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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 uses¹, and in particular Article 4 (1) thereof,

Whereas:

(1) A number of substantial changes are to be made to Commission Directive [../EC] on infant formulae and follow-on formulae². In the interests of clarity that Directive should be recast .

~~(1) Commission Directive 91/321/EEC of 14 May 1991 on infant formulae and follow-on formulae³ has been substantially amended several times⁴. 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.

(3) bis 1 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

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 Commission Directive 2003/14/EC (OJ L 41, 14.2.2003, p. 37)

³ 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).

⁴ 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.

- (3) bis 2 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 new ingredients included in these products.
- (3) bis 3 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.
- (4) Infant formulae and follow-on formulae 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.
- (5) 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]
- (6) 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.
- (7) Different rules on the maximum levels of pesticide residues in the products concerned cause trade barriers between certain Member States.
- (8) 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 vegetables⁵, in Council Directive 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticides residues in and on cereals⁶, 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 origin⁷, 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 vegetables⁸, are without prejudice to specific provisions applicable to infant formulae and follow-on formulae.

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) 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.
- (10) 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.
- (11) 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.
- (12) This very low common limit should be fixed at 0.01 mg/kg which normally is in practice the minimum detectable level.
- (13) 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.
- (14) 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.
- (15) 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.
- (16) 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.
- (17) 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.
- (18) 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 market⁹ 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.

- (19) 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.
- (20) 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.
- (21) 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.
- (22) 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.
- (23) 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.
- (23) bis 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.
- (24) 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.
- (25) 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

⁹ 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).

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.

- (26) This Directive does not concern the conditions of sale of publications specialising in baby care and of scientific publications.
- (27) On the provisions liable to affect public health, the consultation in accordance with Article 4 of Directive [89/398/EEC] has taken place.
- (28) Issues relating to products intended for export to third countries should be dealt with in a coherent and homogeneous manner in a separate measure.
- (29) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health.
- ☒ (30) 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. ☒
- (31) 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 XI, 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 formulae before [xxx], is placed on the market for the first time the manufacturer 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 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.

3. 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 the Commission concerning notifications under Article 4 (2) of this Directive.

~~34.~~ 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. ☒

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

Article 5

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 6

☒ 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 7

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~~ 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 ~~IX~~ 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.
4. By way of derogation from paragraph 2, for the pesticides listed in Annex ~~X~~ IX ~~⊗~~, 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~~ IX ~~⊗~~, where a Decision concerning the non-inclusion of an active substance in Annex I to Directive 91/414/EEC is taken, Annex ~~IX~~ VIII ~~⊗~~ and Annex ~~X~~ IX ~~⊗~~ to this Directive shall be amended accordingly.
7. Microbiological criteria shall be established as necessary.

Article 8

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 četrus sešus mēnešus vecumam” and “Maisījums zīdaiņiem no četrus mēnešus 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:
‘Modermælksersætning 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 četrus sešus mēnešus vecumam” and “Piens zīdaiņiem no četrus mēnešus 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” 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, 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 of the product and a warning against the health hazards of inappropriate preparation.

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~~(c)~~ (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~~e~~, 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.

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.

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 9

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 8(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 10

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 11

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with Articles 1, 2, 3, 4, 5, 6 7 and 8 and Annexes I, II, III, IV, V, VI and VII by [x] 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 [x+1day].

They shall prohibit, with effect from [x+2 years] trade in products which are not in conformity with [Articles 1, 2, 3, 4, 5, 6 7 and 8 and Annexes I (excluding section 5 – lipids), II (excluding section 4 – lipids), III, IV, V, VI and VII].

☒ They shall prohibit, with effect from [x+5 years] trade in products which are not in conformity with Annex I section 5 – lipids and Annex II section 4 – lipids. ☒

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 12

Directive [...]/EC] is hereby repealed, with effect from [xxx] in Article 11 of this Directive, 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.

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 11*~~

~~Directive 91/321/EEC, as amended by the Acts listed in Annex XI, Part A, is repealed, 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 XI, 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 XII.~~

Article 13

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

Article 14

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 \times ~~6.28~~ [6.25] and [non-protein nitrogen is not greater than 15% total nitrogen]) for cows' milk proteins.

(Protein content = nitrogen content \times 6.25) for soya protein isolates and protein ~~partial~~ hydrolysates.

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

2.1. Formulae manufactured from cows' milk proteins

Minimum	Maximum
0.45 g/100 kJ	0.7 g/100 kJ
(1.8 g/100 kcal)	(3 g/100 kcal)

For an equal energy value, the formula must contain an available quantity of each ~~essential and semi-essential~~ 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 not exceeding 3 providing the scientific evidence from clinical studies the demonstrate the product is suitable .

2.2. Formulae manufactured from protein ~~partial~~ hydrolysates

Minimum	Maximum
0.56 g/100 kJ	0.7 g/100 kJ

(2.25 g/100 kcal)

(3 g/100 kcal)

For an equal energy value, the formula must contain an available quantity of each ~~essential and semi-essential~~ 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 not exceeding 3 providing the scientific evidence from clinical studies demonstrate the product is suitable.

~~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:phenylalanine ratio is not greater than 2. The ratio of methionine:cystine may be greater than 2 but not exceeding 3 providing the scientific evidence from clinical studies demonstrate the product is suitable .

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~~ shall be permitted 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 (7 mg/100 kcal)	[7.2] mg/100 kJ ([30] mg/100 kcal)

~~3.~~ ☒ 5. ☒ LIPIDS

Minimum	Maximum
1.05 g/100 kJ (4.4 g/100 kcal)	1.5 ☒ 1.43 ☒ g/100 kJ (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 ☒ 120 ☒ mg/100 kJ	285 mg/100 kJ

(~~300~~ 500 mg/100 kcal)

(1 200 mg/100 kcal)

5.6 Formulae without added long-chain (20 and 22 carbon atoms) polyunsaturated fatty acids (LCPs)

~~3.5~~ The alpha-linolenic acid content shall not be less than ~~12~~ 24 mg/100 kJ (~~50~~ 100 mg/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.

5.7 Formulae with added long-chain (20 and 22 carbon atoms) polyunsaturated fatty acids (LCP)

~~3.8~~ Long-chain (20 and 22 carbon atoms) polyunsaturated fatty acids (LCP) may be added. In that case ~~their content shall not exceed:~~

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 20.

Long-chain (20 and 22 carbon atoms) polyunsaturated fatty acids (LCP) content shall not exceed:

- 1 % of the total fat content for n-3 LCP and

- 2 % of the total fat content for n-6 LCP (1 % of the total fat content for arachidonic acid)

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

[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 [1] g/L.

7. INOSITOL

Minimum

Maximum

1 mg/100 kJ

10 mg/100 kJ

(4 mg/100 kcal)

(40 mg/100 kcal)

~~4.1~~ 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)

~~4.1.1~~ 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-oligosaccharides 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-oligosaccharides may be used in accordance with the provisions of Article 4. ~~☒~~

~~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 0.31 ☒	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 10 ☒	— 50 ☒
Selenium ² (µg)	—	0.7 [2.2]	— [3]	3 [9] ☒

	☒ [0.7] ☒	☒	☒	
☒ Manganese (µg)	0.24	24	1	100 ☒
☒ Fluoride (µg)	—	24	—	100 ☒

⁺ ~~Limit applicable to formulae with added iron.~~

² ~~Limit applicable to formulae with added selenium.~~

The calcium/phosphorus ratio ~~☒~~ based on measured bioavailability or calculated as 80% of the total phosphorus in cow's milk protein based formula ~~☒~~ 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 ~~☒~~ and phosphorus ~~☒~~, which are as follows:

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Iron (mg)	0.25 ☒ 0.12 ☒	0.5 ☒ 0.45 ☒	4 ☒ 0.45 ☒	2 ☒ 1.9 ☒
Zinc (mg)	0.18	0.6	0.75	2.4
☒ Phosphorus (mg)	7.2	24	30	100 ☒

~~☒~~ The calcium/phosphorus ratio based on measured bioavailability or calculated as 70% of the total phosphorus in soya protein isolate based formula shall not be less than 1.0 nor greater than 2.0. ~~☒~~

~~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 ☒	— ☒ 72 ☒	40 ☒ 60 ☒	— ☒ 300 ☒
Riboflavin (µg)	14 ☒ 19 ☒	— ☒ [96 or	60 ☒ 80 ☒	— ☒ [400

[†] So that the same premix of water soluble vitamins can be used for infant formula, follow-on formula and Foods for Special Medical Purposes consideration should be given to the maximum level to be the same as FSMPs.

Niacin (mg μg) ³	0.2 72	100*] — [287 or 750*]	0.8 300	or 450*] — [1200 or 3000*]
Pantothenic acid (μg)	70 96	— 478	300 400	— 2000
Vitamin B ₆ (μg)	9	— [39 or 75*]	35	— [165 or 300*]
Biotin (μg)	0.4	— [1.8 or 5*]	1.5	— [7.5 or 20*]
Folic Acid (μg)	1 2.4	— [6* or 7.2]	4 10	— [25* or 30]
Vitamin B ₁₂ (μg)	0.025	— 0.125	0.1	— 0.5
Vitamin C (mg)	1.9 2.4	— [7.2* or 6]	8 10	— [25* or 30]
Vitamin K (μg)	1	— 4.8	4	— 20
Vitamin E (mg α -TE) ⁴	0.5/g of polyunsatur- ated 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 polyunsatur- ated 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

* Maximum in FSMP Directive.

¹	RE = all <i>trans</i> 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 (60 kcal/100 ml)	335 [295] kJ/100 ml (80 [70] kcal/100 ml)

2. PROTEINS

(Protein content = nitrogen content \times ~~6.38~~ [6.25] and [non-protein nitrogen is not greater than 15% total nitrogen] ~~<~~) for cows' milk proteins.

(Protein content = nitrogen content \times 6.25) for soya protein isolates.

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

The 'chemical index' of the proteins present shall be at least equal to 80 % of that of the reference protein (~~casein 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 (1.8 g/100 kcal)	[0.8] g/100 kJ ([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 (2.25 g/100 kcal)	[0.8] g/100 kJ ([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 (2.25 g/100 kcal)	[0.8] g/100 kJ ([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 ~~(X)~~.

- ~~(X)~~ 2.4. **In all cases**, ~~(X)~~ amino acids may be added to follow-on formulae ~~(X)~~ solely ~~(X)~~ for the purpose of improving the nutritional value of the proteins~~(X)~~ , and only ~~(X)~~ 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

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

~~3.1~~ 4. LIPIDS

Minimum

~~0.8~~ 0.96 g/100 kJ

~~(3.3)~~ 4.0 g/100 kcal)

Maximum

~~1.5~~ 1.43 g/100 kJ

~~(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~~

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

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

~~3.4~~ 4.5. Linoleic acid (in the form of glycerides = linoleates)

Minimum

~~70~~ 120 mg/100 kJ

~~(300)~~ 500 mg/100 kcal):

~~this limit shall apply only to follow
on formulae containing vegetable
oils~~

Maximum

~~—~~ 285 mg/100 kJ

~~—~~ 1 200 mg/100 kJ

~~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.

4.6 Formulae without added long-chain (20 and 22 carbon atoms) polyunsaturated fatty acids (LCPs)

The alpha-linolenic acid content shall not be less than 24 mg/100 kJ (100 mg/100 kcal).

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

4.7 Formulae with added long-chain (20 and 22 carbon atoms) polyunsaturated fatty acids (LCP) ~~☒~~

Long-chain (20 and 22 carbon atoms) polyunsaturated fatty acids (LCP) may be added. In that case:

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 20.

Long-chain (20 and 22 carbon atoms) polyunsaturated fatty acids (LCP) content shall not exceed:

- 1 % of the total fat content for n-3 LCP and
- 2 % of the total fat content for n-6 LCP (1 % of the total fat content for arachidonic acid)

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

[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 [1] g/L.

~~4.1~~ 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.

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 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-OLIGOSACCHARIDES

Fructo-oligosaccharides and galacto-oligosaccharides 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-oligosaccharides may be used in accordance with the provisions of Article 4.

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)	0.25 0.14	0.5 [0.41]	0.6	2 [2.0]
Zinc (mg)	0.12	— 0.36	0.5	— 1.5
Copper (µg)	8.4	24	35	100
Iodine (µg)	2.4	— 12	10	— 50

	☒			
☒ Selenium (µg)	[0.7]	[2.2]	[3]	[9] ☒
☒ Manganese (µg)	0.24	24	1	100 ☒
☒ Fluoride (µg)	—	24	—	100 ☒

The calcium/phosphorus ratio ☒ based on measured bioavailability or calculated as 80% of the total phosphorus in cow's milk protein based formula ☒ 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, zinc and phosphorus, which are as follows:

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
☒ Iron (mg)	0.22	0.60	0.9	2.5 ☒
Zinc (mg)	0.18	☒ 0.45 ☒	0.75	☒ 2.4 ☒
☒ Phosphorus (mg)	7.2	24	30	100 ☒

☒ The calcium/phosphorus ratio based on measured bioavailability or calculated as 70% of the total phosphorus in soya protein isolate-based formula shall not be less than 1.0 nor greater than 2.0. ☒

~~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	72	60	300 ⊗
⊗ Riboflavin (µg)	19	[96 or 100*]	80	[400 or 450*] ⊗
⊗ Niacin (µg) ⊗ ³ ⊗	72	[287 or 750*]	300	[1200 or 3000*] ⊗
⊗ Pantothenic acid (µg)	96	478	400	2000 ⊗
⊗ Vitamin B ₆ (µg)	9	[39 or 75*]	35	[165 or 300*] ⊗
⊗ Biotin (µg)	0.4	[1.8 or 5*]	1.5	[7.5 or 20*] ⊗
⊗ Folic Acid (µg)	2.4	[6* or 7.2*]	10	[25* or 30] ⊗
⊗ Vitamin B ₁₂ (µg)	0.025	0.125	0.1	0.5
Vitamin C (mg)	1.9 ⊗ 2.4 ⊗	— ⊗ [6* or 7.2] ⊗	8 ⊗ 10 ⊗	— ⊗ [25* or 30] ⊗
⊗ Vitamin K (µg)	1	4.8	4	20 ⊗

[†] So that the same premix of water soluble vitamins can be used for infant formula, follow-on formula and Foods for Special Medical Purposes consideration should be given to the maximum level to be the same as FSMPs.

* Max level in FSMP directive

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 <i>trans</i> retinol equivalent.			
²	In the form of cholecalciferol, of which 10 μ g = 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).			

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

Vitamin E	Calcium L-ascorbate
	6-palmityl-L-ascorbic acid (ascorbyl palmitate)
	Potassium ascorbate
	D-alpha tocopherol
	DL-alpha tocopherol
	D-alpha tocopherol acetate
Vitamin K	DL-alpha tocopherol acetate
	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)
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 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) The formulae shall satisfy the provisions laid down in Section 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

<p>allergen or reduced antigen properties.</p>	<p>formulae;</p> <p>(b) The label shall indicate that the product must not be consumed by infants allergic to the intact proteins from which it is made unless generally accepted clinical tests provide proof of the formulae's tolerance in more than 90 % of infants (confidence interval 95 %) hypersensitive to proteins from which the hydrolysate is made;</p> <p>(c) The formulae administered orally should not induce sensitization, in animals, to the intact proteins from which the formulae are derived;</p> <p>(d) Objective and scientifically verified data as proof to the claimed properties must be available.</p>
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⁺ ~~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 <input checked="" type="checkbox"/> 9 <input checked="" type="checkbox"/>	24 <input checked="" type="checkbox"/> 38 <input checked="" type="checkbox"/>
Histidine	11 <input checked="" type="checkbox"/> 10 <input checked="" type="checkbox"/>	45 <input checked="" type="checkbox"/> 40 <input checked="" type="checkbox"/>
Isoleucine	17 <input checked="" type="checkbox"/> 22 <input checked="" type="checkbox"/>	72 <input checked="" type="checkbox"/> 90 <input checked="" type="checkbox"/>
Leucine	37 <input checked="" type="checkbox"/> 40 <input checked="" type="checkbox"/>	156 <input checked="" type="checkbox"/> 166 <input checked="" type="checkbox"/>
Lysine	29 <input checked="" type="checkbox"/> 27 <input checked="" type="checkbox"/>	122 <input checked="" type="checkbox"/> 113 <input checked="" type="checkbox"/>
Methionine	7 <input checked="" type="checkbox"/> 5 <input checked="" type="checkbox"/>	29 <input checked="" type="checkbox"/> 23 <input checked="" type="checkbox"/>
Phenylalanine	15 <input checked="" type="checkbox"/> 20 <input checked="" type="checkbox"/>	62 <input checked="" type="checkbox"/> 83 <input checked="" type="checkbox"/>
Threonine	19 <input checked="" type="checkbox"/> 18 <input checked="" type="checkbox"/>	80 <input checked="" type="checkbox"/> 77 <input checked="" type="checkbox"/>
Tryptophan	7 <input checked="" type="checkbox"/> 8 <input checked="" type="checkbox"/>	30 <input checked="" type="checkbox"/> 32 <input checked="" type="checkbox"/>
Tyrosine	14 <input checked="" type="checkbox"/> 18 <input checked="" type="checkbox"/>	59 <input checked="" type="checkbox"/> 76 <input checked="" type="checkbox"/>
Valine	19 <input checked="" type="checkbox"/> 21 <input checked="" type="checkbox"/>	80 <input checked="" type="checkbox"/> 88 <input checked="" type="checkbox"/>

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 ⁺	Breast milk ⁺
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 ⊗

⁺ ~~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 [†]	Per g of proteins
Sodium (mg)	550	15
Potassium (mg)	1680	43
Chloride (mg)	1050	28
Calcium (mg)	1350	35
Phosphorus (mg)	1070	28
Magnesium (mg)	135	3.5
Copper (µg)	225	6
Iodine	NS[‡]	NS

~~[†] SNF: 'solids no fats'~~

~~[‡] 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
<input checked="" type="checkbox"/> Vitamin E <input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> (mg TE) 5 <input checked="" type="checkbox"/>
<input checked="" type="checkbox"/> Vitamin K <input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> (µg) 12 <input checked="" type="checkbox"/>
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
<input checked="" type="checkbox"/> Pantothenic acid <input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> (mg) 3 <input checked="" type="checkbox"/>
<input checked="" type="checkbox"/> Biotin <input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> (µg) 10 <input checked="" type="checkbox"/>
Calcium	(mg) 400 550
<input checked="" type="checkbox"/> Phosphorus <input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> (mg) 550 <input checked="" type="checkbox"/>
<input checked="" type="checkbox"/> Potassium <input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> (mg) 1000 <input checked="" type="checkbox"/>
<input checked="" type="checkbox"/> Sodium <input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> (mg) 400 <input checked="" type="checkbox"/>
<input checked="" type="checkbox"/> Chloride <input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> (mg) 500 <input checked="" type="checkbox"/>
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 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
Haloxifop (sum of haloxifop, its salts and esters including conjugates, expressed as haloxifop)
Heptachlor and <i>trans</i> -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 11)

Part B

List of time limits for transposition into national law
(referred to in Article 11)

Directive	Time limit for transposition	Permission of trade in products complying with this Directive	Prohibition of trade in products not complying with this Directive

ANNEX XI

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 12	Article
Article 13	Article
Annexes I to VI	Annexes I to VI
Annex VII	-
Annex VIII	Annex VII
Annex IX	Annex VIII
Annex X	Annex IX