COMMISSION OF THE EUROPEAN COMMUNITIES

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Working Document

Draft

COMMISSION DIRECTIVE ../../EC

of [...]

on infant formulae and follow-on formulae

(Recast version)

This is a preliminary working document and does not necessarily reflect the views of the European Commission.

Draft

COMMISSION DIRECTIVE ../../EC

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,

Whereas:

(1) ⊠ Commission Directive 91/321/EEC of 14 May 1991 on infant formulae and follow-on formulae[2] has been substantially amended several times[3] and a number of substantial changes are to be made to the Directive. In the interests of clarity that Directive should be codified and recast ⊠.

~~(1) Commission Directive 91/321/EEC of 14 May 1991 on infant formulae and follow-on formulae has been substantially amended several times. In the interests of clarity and rationality the said Directive should be codified.~~

(2) 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.

(3) 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 ~~partial~~ 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 ~~therefore~~ be adopted at a later date.

(4) ⊠ It is important that other ingredients used in the manufacture of infant formulae and follow-on formulae are suitable for the particular nutritional use by infants and

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1 ~~OJ L 186, 30.6.1989, p. 27.~~ ⊠ OJ L [...], [...], p. [...]. ⊠

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

3 See Annex XI, Part A.

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.

(5) Given the particular nature of infant formulae, additional means to those usually available to monitoring bodies should be available in order to facilitate efficient monitoring of new ingredients included in these products and for certain products that have levels of protein close to the minimum level. Therefore, manufacturers or, where a product is manufactured in a third State, the importer, shall notify the competent authority of the Member State where the product is being marketed.

(6) In order to facilitate the application of the provisions relating to the notification of the placing on the market of infant formula containing new ingredients, it is appropriate to provide for systems for the exchange of information between Member States and between the Member States and the Commission. ⌫

(7) Infant formulae ⌦ and follow-on ⌫based on protein ~~partial~~ 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.

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

(9) Because of the persons for ~~which~~⌦ whom ⌫ the products are intended ~~it will be necessary to lay down~~ microbiological criteria and maximum levels for contaminants ⌦ should be laid down ⌫. ~~Given the complexity of the subject these should be adopted at a later stage.~~

(10) Different rules on the maximum levels of pesticide residues in the products concerned cause trade barriers between certain Member States.

(11) Maximum levels for pesticide residues stipulated in 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[4], in Council Directive 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticides residues in and on cereals[5], 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[6], and in Council Directive 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in and

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4 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).

5 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).

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

on certain products of plant origin, including fruit and vegetables[7], are without prejudice to specific provisions applicable to infant formulae and follow-on formulae.

(12) Taking into account the Community's international obligations, in cases where the relevant scientific evidence is insufficient, the precautionary principle 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.

(13) 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 values (ADI) of pesticides and pesticide residues for the protection of the health of infants and young children.

(14) 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.

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

(16) 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.

(17) 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) The health of infants and young children can be better protected by applying additional requirements which can be enforced by analysis regardless of a product's origin.

(20) 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.

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

(21) 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[8] 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.

(22) Infant formula is the only processed foodstuff which wholly satisfies the nutritional requirements of infants during the first ~~four to six~~ months of life ⌦ up to 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.

(23) Pursuant to Article ⌦ [9] ⌫ ~~7~~(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. 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.

(24) 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.

(25) 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.

(26) Pursuant to Article 2(2) of Directive 2000/13/EC, 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 authorised. ⌦ Health claims on infant formula should only be authorised for use on the Community market after a scientific assessment of these claims by the European Food Safety Authority. ⌫

(27) ⌦ In certain cases it is useful for consumers to have additional information on the composition of infant formulae with respect to certain specific aspects that are relevant to ethical or religious considerations. Therefore it is appropriate to amend the Directive to permit statements on a product that reflect religious or other considerations which might influence dietary choices. ⌫

(28) 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

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[8] 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).

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.

(29) 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.

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

(31) On the provisions liable to affect public health, the consultation in accordance with Article 4 of Directive [89/398/EEC] has taken place.

(32) Issues relating to products intended for export to third countries should be dealt with in a coherent and homogeneous manner in a separate measure.

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

(34) ⊠ 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. The obligation to transpose the provisions which are unchanged arises under the earlier Directive. ⌫

(35) 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 XII, Part B,

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 following definitions shall apply:

(a) 'infants' means children under the age of twelve 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 ⊠ up to the introduction of appropriate complementary feeding ⊠;

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

(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

Member States shall ensure that the products referred to in points (c) and (d) of Article 2 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 ⊠ up to the introduction of appropriate complementary feeding ⊠.

Article 4

1. Infant formulae shall be manufactured from protein sources defined in 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 safety considerations including, as necessary, appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies. ⊠

2. ⊠ When an infant formula containing an ingredient which has not been used in the manufacture of infant formula before [date of entry into force], is placed on the market it shall be notified according to the procedure in Article 5. ⊠

3. Follow-on formulae shall be manufactured from protein sources defined in Annex II and other food ingredients⊠ , ⊠ as the case may be⊠ , ⊠ whose suitability for particular nutritional use by infants aged over ~~four~~ ⊠ 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 safety considerations, including, as necessary, appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies. ⊠

⊠ 4. ⊠ The prohibitions and limitations on the use of food ingredients laid down in Annexes I and II shall be observed.

Article 5

1. The following notification procedure shall apply when the requirement to notify the placing on the market of an infant formula is mentioned in Article 4(2) or Annex I, point 2.1 or 2.2.

When the product is placed on the market for the first time the manufacturer or, where the product is manufactured in a third State, the importer, shall notify the competent authority of the Member State where the product is being marketed by forwarding it a model of the label used for the product.

Where the same product is subsequently placed on the market in another Member State the manufacturer or, where appropriate, the importer, shall provide the competent authority of that Member State with the same information, together with an indication of the recipient of the first notification.

The competent authority shall be empowered to require the manufacturer or, where appropriate, the importer, to produce the scientific work and the data establishing the suitability of the ingredient for particular nutritional use by infants from birth.

2. The Commission shall organise an exchange of information between the competent authorities of the Member States and between the competent authorities of Member States and itself concerning notifications under this Article.

Member States shall designate the authority or authorities which are to be responsible for the exchange of information under this paragraph and shall inform the Commission accordingly.

Detailed guidance for implementing this paragraph may be adopted in accordance with the procedure laid down in [Article 13 of Directive 89/398/EEC].

3. Where a Member State has detailed scientific grounds for establishing that the suitability of an infant formula containing an ingredient that is subject to this notification procedure has not been demonstrated, albeit freely circulating in one or more Member States, that Member State may temporarily suspend or restrict trade in that product within its territory. It shall immediately inform the Commission and the other Member States and give reasons for its decision.

The Commission shall examine as soon as possible the grounds adduced by the Member State concerned, consult the Member States within the Standing Committee on the Food Chain and Animal Health, and shall then deliver its opinion without delay, if necessary after consultation of the European Food Safety Authority (henceforth referred to as the "Authority").

Depending on the outcome of the consultations mentioned above the Commission shall take, if necessary, appropriate measures at the Community level.

Article 6

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 7

⊠ 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. Purity criteria for substances listed in Annex III specified by Community legislation for their use in the manufacture of foodstuffs for purposes other than those covered by this Directive, shall apply.

3. For those substances listed in Annex III for which purity criteria are not specified by Community legislation, and until the adoption of such specifications, generally acceptable purity criteria recommended by international bodies shall apply. National rules setting stricter purity criteria may be maintained. ◁

Article 8

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, 3 and 4 shall be established.

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.

3. The pesticides listed in Annex ~~IX~~⊠ 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 ~~IX~~⊠ VII ◁ 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 ~~IX~~ VII 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.

4. By way of derogation from paragraph 2, for the pesticides listed in Annex ~~X~~ VIII, the maximum residue levels specified therein shall apply.

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

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

7. Microbiological criteria shall be established as necessary.

Article 9

1. The name under which the products defined in points (c) and (d) of Article 2 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:

– "Maisījums zīdaiņiem līdz četru-sešu mēnešu vecumam" and "Maisījums zīdaiņiem no četru mēnešu vecuma",

– in Lithuanian:

"mišinys kūdikiams iki 4 – 6 mėn" and "mišinys kūdikiams, vyresniems kaip 4 mėn",

– 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'.

However, the name of products 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:

"Piens zīdaiņiem līdz četru-sešu mēnešu vecumam" and "Piens zīdaiņiem no četru mēnešu vecumam",

– in Lithuanian:

"pieno mišinys kūdikiams iki 4 – 6 mėn" and "pieno mišinys kūdikiams, vyresniems kaip 4 mėn",

– 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~~go~~" 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'.

2. 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 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)~~ ⊠ (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 ~~four~~ ⊠ six ⊠ 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~~ ⊠ six ⊠ months of life. ⊠ In addition, the label shall include a statement to the effect 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. ⌫;

~~(d)~~ ⌦ (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;

~~(e)~~ ⌦ (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 ~~and taurine~~, expressed in numerical form, per 100 ml of the product ready for use;

~~(f)~~ ⌦ (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 ⌫.

3. 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)~~ ⌦ (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 ~~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].

4. 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 'humanized', 'maternalized',⌦ 'adapted', ⌫or similar terms shall be prohibited. ~~The term 'adapted' may only be used in conformity with paragraph 6~~ ⌦ ~~7~~ ⌫ ~~and Annex IV, point 1.~~

5. 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.

6. 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.

7. The labelling may bear ⌦ nutrition and health ⌫ 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. ⌦ Amendments to the list of such claims shall be adopted

in accordance with the procedure referred to in the procedure referred to in Article 12 of this Directive. ⌫

⌦ 8. In addition, the labelling of infant formulae may bear statements concerning the suitability of the product for use in a diet whose composition is influenced by religious or other considerations affecting food choice.

9. Infant formulae and follow-on formulae shall be labelled in such a way as to avoid any risk of confusion between infant formulae and follow-on formulae. ⌫

~~8~~⌦ 10 ⌫. The requirements, prohibitions and restrictions referred to in paragraphs 4 to 9 shall also apply to:

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

(b) advertising.

Article 10

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 9(4), (5), (6), (7) ⌦ , ⌫ ~~and~~ (8) ⌦ , (9) and (10) ⌫ (b) and contain only information of a scientific and factual nature. Such information shall not imply or create a belief that bottle-feeding is equivalent or superior to breast-feeding.

2. There shall be no point-of-sale advertising, giving of samples or any other promotional device to induce sales of infant formula directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales.

3. Manufacturers and distributors of infant formulae shall not provide, to the general public or to pregnant women, mothers or members of their families, free or low-priced products, samples or any other promotional gifts, either directly or indirectly via the health care system or health workers.

Article 11

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~~, whether manufactured industrially or home-prepared, as the case may be~~.

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 12

⊠ 1. Amendments to the list of nutrition claims shall be adopted in accordance with the procedure referred to in Article [13 of Directive 89/398/EEC] and, where appropriate, after consulting the Authority.

2. Amendments to the list of health claims shall be adopted in accordance with the following procedure:

(a) The application for authorisation of a health claim for infant formulae shall be sent to the Commission. The Commission shall:

(i) acknowldege receipt of an application in writing within 14 working days of its receipt. The acknowledgement shall state the date of receipt of the application.

(ii) inform without delay the Authority; and

(iii) make the application and any supplementary information supplied by the applicant available to the Authority;

(b) The Authority shall:

(i) inform without delay the Member States of the application and shall make the application and any supplementary information supplied by the applicant available to them;

(ii) make the summary of the application referred to in paragraph 3(g) available to the public.

3. The application shall include the following:

(a) the name and address of the applicant;

(b) the nutrient or other substance in respect of which the health claim is to be made and its particular characteristics;

(c) a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out with regard to the health claim and any other material which is available to substantiate the health claim;

(d) where appropriate, an indication of the information which should be regarded as proprietary accompanied by verifiable justification;

(e) a copy of other scientific studies which are relevant to the health claim;

(f) a proposal for the wording of the health claim for which authorisation is sought including, as the case may be, specific conditions for use;

(g) a summary of the application.

4. In giving its opinion, the Authority shall endeavour to respect a time limit of six months from the date of receipt of a valid application. Such time limit shall be extended whenever the Authority seeks supplementary information from the applicant as provided for in paragraph 5.

5. The Authority or a national competent authority through the Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a specified time limit.

6. In order to prepare its opinion, the Authority shall:

(a) verify that the proposed wording of the health claim is substantiated by scientific data;

(b) give advice on whether the proposed wording of the health claim is understandable and meaningful to the average consumer.

7. In the event of an opinion in favour of authorising the health claim, the opinion shall include the following particulars:

(a) the name and address of the applicant;

(b) the nutrient or other substance in respect of which a claim is to be made and its particular characteristics;

(c) the recommended wording of the proposed health claim, including, as the case may be, the specific conditions of use.

8. The Authority shall forward its opinion to the Commission, the Member States and the applicant, including a report describing its assessment of the health claim and stating the reasons for its opinion and the information on which its opinion was based.

9. The Authority in conformity with Article 38(1) of Regulation (EC) No 178/2002 shall make its opinion public.

The applicant or members of the public may make comments to the Commission within 30 days from such publication.

10. Within three months after receiving the opinion of the Authority, the Commission shall submit to the Committee referred to in Article [13 of Directive 89/398/EEC] a draft measure amending the list of permitted health claims, taking into account the opinion of the Authority, any relevant provisions of Community law and other legitimate factors relevant to the matter under consideration. Where the draft measure is not in accordance with the opinion of the Authority, the Commission shall provide an explanation for the differences.

Any draft measure to amend the list of permitted health claims shall include the particulars referred to in paragraph (7) (b) and (c) of this Article.

Amendments to the list of health claims shall be adopted in accordance with the procedure referred to in Article [13 of Directive 89/398/EEC]. ⌫

Article ⌦ 13 ⌫

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

   They shall apply those provisions from [*12 months after the last day of the month of publication +1day*].

   They shall prohibit, with effect from [*12 months after the last day of the month of publication +2 years*] trade in products which are not in conformity 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 ⌦ 14 ⌫

Directive 91/321/EEC, as amended by the Acts listed in Annex IX, Part A, is hereby repealed, with effect from ⌦ [*12 months after the last day of the month of publication +2 years*]

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 IX, Part B. ⌫.

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 X.

Article ⌦ 15 ⌫

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

Article ⌦ 15 ⌫

This Directive is addressed to the Member States.

Done at Brussels,

For the Commission,
[...]
Member of the Commission

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 /100 ml	~~315~~⌦ 295 ⌫ kJ /100 ml
(60 kcal/100 ml)	(~~75~~⌦ 70 ⌫ kcal/100 ml)

2. PROTEIN

(Protein content = nitrogen content × ~~6.38~~⌦ 6.25 ⌫) for cows' milk proteins.

(Protein content = nitrogen content × 6.25) for soya protein isolates and protein 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)

In the case of infant formula with a protein content between the minimum and 0.5 g/100 kJ (2 g/100 kcal), the suitability of the product for the particular nutritional use of infants shall be demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies. The placing on the market of such a product shall be notified according to the procedure in Article 5.

For an equal energy value, the formula must contain an available quantity of each ~~essential and semi-essential~~ ⌦ 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 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 ~~partial~~ hydrolysates

Minimum	Maximum
~~0.56~~ ⌦ 0.45 ⌫ g/100 kJ	0.7 g/100 kJ
(~~2.25~~⌦ 1.8 ⌫ g/100 kcal)	(3 g/100 kcal)

In the case of infant formula with a protein content between the minimum and 0.56 g/100 kJ (2.25 g/100 kcal), the suitability of the product for the particular nutritional use of infants shall be demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies. The placing on the market of such a product shall be notified according to the procedure in Article 5.

For an equal energy value, the formula must contain an available quantity of each ~~essential and semi-essential~~ ⌦ 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:phenylanalnine 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 is demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies . ⌫

~~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).

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 ~~soya~~ protein isolates ~~must~~ ⌦ from soya shall ⌫ 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~~ ⊠ 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:phenylanalnine 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 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 1.8 μmoles/100 kJ (7.5 μmoles/100 kcal).

2.4. **In all cases, ~~the addition of~~ amino acids ~~is permitted~~ ⊠ 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, ⊠ 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)

~~3.~~ ⊠ 5. ⊠ **LIPIDS**

Minimum	Maximum
1.05 g/100 kJ	~~1.5~~⊠ 1.43 ⊠ g/100 kJ
(4.4 g/100 kcal)	(~~6.5~~⊠ 6.0 ⊠ g/100 kcal)

~~3.1~~⊠ 5.1 ⊠ The use of the following substances shall be prohibited:

– sesame seed oil,

– cotton seed oil.

~~3.2~~⊠ 5.2 ⊠ **Lauric acid⊠ and myristic acid ⊠**

Minimum	Maximum
—	⊠ separately or as a whole: ⊠

~~15~~ ⊠ 20 ⊠ % of the total fat content

~~3.3 Myristic acid~~

~~Minimum~~	~~Maximum~~
~~—~~	~~15 % of the total fat content~~

⊠ 5.3 ⊠ The trans fatty acid content shall not exceed 4⊠ 3 ⊠ % of the total fat content.

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

~~3.4~~⊠ 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)

~~3.5.~~ The alpha-linolenic acid content shall not be less than 12 mg/100 kJ (50mg/100 kcal).

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

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

~~3.6 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 ⊠ (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. ⊠

⊠ 6. PHOSPHOLIPIDS

The amount of phospholipids 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) ⌫

~~4.~~⌦ 8. ⌫ CARBOHYDRATES

Minimum	Maximum
~~1.7~~⌦ 2.2 ⌫ g/100 kJ	3.4 g/100 kJ
(~~7~~⌦ 9 ⌫ g/100 kcal)	(14 g/100 kcal)

~~4.1.~~⌦ 8.1. ⌫ Only the following carbohydrates may be used:

- lactose,
- maltose,
- ~~sucrose,~~
- malto-dextrins,
- glucose syrup or dried glucose syrup,
- pre-cooked starch) naturally free of gluten
- gelatinized starch)
- ⌦ Sucrose may only be added to formulae based on protein hydrolysates. If added, the sucrose content shall not exceed 20 % of the total carbohydrate content. ⌫
- ⌦ Glucose may only be added to formulae based on protein hydrolysates. If added, the glucose content shall not exceed 0.5 g/100 kJ (2 g/100 kcal). ⌫

~~4.2.~~⌦ 8.2. ⌫ **Lactose**

Minimum	Maximum
~~0.85~~⌦ 1.1 ⌫ g/100 kJ	—
(~~3.5~~⌦ 4.5 ⌫ g/100 kcal)	—

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

~~4.3. Sucrose~~

~~Minimum~~	~~Maximum~~
—	~~20 % of the total carbohydrate content~~

~~4.4.~~⊠ 8.3. ◁ **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-oligosacharides may be added. 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-oligosacharides may be used in accordance with the provisions of Article 4 (1).

~~5.~~⊠ 10. ◁ **MINERAL SUBSTANCES**

~~5.1.~~⊠ 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	~~35~~⊠ 38 ◁	60	~~145~~⊠ 160 ◁
Chloride (mg)	12	~~29~~⊠ 38 ◁	50	~~125~~⊠ 160 ◁
Calcium (mg)	12	—⊠ 33 ◁	50	— ⊠ 140 ◁
Phosphorus (mg)	6	22	25	90
Magnesium (mg)	1.2	3.6	5	15
Iron (mg)[+]	~~0.12~~⊠ 0.07 ◁	~~0.36~~⊠ 0.3 ◁	~~0.5~~⊠ 0.3 ◁	~~1.5~~⊠ 1.3 ◁
Zinc (mg)	0.12	0.36	0.5	1.5
Copper (μg)	~~4.8~~⊠ 8.4 ◁	~~19~~⊠ 24 ◁	~~20~~⊠ 35 ◁	~~80~~⊠ 100 ◁
Iodine (μg)	~~1.2~~⊠ 2.4 ◁	— ⊠ 12.5 ◁	~~5~~⊠ 10 ◁	—⊠ 50 ◁

Selenium[3] (μg)	— ⌦ 0.25 ⌫	~~0.7~~⌦ 2.2 ⌫	—⌦ 1 ⌫	~~3~~⌦ 9 ⌫
⌦ Manganese (μg)	0.25	24	1	100 ⌫
⌦ Fluoride (μg)	—	24	—	100 ⌫

~~[2] Limit applicable to formulae with added iron.~~

~~[3] Limit applicable to formulae with added selenium.~~

The calcium/phosphorus ratio shall not be less than ~~1.2~~⌦ 1.0 ⌫ nor greater than 2.0.

~~5.2.~~⌦ 10.2. ⌫ Formulae manufactured from soya proteins ⌦ isolates ⌫, alone or in a mixture with cows' milk proteins

All requirements of paragraph ~~5.1.~~⌦ 10.1 ⌫ shall be applicable except those concerning iron and ~~zinc~~⌦ phosphorus ⌫, which are as follows:

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Iron (mg)	~~0.25~~⌦ 0.12 ⌫	0.5	~~1~~⌦ 0.45 ⌫	2
~~Zinc (mg)~~	~~0.18~~	~~0.6~~	~~0.75~~	~~2.4~~
⌦ Phosphorus (mg)	7.2	24	30	100 ⌫

~~6.~~⌦ 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)	~~10~~⌦ 14 ⌫	—⌦ 75 ⌫	~~40~~⌦ 60 ⌫	— ⌦ 300 ⌫
Riboflavin (μg)	~~14~~⌦ 19 ⌫	—⌦ 96 ⌫	~~60~~⌦ 80 ⌫	—⌦ 400⌫
Niacin (~~mg NE~~⌦ μg ⌫)[3]	~~0.2~~⌦ 75 ⌫	— ⌦ 375 ⌫	~~0.8~~⌦ 300 ⌫	— ⌦ 1500 ⌫
Pantothenic acid (μg)	~~70~~⌦ 96 ⌫	— ⌦ 480 ⌫	~~300~~⌦ 400 ⌫	— ⌦ 2000 ⌫
Vitamin B_6 (μg)	9	—⌦ 42 ⌫	35	—

				⌦ 175 ⌫
Biotin (μg)	0.4	—⌦ 1.8 ⌫	1.5	—⌦ 7.5 ⌫
Folic Acid (μg)	~~1~~⌦ 2.5 ⌫	— ⌦ 12.5 ⌫	~~4~~⌦ 10 ⌫	—⌦ 50 ⌫
Vitamin B_{12} (μg)	0.025	— ⌦ 0.125 ⌫	0.1	—⌦ 0.5 ⌫
Vitamin C (mg)	~~1.9~~⌦ 2.5 ⌫	—⌦ 7.5 ⌫	~~8~~⌦ 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 number of 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 number of 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] ~~NE = Niacin equivalent = mg nicotinic acid + mg tryptophan/60~~ 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). ⌫

~~7.~~ ⌦ 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 product ready for use

1. **ENERGY**

Minimum	Maximum
250 kJ/100 ml	~~335~~ ⊠ 295 ⊠ kJ/100 ml
(60 kcal/100 ml)	(~~80~~ ⊠ 70 ⊠ kcal/100 ml)

2. **PROTEINS**

(Protein content = nitrogen content × ~~6.38~~ ⊠ 6.25 ⊠) for cows' milk proteins.

(Protein content = nitrogen content × 6.25) for soya protein isolates ⊠ and protein hydrolysates ⊠.

~~Minimum~~	~~Maximum~~
~~0,5 g/100 kJ~~	~~1 g/100 kJ~~
~~(2,25 g/100 kcal)~~	~~(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 or breast milk as defined in Annex VI).~~

~~The 'chemical index' shall mean the lowest of the ratios between the quantity of each essential ⊠ indispensable ⊠ 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.~~

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:phenylanalnine 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:phenylanalnine 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:phenylanalnine 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.

~~→ 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. TAURINE

If added, the amount of taurine shall not be greater than 2.9 mg/100 kJ (12 mg/100 kcal).

~~3.~~⌦ 4. ⌫ **LIPIDS**

Minimum	Maximum
~~0.8~~⌦ 0.96 ⌫ g/100 kJ	~~1.5~~⌦ 1.43 ⌫ g/100 kJ
(~~3.3~~⌦ 4.0 ⌫ g/100 kcal)	(~~6.5~~⌦ 6.0 ⌫ g/100 kcal)

~~3.1~~⌦ 4.1 ⌫ The use of the following substances shall be prohibited:

- sesame seed oil,
- cotton seed oil,

~~3.2.~~⌦ 4.2. ⌫ **Lauric acid⌦ and myristic acid ⌫**

Minimum	Maximum
—	⌦ separately or as a whole: ⌫
	~~15~~⌦ 20 ⌫ % of the total fat content

~~3.3 Myristic acid~~

~~Minimum~~	~~Maximum~~
~~—~~	~~15 % of the total fat content~~

~~3.4.~~⌦ 4.3. ⌫ **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 kJ ⌫
~~this limit shall apply only to follow-on formulae containing vegetable oils~~	

4.4 The *trans* fatty acid content shall not exceed 4⌦ 3 ⌫ % of the total fat content.

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

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

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

4.8 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 (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 shall not be greater than 2 g/L.

~~4.~~ ⟩ 6. ⟨ CARBOHYDRATES

Minimum	Maximum
~~1.7~~ ⟩ 2.2 ⟨ g/100 kJ	3.4 g/100 kJ
(~~7~~ ⟩ 9 ⟨ g/100 kcal)	(14 g/100 kcal)

~~4.1~~ ⟩ 6.1 ⟨ The use of ingredients containing gluten shall be prohibited.

~~4.2~~ ⟩ 6.2 ⟨ Lactose

Minimum	Maximum
~~0.45~~ ⟩ 1.1 ⟨ g/100 kJ	—
(~~1.8~~ ⟩ 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.

~~4.3~~ ⟩ 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 *Clostridim botulinum*. ⟨

6.4 Glucose

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

7. FRUCTO-OLIGOSACCHARIDES AND GALACTO-OLIGOSACHARIDES

Fructo-oligosaccharides and galacto-oligosacharides may be added. 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-oligosacharides may be used in accordance with the provisions of Article 4 (3).

~~5.~~⌦ 8. ⌫ MINERAL SUBSTANCES

~~5.1~~⌦ 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)	~~0.25~~⌦ 0.14 ⌫	0.5	~~1~~⌦ 0.6 ⌫	2
Zinc (mg)	0.12	— ⌦ 0.36 ⌫	0.5	— ⌦ 1.5 ⌫
⌦ Copper (μg)	8.4	24	35	100 ⌫
Iodine (μg)	~~1.2~~⌦ 2.4 ⌫	— ⌦ 12.5 ⌫	~~5~~⌦ 10 ⌫	—⌦ 50 ⌫
⌦ Selenium (μg)	0.25	2.2	1	9 ⌫
⌦ Manganese (μg)	0. 25	24	1	100 ⌫
⌦ Fluoride (μg)	—	24	—	100 ⌫

The calcium/phosphorus ratio shall not ⌦ be less than 1.0 nor greater than ⌫~~exceed~~ 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 be applicable except those concerning iron and phosphorus, which are as follows:

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
⊠ Iron (mg)	0.22	0.6	0.9	2.5 ⊠
⊠ Phosphorus (mg)	7.2	24	30	100 ⊠

~~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)~~	

~~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.⊠ 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	75	60	300 ⊠
⊠ Riboflavin (μg)	19	96	80	400 ⊠
⊠ Niacin (μg) [3] ⊠	75	375	300	1500 ⊠

⊠ Pantothenic acid (μg)	96	480	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	12.5	10	50 ⊠
⊠ Vitamin B_{12} (μg)	0.025	0.12	0.1	0.5 ⊠
Vitamin C (mg)	~~1.9~~⊠ 2.5 ⊠	—⊠ 7.5 ⊠	~~8~~⊠ 10 ⊠	—⊠ 30 ⊠
⊠ Vitamin K (μg)	1	6	4	25 ⊠
Vitamin E (mg α-TE)[3⊠ 4 ⊠]	0.5⊠ mg ⊠/g of polyunsaturated fatty acids expressed as linoleic acid ⊠ as corrected for the number of double bonds [5] ⊠ but in no case less than 0.1 mg per 100 available kJ	—⊠ 1.2 ⊠	0.5⊠ mg ⊠/g of polyunsaturated fatty acids expressed as linoleic acid ⊠ as corrected for the number of 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] ~~NE = Niacin equivalent = mg nicotinic acid + mg tryptophan/60~~. Preformed niacin.

[3⊠ 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). ⊠

~~7.~~⊠ 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
	~~Beta-carotene~~
	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-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- 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

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

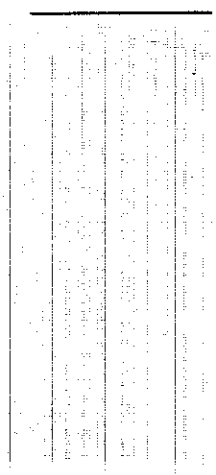
Choline

Choline chloride

Choline citrate

Choline bitartrate

Inositol



ANNEX IV

COMPOSITIONAL CRITERIA FOR INFANT FORMULAE, WARRANTING A CORRESPONDING CLAIM

⊠ 1. NUTRITION CLAIMS ⊠

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.~~⊠ 1.1. ⊠ Lactose only	Lactose is the only carbohydrate present.
~~5.~~⊠ 1.2. ⊠ Lactose free	~~No lactose is present~~⊠ Lactose content is not greater than 2.4 mg/100 kJ (10 mg/100 kcal) ⊠
~~6. Iron enriched~~	~~Iron is added.~~
⊠ 1.3. Added LCP or an equivalent 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 Claims on the addition of the following optional ingredients:	
1.4.1 taurine)	Voluntarily added at a level that would be appropriate for the intended particular use of infants and in accordance with the conditions specified in Annex I.
1.4.2 fructo- oligosaccharides) and galacto-oligosaccharides)	
1.4.3 nucleotides)	

⊠ 2. HEALTH CLAIMS ⊠

⊠ Claim related to ⊠		⊠ Conditions warranting the claim ⊠
~~7.~~ ⊠ 2.1. ⊠ Reduction of risk to allergy to milk proteins. This claim may include terms referring to reduced	(a)	Objective and scientifically verified data as proof to the claimed properties must be available.
	(b)	The formulae shall satisfy the provisions laid down in Section 2.2 of Annex I and the amount of

allergen or reduced antigen properties.		immunoreactive protein measured with methods gererally 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 sensitization, in animals, to the intact proteins from which the formulae are derived;

~~* When determined by a method the detection limits of which will be established at a later stage.~~

ANNEX V

~~ESSENTIAL AND SEMI-ESSENTIAL~~ ⊠ INDISPENSABLE AND CONDITIONALLY INDISPENSABLE ⊠ AMINO ACIDS IN BREAST MILK

For the purpose of this Directive, the ~~essential and semi-essential~~ ⊠ indispensable and conditionally indispensable ⊠ amino acids in breast milk, expressed in mg per 100 kJ and 100 kcal, shall be the following:

	Per 100 kJ[1]	Per 100 kcal
~~Arginine~~	~~16~~	~~69~~
Cystine	~~6~~⊠ 9 ⊠	~~24~~⊠ 38 ⊠
Histidine	~~11~~⊠ 10 ⊠	~~45~~⊠ 40 ⊠
Isoleucine	~~17~~⊠ 22 ⊠	~~72~~⊠ 90 ⊠
Leucine	~~37~~⊠ 40 ⊠	~~156~~⊠ 166 ⊠
Lysine	~~29~~⊠ 27 ⊠	~~122~~⊠ 113 ⊠
Methionine	~~7~~⊠ 5 ⊠	~~29~~⊠ 23 ⊠
Phenylalanine	~~15~~⊠ 20 ⊠	~~62~~⊠ 83 ⊠
Threonine	~~19~~⊠ 18 ⊠	~~80~~⊠ 77 ⊠
Tryptophan	~~7~~⊠ 8 ⊠	~~30~~⊠ 32 ⊠
Tyrosine	~~14~~⊠ 18 ⊠	~~59~~⊠ 76 ⊠
Valine	~~19~~⊠ 21 ⊠	~~80~~⊠ 88 ⊠

[1] 1 kJ = 0.239 kcal.

~~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~~ ~~2.1~~
~~Histidine~~	~~2.9~~	~~2.5~~ ~~2.2~~
~~Isoleucine~~	~~5.4~~	~~4.0~~ ~~5.0~~
~~Leucine~~	~~9.5~~	~~8.5~~ ~~9.2~~
~~Lysine~~	~~8.1~~	~~6.7~~ ~~6.3~~
~~Methionine~~	~~2.8~~	~~1.6~~ ~~1.3~~
~~Phenylalanine~~	~~5.2~~	~~3.4~~ ~~4.6~~
~~Threonine~~	~~4.7~~	~~4.4~~ ~~4.3~~
~~Tryptophan~~	~~1.6~~	~~1.7~~ ~~1.8~~
~~Tyrosine~~	~~5.8~~	~~3.2~~ ~~4.2~~
~~Valine~~	~~6.7~~	~~4,5~~ ~~4.9~~

~~[1] Amino acid content of foods and biological data on protein. FAO Nutritional Studies, No 24, Rome 1970, items 375 and 383.~~

~~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 shall be the following:~~

	~~Per 100 g SNF[1]~~	~~Per g of proteins~~
~~Sodium (mg)~~	~~550~~	~~15~~
~~Potassium (mg)~~	~~1680~~	~~42~~
~~Chloride (mg)~~	~~1050~~	~~28~~
~~Calcium (mg)~~	~~1350~~	~~35~~
~~Phosphorus (mg)~~	~~1070~~	~~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.~~

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~~ 7
Vitamin E	(mg TE) 5
Vitamin K	(μg) 12
Vitamin C	(mg) ~~25~~ 45
Thiamin	(mg) 0.5
Riboflavin	(mg) ~~0.8~~ 0.7
Niacin ~~equivalents~~	(mg) ~~9~~ 7
Vitamin B6	(mg) 0.7
Folate	(μg) ~~100~~ 125
Vitamin B12	(μg) ~~0.7~~ 0.8
Pantothenic acid	(mg) 3
Biotin	(μg) 10
Calcium	(mg) ~~400~~ 550
Phosphorus	(mg) 550
Potassium	(mg) 1000
Sodium	(mg) 400
Chloride	(mg) 500
Iron	(mg) ~~6~~ 8
Zinc	(mg) ~~4~~ 5
Iodine	(μg) ~~70~~ 80
Selenium	(μg) ~~10~~ 20
Copper	(mg) ~~0.4~~ 0.5

⌦ Magnesium ⌫	⌦ (mg) 80 ⌫
⌦ Manganese ⌫	⌦ (mg) 1.2 ⌫
[⌦ Chromium ⌫	⌦ (μg)20 ⌫]
[⌦ Molybdenum ⌫	⌦ (μg) 25 ⌫]
⌦ Fluoride ⌫	⌦ (mg) 0.7 ⌫

ANNEX ~~IX~~ VII

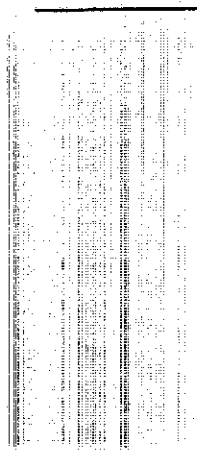
PESTICIDES WHICH SHALL NOT BE USED IN AGRICULTURAL PRODUCTION INTENDED FOR THE PRODUCTION OF INFANT FORMULAE AND FOLLOW-ON FORMULAE

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~~ ⊠ VIII ⊠

SPECIFIC MAXIMUM RESIDUE LEVELS OF PESTICIDES OR METABOLITIES 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 IX

Part A

Repealed Directive, with its successive amendments
(referred to in Article 14)

Commission Directive 91/321/EEC[9]	(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 14)

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

[9] 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 X

CORRELATION TABLE

Directive [91/321/EEC]	This Directive
Article 1	Article
Article 2	Article
Article 3	Article
Article 4	Article
Article 5	Article
Article 6	Article
Article 7	Article
Article 8	Article
Article 9	Article
Article 10	Article
Article 11	-
-	Article
-	Article
-	Article
-	Article
Annexes I to IV	Annexes I to IV
Annex VI	-
Annex VII	-
Annex VIII	Annex VI
Annex IX	Annex VII
Annex X	Annex VIII