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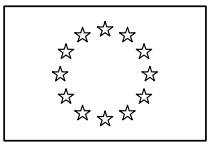

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
C(2006) final

Draft

COMMISSION DIRECTIVE

of

on infant formulae and follow-on formulae

(Text with EEA relevance)

(Recast version)

Draft

COMMISSION DIRECTIVE

of

on infant formulae and follow-on formulae

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive [89/398/EEC] of the European Parliament and of the Council of […] on foodstuffs intended for particular nutritional uses[1], and in particular Article 4 (1). thereof,

After consulting the European Food Safety Authority ("the Authority"),

Whereas:

(1) Directive [89/389/EEC] concerns foodstuffs for particular nutritional uses. The specific provisions applicable to certain groups of foods for particular nutritional uses are laid down by specific Directives.

(2) Commission Directive 91/321/EEC of 14 May 1991 on infant formulae and follow-on formulae[2] is a specific Directive adopted pursuant to Directive [89/389/EC]. That Directive has been substantially amended several times[3]. Since further amendments are to be made, it should be recast in the interests of clarity.

(3) In the light of discussions in international fora, in particular Codex Alimentarius, in relation to the timing of the introduction of complementary foods into the diet of infants it is appropriate to amend the current definitions of infant formulae and follow-on formulae and certain provisions on the labelling of follow-on formulae in Directive 91/321/EEC.

(4) Infant formula is the only processed foodstuff which wholly satisfies the nutritional requirements of infants during the first months of life until the introduction of appropriate complementary feeding. 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.

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1 OJ L […], […], p. […].

2 OJ L 175, 4.7.1991, p. 35. Directive as last amended by Commission Directive 2003/14/EC (OJ L 41, 14.2.2003, p. 37).

3 See Annex X, Part A.

(5) The essential composition of infant formulae and follow-on formulae must satisfy the nutritional requirements of infants in good health as established by generally accepted scientific data.

(6) The requirements on the essential composition of infant formulae and follow-on formulae should include detailed provisions on the protein content. Notwithstanding that traditionally different appropriate conversion factors have been used for the calculation of the protein content from the nitrogen content of different protein sources, recent scientific advice is that for the specific purposes of calculating the protein content of infant formulae and follow-on formulae it is appropriate to use a single conversion factor adapted to these products. As infant formulae and follow-on formulae are sophisticated products that are specially formulated for their intended purpose, additional essential requirements on protein, including minimum and maximum levels of protein and minimum levels of certain amino acids, should be established. The protein requirements specified in this Directive relate to the final products as such, prepared ready for consumption.

(7) 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, as well as infant formulae based on protein hydrolysates, can already be defined. The same is not true for preparations based wholly or partly on other sources of protein. For this reason specific rules for such products, if necessary, should be adopted at a later date.

(8) It is important that ingredients used in the manufacture of infant formulae and follow-on formulae are suitable for the particular nutritional use by infants and that their suitability has been demonstrated, when necessary, by appropriate studies. Guidance on the design and conduct of appropriate studies have been published by expert scientific groups such as the Scientific Committee on Food, the UK Committee on the Medical Aspects of Food and Nutrition Policy, and the European Society for Paediatric Gastroenterology, Hepatology and Nutrition. Such guidance should be taken into consideration when ingredients are introduced into infant formulae or follow-on formulae.

(9) A number of the substances that may be used in the manufacture of infant formulae and follow-on formulae may also be used in foodstuffs as food additives. In that context, purity criteria have already been or are to be adopted at Community level in accordance with Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption[4]. Those purity criteria should apply to those substances whatever the purpose of their use in foodstuffs

(10) Pending the adoption of purity criteria for substances for which such criteria has not yet been adopted at Community level, and in order to ensure a high level of protection for public health, generally acceptable purity criteria recommended by international organisations or agencies such as the Joint FAO/WHO Expert Committee on Food

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4 OJ L 40, 11.2.1989, p. 27. Directive as last amended by Regulation (EC) No. 1882/2003 of the European Parliament and the Council (OJ L 284, 31.10.2003, p. 1).

Additives (JECFA), European Pharmacopoeia (EUP) should apply. Member States should be permitted to maintain national rules setting stricter purity criteria.

(11) Given the particular nature of infant formula, additional means to those usually available to monitoring bodies should be available in order to facilitate efficient monitoring of those products.

(12) Infant formulae based on protein hydrolysates are distinct from semi-elemental diet products based on high degree hydrolysates used for the dietary management of diagnosed medical conditions, which are not covered by this Directive.

(13) This Directive reflects current knowledge about the products concerned. Any amendment, to allow innovation based on scientific and technical progress, should be decided by the procedure referred to in Article [15(2)] of Directive [89/398/EC].

(14) Maximum levels for pesticide residues set out in relevant Community legislation, in particular Council Directive 76/895/EEC of 23 November 1976 relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables[5], in Council Directive 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals[6], in Council Directive 86/363/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin[7], and in Council Directive 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables[8], should apply without prejudice to specific provisions set out in this Directive.

(15) Taking into account the Community's international obligations, in cases where the relevant scientific evidence is insufficient, the precautionary principle referred to in Article 7 of Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[9] allows the Community to provisionally adopt measures on the basis of available pertinent information, pending an additional assessment of risk and a review of the measure within a reasonable period of time.

(16) On the basis of the two opinions given by the Scientific Committee for Food on 19 September 1997 and 4 June 1998 there are at present doubts as to the adequacy of existing acceptable daily intake (ADI) values of pesticides and pesticide residues for the protection of the health of infants and young children. Therefore, as far as foodstuffs for particular nutritional uses intended for infants and young children are concerned, it is appropriate to adopt a very low common limit for all pesticides. This

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5 OJ L 340, 9.12.1976, p. 26. Directive as last amended by Commission Directive 2003/118/EC (OJ L 327, 16.12.2003, p. 25).

6 OJ L 221, 7.8.1986, p. 37. Directive as last amended by Commission Directive 2004/2/EC (OJ L 14, 21.1.2004, p. 10).

7 OJ L 221, 7.8.1986, p. 43. Directive as last amended by Directive 2004/2/EC.

8 OJ L 350, 14.12.1990, p. 71. Directive as last amended by Directive 2004/2/EC.

9 OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No. 575/2006 (OJ L 100, 8.4.2006, p. 3).

very low common limit should be fixed at 0.01 mg/kg which normally is in practice the minimum detectable level.

(17) Severe limitations on pesticide residues should be required. With careful selection of raw materials, and given that infant formulae and follow-on formulae undergo extensive processing during their manufacture, it is feasible to produce products containing very low levels of pesticide residues. However, in the case of a small number of pesticides or metabolites of pesticides even a maximum residue level of 0.01 mg/kg might, under worst-case intake conditions, allow infants and young children to exceed the ADI. This is the case for pesticides or metabolites of pesticides with an ADI lower than 0.0005 mg/kg body weight.

(18) This Directive establishes the principle of the prohibition of the use of these pesticides in the production of agricultural products intended for infant formulae and follow-on formulae. However, this prohibition does not necessarily guarantee that products are free from such pesticides, since some pesticides contaminate the environment and their residues may be found in the products concerned.

(19) Most of the pesticides which have ADI values lower than 0.0005 mg/kg body weight are already prohibited in the Community. The prohibited pesticides should not be detectable in infant formulae and follow-on formulae by state of the art analytical methods. However, some pesticides degrade slowly and still contaminate the environment. They might be present in infant formulae and follow-on formulae even if they have not been used. For the purposes of control, a harmonised approach should be followed.

(20) Pending Commission Decisions on whether they satisfy the safety requirements of Article 5 of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market[10] the continued use of authorised pesticides should be permitted as long as their residues comply with the maximum residue levels established in this Directive. The latter should be set at levels ensuring that their respective ADI values are not exceeded by infants and young children under worst-case intake conditions.

(21) The Annexes to this Directive dealing with pesticides should be amended following the completion of the review programme being carried out under Directive 91/414/EEC.

(22) Pursuant to Article [9] (1) of Directive [89/398/EEC] the products covered by this Directive are subject to the general rules laid down by Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs[11]. 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.

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10 OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2003/119/EC (OJ L 325, 12.12.2003, p. 41).

11 OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2003/89/EC (OJ L 308, 25.11.2003, p. 15).

(23) In particular, the nature and destination of the products covered by this Directive require nutritional labelling showing the energy value and principal nutrients they contain. On the other hand, the method of use should be specified in accordance with point (9) of Article 3(1) and Article 11 (2) of Directive 2000/13/EC, in order to prevent inappropriate uses likely to be detrimental to the health of infants.

(24) Given the nature of infant formulae and follow-on formulae the detailed rules as to nutrient declaration on the labelling need to be clarified in order to avoid any problems which may arise from the application of other relevant Community legislation.

(25) Regulation EC No. […] of […] on nutrition and health claims made on food[12] establishes the rules and conditions for the use of nutrition and health claims made on foods. However, Article 1(4) of that Regulation states that it shall apply without prejudice to, in particular, Directive [89/398/EEC] and Directives adopted relating to foodstuffs for particular nutritional uses.

(26) It is appropriate to set out specific conditions for the use of nutrition and health claims made on infant formulae in this Directive. In this respect, it is necessary, in order to supply objective and scientifically verified information, to define the conditions under which nutrition and health claims are authorised, and to establish a list of authorised claims. In accordance with Article 4 paragraph 1 subparagraph 3 of Directive [89/398/EEC], modification of that list of nutrition and health claims should be adopted, when necessary, after consultation of the Authority.

(27) 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 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.

(28) 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.

(29) This Directive does not concern the conditions of sale of publications specialising in baby care and of scientific publications.

(30) Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes[13] lays down compositional and labelling requirements for dietary foods for special medical purposes. The Annex to that Directive sets out values for minerals in nutritionally complete foods intended for use by infants. There has been new scientific advice as regards the minimum level of manganese in foods intended for infants. Therefore, it is appropriate to amend the levels of manganese in dietary foods for special medical purposes intended for infants set out in that Annex. Directive 1999/21/EC should therefore be amended accordingly.

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12 OJ L […], […], p.[…].

13 OJ L 91, 7.4.1999, p. 29. Directive as amended by the 2003 Act of Accession.

(31) Due to the specific nature of dietary foods for special medical purposes intended for infants and to the necessity to assess the new formulation of such products, manufacturers require a longer period to adapt their products to the essential composition that derive from the new requirements set out in this Directive.

(32) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive change as compared with the earlier Directive[s]. The obligation to transpose the provisions which are unchanged arises under the earlier Directive.

(33) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Annex X, Part B.

(34) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive is a 'specific Directive' within the meaning of Article 4 (1) 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.

Article 2

For the purposes of this Directive, the definitions of 'claim', 'nutrition claim', 'health claim' and 'reduction of disease risk claim' as set out in Articles 2(1), (4), (5) and (6) of Regulation EC No.[…] shall apply.

The following definitions shall also apply:

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

(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.

Article 3

Infant formulae and follow-on formulae may be marketed within the Community only if they comply with 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 months of life until the introduction of appropriate complementary feeding.

Article 4

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

Article 5

Infant formulae shall be manufactured from protein sources defined in point 2 of Annex I 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.

Such suitability 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.

Article 6

Follow-on formulae shall be manufactured from protein sources defined in point 2 of Annex II 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.

Such suitability 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.

Article 7

1. Infant formulae shall comply with the compositional criteria set out in Annex I taking into account the specifications in Annex V.

   In the case of infant formulae manufactured from cows’ milk protein referred to in point 2.1 of Annex I 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 referred to in point 2.2 of Annex I with a protein content between the minimum and 0.56 g/100 kJ (2.25 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 and shall be in accordance with the appropriate specifications in Annex VI.

2. Follow-on formulae shall comply with the compositional criteria set out in Annex II taking into account the specifications in Annex V.

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. The prohibitions and limitations on the use of food ingredients in infant formulae and follow-on formulae set out in Annexes I and II shall be observed.

Article 8

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:

   (a) mineral substances,

   (b) vitamins,

   (c) amino acids and other nitrogen compounds,

   (d) other substances having a particular nutritional purpose.

2. Purity criteria for substances as provided for in Community legislation concerning the use of substances listed in Annex III, in the manufacture of foodstuffs for purposes other than those covered by this Directive, shall apply.

3. 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.

Article 9

1. To facilitate efficient official monitoring of infant formulae, when a food business operator places an infant formula on the market he shall notify the competent authority of the Member States where the product is being marketed by forwarding to it a model of the label used for the product.

2. The competent authorities within the meaning of this Article are those referred to in Article [9(4)] of Directive [89/398/EEC].

Article 10

1. 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.

2. The pesticides listed in Annex VIII shall not be used in agricultural products intended for the production of infant formulae and follow-on formulae.

   However, for the purpose of control:

   (a) pesticides listed in Table 1 of Annex VIII 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 Annex VIII 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.

3. By way of derogation from paragraph 1, for the pesticides listed in Annex IX, the maximum residue levels specified therein shall apply.

4. The levels referred to in paragraphs 2 and 3 shall apply to the products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers.

Article 11

Except as provided for in Article 12, the name under which infant formulae and follow-on formulae are sold shall be, respectively:

– in Spanish:

  ‘Preparado para lactantes’ and ‘Preparado de continuación’,

– in Czech:

  ‘počáteční kojenecká výživa’ and ‘pokračovací kojenecká výživa’,

– in Danish:

  ‘Modermælkserstatning’ and ‘Tilskudsblanding’,

– in German:

‘Säuglingsanfangsnahrung’ and ‘Folgenahrung’,

– in Estonian:

‘imiku piimasegu” and “jätkupiimasegu’,

– in Greek:

‘Παρασκεύασμα για βρέφη’ and ‘Παρασκεύασμα δεύτερης βρεφικής ηλικίας’,

– in English:

‘infant formula’ and ‘follow-on formula’,

– in French:

‘Préparation pour nourrissons’ and ‘Préparation de suite’,

– in Italian:

‘Alimento per lattanti’ and ‘Alimento di proseguimento’,

– in Latvian:

‘Mākslīgais maisījums zīdaiņiem’ and ‘Mākslīgais maisījums zīdaiņiem, uzsākot papildus ēdinēšanu’,

– in Lithuanian:

‘mišinys kūdikiams iki papildomo maitinimo įvedimo’ and ‘mišinys kūdikiams, įvedus papildomą maitinimą’,

– in Hungarian:

‘anyatej-helyettesítő tápszer’ and ‘anyatej-kiegészítő tápszer’,

– in Maltese:

‘formula tat-trabi’ and ‘formula tal-prosegwiment’,

– in Dutch:

‘Volledige zuigelingenvoeding’ and ‘Opvolgzuigelingenvoeding’,

– in Polish:

‘preparat do początkowego żywienia niemowląt’ and ‘preparat do dalszego żywienia niemowląt’,

– in Portuguese:

‘Fórmula para lactentes’ and ‘Fórmula de transição’,

– in Slovak:

‘počiatočná dojčenská výživa’ and ‘následná dojčenská výživa’.

– in Slovenian:

‘začetna formula za dojenčke’ and ‘nadaljevalna formula za dojenčke’,

– in Finnish:

‘Äidinmaidonkorvike’ and ‘Vieroitusvalmiste’,

– in Swedish:

‘Modersmjölksersättning’ and ‘Tillskottsnäring’.

Article 12

The name of infant formulae and follow-on formulae manufactured entirely from cows' milk proteins, shall be respectively:

– in Spanish:

‘Leche para lactantes’ and ‘Leche de continuación,

– in Czech:

‘počáteční mléčná kojenecká výživa’ and ‘pokračovací mléčná kojenecká výživa’,

– in Danish:

‘Modermælkserstatning udelukkende baseret på mælk’ and ‘Tilskudsblanding udelukkende baseret på mælk’,

– in German:

‘Säuglingsmilchnahrung’ and ‘Folgemilch’,

– in Estonian:

‘Piimal põhinev imiku piimasegu’ and ‘Piimal põhinev jätkupiimasegu’,

– in Greek:

‘Γάλα για βρέφη’ and ‘Γάλα δεύτερης βρεφικής ηλικίας’,

– in English:

‘Infant milk’ and ‘follow-on milk’,

– in French:

‘Lait pour nourrissons’ and ‘Lait de suite’,

– in Italian:

‘Latte per lattanti’ and ‘Latte di proseguimento’,

– in Latvian:

‘Govs piens olbaltumu saturošs mākslīgais maisījums zīdaiņiem’ and ‘Govs piens olbaltumu saturošs mākslīgais maisījums zīdaiņiem, uzsākot papildus ēdinēšanu’,

– in Lithuanian:

‘pieno mišinys kūdikiams iki papildomo maitinimo įvedimo’ and ‘pieno mišinys kūdikiams vedus papildomą maitinimą’,

– in Hungarian:

‘tejalapú anyatej-helyettesítő tápszer’ and ‘tejalapú anyatej-kiegészítő tápszer’,

– in Maltese:

‘ħalib tat-trabi’ and ‘ħalib tal-prosegwiment’,

– in Dutch:

‘Volledige zuigelingenvoeding op basis van melk’ or ‘Zuigelingenmelk’ and ‘Opvolgmelk’,

– in Polish:

‘mleko początkowe’ and ‘mleko następne’,

– in Portuguese:

‘Leite para lactentes’ and ‘Leite de transição’,

– in Slovak:

‘počiatočná dojčenská mliečna výživa’ and ‘následná dojčenská mliečna výživa’,

– in Slovenian:

‘začetno mleko za dojenčke’ and ‘nadaljevalno mleko za dojenčke’,

– in Finnish:

‘Maitopohjainen äidinmaidonkorvike’ and ‘Maitopohjainen vieroitusvalmiste’,

– in Swedish:

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

Article 13

1. The labelling shall bear, in addition to those provided for in Article 3 of Directive 2000/13/EC, 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 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 Annexes I and II 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.

2. The labelling may bear:

   (a) for infant formulae and follow-on formulae the average quantity of nutrients mentioned in Annex III when such declaration is not covered by the provisions of paragraph 1(d) 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 VII, expressed as a percentage of the reference values given therein, per 100 ml of the product ready for use.

3. 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.

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 idealise 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 of infant formulae may bear nutrition and health claims only in the cases listed in Annex IV and in accordance with the conditions set out therein.

7. 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.

8. The requirements, prohibitions and restrictions referred to in paragraphs 3 to 7 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 14

1. Advertising of infant formulae shall be restricted to publications specialising 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 13(3), (4), (5), (6), (7) and (8)(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 15

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) 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. 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 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.

Article 16

1. Directive 91/321/EEC, as amended by the Directives set out in Annex X, Part A, is repealed with effect from [*dd/mm/yyyy (12 months after the last day of the month of publication+1 day)*], without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives as set out in Annex X, Part B.

2. References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex XI.

Article 17

In the Annex to Directive 1999/21/EC, the row relating to manganese set out in the second part of Table I concerning minerals, is replaced by the following:

'Manganese (µg)	0,25	25	1	100'

Article 18

The new requirements set out in paragraphs 1 and 2 of Article 7 of this Directive shall not apply to dietary foods for special medical purposes intended specifically for infants as referred to in point 4 of the Annex to Directive 1999/21/EC until [*dd/mm/yyy – (12 months after the last day of the month of publication+ 1 day) + 4 years]*.

Article 19

1. Member States shall adopt and publish, by [dd/mm/yyyy -*12 months after the last day of the month of publication*] at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

   Member States shall apply those provisions in such a way as to:

   – permit trade in products complying with this Directive by [dd/mm/yyyy -*12 months after the last day of the month of publication+1day*],

   – without prejudice to Article 18, prohibit, with effect from [dd/mm/yyyy -*12 months after the last day of the month of publication +2 years*] trade in products which do not comply with this Directive.

   When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive .

Article 20

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

Article 21

This Directive is addressed to the Member States.

Done at Brussels,

For the Commission,
Markos KYPRIANOU
Member of the Commission

ANNEX I

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

NB: The values 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 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 Article 7(1).

For an equal energy value, the formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex V. 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 providing 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 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 Article 7(1).

For an equal energy value, the formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex V. 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 providing 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 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 formulae.

For an equal energy value the formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex V). 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 providing 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 -	naturally free of gluten
– gelatinised starch -	

8.2 Lactose

Minimum	Maximum
1.1 g/100 kJ	—

(4.5 g/100 kcal) —

This provision shall not apply to 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 gelatinized 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 Article 5.

10. MINERAL SUBSTANCES

10.1 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 1.0 nor greater than 2.0.

10.2 Formulae manufactured from soya protein, alone or in a mixture with cows' milk proteins

All requirements of paragraph 10.1 shall apply except those concerning iron and phosphorus, which are 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	1500
Pantothenic acid (µg)	95	475	400	2000

Vitamin B_6 (µg)	9	42	35	175
Biotin (µg)	0.4	1.8	1.5	7.5
Folic Acid (µg)	2.5	12	10	50
Vitamin B_{12} (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 (18:2n-6); 0.75 mg α-TE/1 g α-linolenic acid (18:3n-3); 1.0 mg α-TE/1 g arachidonic acid (20:4n-6); 1.25 mg α-TE/1 g eicosapentaenoic acid (20:5n-3); 1.5 mg α-TE/1 g docosahexaenoic acid (22:6n-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).

ANNEX II

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

NB: The values 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. 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 formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex V). 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. 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 formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex V). 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 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 formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex V. 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

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	285 mg/100 kJ ⇦
(300 mg/100 kcal):	(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	3.4 g/100 kJ
(9 ⇦ g/100 kcal)	(14 g/100 kcal)

6.1 The use of ingredients containing gluten shall be prohibited.

6.2 Lactose

Minimum	Maximum
1.1 g/100 kJ	—
(4.5 g/100 kcal)	

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 Article 6.

8. MINERAL SUBSTANCES

8.1 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. Formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins

All requirements of paragraph 8.1 shall apply except those concerning iron, and phosphorus, which are as follows:

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
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	
	Minimum	Maximum	Minimum	Maximum
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	1500
Pantothenic acid (µg)	95	475	400	2000
Vitamin B_6 (µg)	9	42	35	175
Biotin (µg)	0.4	1.8	1.5	7.5
Folic Acid (µg)	2.5	12	10	50
Vitamin B_{12} (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 (18:2n-6); 0.75 mg α-TE/1 g α-linolenic acid (18:3n-3); 1.0 mg α-TE/1 g arachidonic acid (20:4n-6); 1.25 mg α-TE/1 g eicosapentaenoic acid (20:5n-3); 1.5 mg α-TE/1 g docosahexaenoic acid (22:6n-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).

ANNEX III

NUTRITIONAL SUBSTANCES

1. **Vitamins**

Vitamin	Vitamin formulation
Vitamin A	Retinyl acetate
	Retinyl palmitate
	Retinol
Vitamin D	Vitamin D_2 (ergocalciferol)
	Vitamin D_3 (cholecalciferol)
Vitamin B_1	Thiamin hydrochloride
	Thiamin 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
	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′- monophosphate and its sodium salt

uridine 5′- monophosphate and its sodium salt

adenosine 5′- monophosphate and its sodium salt

guanosine 5′- monophosphate and its sodium salt

inosine 5′- monophosphate and its sodium salt

4. Others

Choline

Choline chloride

Choline citrate

Choline bitartrate

Inositol

ANNEX IV

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	) Voluntarily added at a level that would be appropriate for the intended particular use by infants and in accordance with the conditions set out in Annex I.
1.4.3 nucleotides	)

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

Health 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 formulae shall satisfy the provisions set out in point 2.2 of Annex I 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 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;
	(d)	The formulae administered orally should not induce sensitisation, in animals, to the intact proteins from which the formulae are derived.

ANNEX V

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.

ANNEX VI

SPECIFICATION FOR THE PROTEIN SOURCE AND 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

ANNEX VII

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) 1000
Sodium	(mg) 400
Chloride	(mg) 500
Iron	(mg) 8
Zinc	(mg) 5
Iodine	(µg) 80
Selenium	(µg) 20
Copper	(mg) 0.5

Magnesium	(mg) 80
Manganese	(mg) 1.2

ANNEX VIII

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

ANNEX IX

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

ANNEX X

Part A

Repealed Directive, with its successive amendments
(referred to in Article 16)

Commission Directive 91/321/EEC[1]	(OJ L 175, 4.7.1991, p. 35)
Commission Directive 96/4/EC	(OJ L 49, 28.2.1996, p. 12)
Commission Directive 1999/50/EC	(OJ L 139, 2.6.1999, p. 29)
Commission Directive 2003/14/EC	(OJ L 41, 14.2.2003, p. 37)

Part B

List of time limits for transposition into national law
(referred to in Article 16)

Directive	Time limit for transposition	Permission of trade in products complying with this Directive	Prohibition of trade in products not complying with this Directive
91/321/EEC		1 December 1992	1 June 1994
96/4/EC	31 March 1997	1 April 1997	31 March 1999
1999/50/EC	30 June 2000	30 June 2000	1 July 2002
2003/14/EC	6 March 2004	6 March 2004	6 March 2005

[1] Directive 91/321/EEC was also amended by the following non-repealed Acts:
- Act of Accession of Austria, Finland and Sweden;
- 2003 Act of Accession.

ANNEX XI

CORRELATION TABLE

Directive 91/321/EEC	This Directive
Article 1(1)	Article 1
Article 1(2)	Article 2
Article 2	Article 3
Article 3(1)	Article 5
Article 3(2)	Article 6
Article 3(3)	Article 7(4)
Article 4	Article 7(1) to (3)
Article 5(1), first subparagraph	Article 8(1)
Article 5(1), second subparagraph	Article 8(2) and (3)
Article 5(2)	—
—	Article 9
Article 6(1) , first sentence	Article 4
Article 6(1), second sentence	—
Article 6(2)	Article 10(1)
Article 6(3)(a), introductory phrase	Article 10(2), introductory phrase
Article 6(3)(a)(i)	Article 10(2)(a)
Article 6(3)(a)(ii)	Article 10(2)(b)
Article 6(3)(b), first subparagraph	Article 10(3)
Article 6(3)(b), second subparagraph	—
Article 6(3)(c)	Article 10(4)
Article 6(4)	—
Article 7(1), first subparagraph	Article 11
Article 7(1), second subparagraph	Article 12

Article 7(2)(a)	Article 13(1)(a)
Article 7(2)(b)	—
Article 7(2)(c)	Article 13(1)(b)
Article 7(2)(d)	Article 13(1)(c)
Article 7(2)(e)	Article 13(1)(d)
Article 7(2)(f)	Article 13(1)(e)
Article 7(2a)	Article 13(2)
Article 7(3)	Article 13(3)
Article 7(4)	Article 13(4)
Article 7(5)	Article 13(5)
Article 7(6)	Article 13(6)
—	Article 13(7)
Article 7(7)	Article 13(8)
Article 8	Article 14
Article 9	Article 15
Article 10	—
—	Article 16
—	Article 17
—	Article 18
—	Article 19
—	Article 20
Article 11	Article 21
Annexes I to V	Annexes I to V
Annex VI	—
Annex VII	—
—	Annex VI
Annexes VIII to X	Annexes VII to IX

—	Annex X
—	Annex XI