg) 9
Vitamin B6	(mg) 0,7
Folate	(µg) 100
Vitamin B12	(µg) 0,7
Calcium	(mg) 400
Iron	(mg) 6
Zinc	(mg) 4
Iodine	(µg) 70
Selenium	(µg) 10
Copper	(mg) 0,4

▼**M3**

ANNEX IX

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

▼**M3**

ANNEX X

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