

31991L0321**Commission Directive 91/321/EEC of 14 May 1991 on infant formulae and follow-on formulae***Official Journal L 175 , 04/07/1991 P. 0035 - 0049**Finnish special edition: Chapter 15 Volume 10 P. 0107**Swedish special edition: Chapter 15 Volume 10 P. 0107*

COMMISSION DIRECTIVE of 14 May 1991 on infant formulae and follow-on formulae (91/321/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

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

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

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

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

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

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

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

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

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

Whereas, in an effort to provide better protection for the health of infants, the rules of composition, labelling and advertising laid down in this Directive should be in conformity with the principles and the aims of the International Code of Marketing of Breast-Milk Substitutes adopted by the 34th World Health Assembly, bearing in mind the particular legal and factual situations existing in the Community;

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

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

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

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

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

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

2. For the purposes of this Directive,

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

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

(c) 'infant formulae' means foodstuffs intended for particular nutritional use by infants during the first four to six months of life and satisfying by themselves the nutritional requirements of this category of persons;

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

Article 2

Member States shall ensure that the products referred to in Article 1 (2) (c) and (d) may be marketed within the Community only if they conform to the definitions and rules laid down in this Directive. No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first four to six months of life.

Article 3

1. Infant formulae shall be manufactured from protein sources defined in the Annexes and other food ingredients, as the case may be, whose suitability for particular nutritional use by infants from birth has been established by generally accepted scientific data.
2. Follow-on formulae shall be manufactured from protein sources defined in the Annexes and other food ingredients as the case may be whose suitability for particular nutritional use by infants aged over four months has been established by generally accepted scientific data.
3. The prohibitions and limitations on the use of food ingredients laid down in Annexes I and II shall be observed.

Article 4

1. Infant formulae must comply with the compositional criteria specified in Annex I.
2. Follow-on formulae must comply with the compositional criteria specified in Annex II.
3. In order to make infant formulae and follow-on formulae ready for use, nothing more shall be required, as the case may be, than the addition of water.

Article 5

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

- mineral substances,
- vitamins,
- amino acids and other nitrogen compounds,
- other substances having a particular nutritional purpose.

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

2. The provisions relating to the use of additives in the manufacture of infant formulae and follow-on formulae shall be laid down in a Council directive. Article 6 1. Infant formulae and follow-on formulae shall not contain any substance in such quantity as to endanger the health of infants. Where necessary the maximum levels of any such substance shall be stipulated at a later date.

2. Microbiological criteria shall be established at a later date.

Article 7

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

- in English:

'infant formula' and 'follow-on formula',

- in Danish:

'Modermælkserstatning' and 'Tilskudsblanding',

- in German:

'Säuglingsanfangsnahrung' and 'Folgenahrung',

- in Greek:

'Διαιτίαση αβλαβής άέά άñÝοες » and 'Διαιτίαση αβλαβής αεαγύααήçò άñααοεέêò çέέêssào »,

- in Spanish:

'Preparado para lactentes' and 'Preparado de continuación',

- in French:

'Préparation pour nourrissons' and 'Préparation de suite',

- in Italian:

'Alimento per lattanti' and 'Alimento di proseguimento',

- in Dutch:

'Volledige zuigelingenvoeding' and 'Opvolgzuigelingenvoeding',

- in Portuguese:

'Fórmula para lactentes' and 'Fórmula de transição'.

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

- in English:

'Infant milk' and 'follow-on milk',

- in Danish:

'Modermælkserstatning udelukkende baseret paa mælk' and 'Tilskudsblanding udelukkende baseret paa mælk',

- in German:

'Säuglingsmilchnahrung' and 'Folgemilch',

- in Greek:

'ΆΥΕέά άέά άñΥοεç » and 'ΆΥΕέά αεαάγôααñçò άñααοεέêρò çέέêσσάò »,

- in Spanish:

'Leche para lactentes' and 'Leche de continuación',

- in French:

'Lait pour nourrissons' and 'Lait de suite',

- in Italian:

'Latte per lattanti' and 'Latte di proseguimento',

- in Dutch:

'Volledige zuigelingenvoeding op basis van melk' or 'Zuigelingenmelk' and 'Opvolgmelk',

- in Portuguese:

'Leite para lactentes' and 'Leite de transição'.

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

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

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

(c) in the case of follow-on formulae, a statement to the effect that the product is suitable only for particular nutritional use by infants over the age of four months, that it should form only part of a diversified diet and that it is not to be used as a substitute for breast milk during the first four months of life;

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

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

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

3. The labelling of infant formulae and follow-on formulae shall be designed to provide the necessary information about the appropriate use of the products so as not to discourage breast-feeding. The use of the terms 'humanized', 'maternalized', or similar terms shall be prohibited. The term 'adapted' may only be used in conformity with paragraph 6 and Annex IV, point 1.

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

(a) a statement concerning the superiority of breast-feeding;

(b) a statement recommending that the product be used only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care;

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

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

7. The requirements, prohibitions and restrictions referred to in paragraphs 3 to 6 shall also apply to:

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

(b) advertising.

Article 8

1. Advertising of infant formulae shall be restricted to publications specializing in baby care and scientific publications. Member States may further restrict or prohibit such advertising. Such advertisements for infant formulae shall be subject to the conditions laid down in Article 7 (3), (4), (5), (6) and (7) (b) and contain only information of a scientific and factual nature. Such information shall not imply or create a belief that bottle-feeding is equivalent or superior to breast-feeding.

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

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

Article 9

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

2. Member States shall ensure that informational and educational materials, whether written or audiovisual, dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children, shall include clear information on all the following points:

- (a) the benefits and superiority of breast-feeding;
- (b) maternal nutrition and the preparation for and maintenance of breast-feeding;
- (c) the possible negative effect on breast-feeding of introducing partial bottle-feeding;
- (d) the difficulty of reversing the decision not to breast-feed;
- (e) where needed, the proper use of infant formulae, whether manufactured industrially or home-prepared.

When such materials contain information about the use of infant formulae, they shall include the social and financial implications of its use; the health hazards of inappropriate foods or feeding methods, and, in particular, the health hazards of improper use of infant formulae. Such material shall not use any pictures which may idealize the use of infant formulae.

3. Member States shall ensure that donations of informational or educational equipment or materials by manufacturers or distributors shall be made only on request and with the written approval of the appropriate national authority or within guidelines given by that authority for this purpose. Such equipment or materials may bear the donating company's name or logo, but shall not refer to a proprietary brand of infant formulae and shall be distributed only through the health care system.

4. Member States shall ensure that donations or low-price sales of supplies of infant formulae to institutions or organizations, whether for use in the institutions or for distribution outside them, shall only be used by or distributed for infants who have to be fed on infant formulae and only for as long as required by such infants.

Article 10

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

- permit trade in products complying with this Directive, by 1 December 1992,
- prohibit trade in products which do not comply with this Directive, with effect from 1 June 1994.

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

Article 11

This Directive is addressed to the Member States. Done at Brussels, 14 May 1991. For the Commission

Martin BANGEMANN

Vice-President

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

ANNEX I

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

NB: The values refer to the product ready for use

1. Energy Minimum Maximum 250 kJ 315 kJ (60 kcal/100 ml) (75 kcal/100 ml) 2. Proteins (Protein content = nitrogen content \times 6,38) for cows' milk proteins. (Protein content = nitrogen content \times 6,25) for soya protein isolates. 2.1. Formulae manufactured from unmodified cows' milk proteins Minimum Maximum 0,56 g/100 kJ 0,7 g/100 kJ (2,25 g/100 kcal) (3 g/100 kcal) The chemical index of the proteins present shall be equal to at least 80 % of that of the reference protein (breast milk, as defined in Annex VI); nevertheless, for calculation purposes, the concentrations of methionine and cystine may be added together. 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. 2.2 Formulae manufactured from modified cows' milk proteins (alteration of the casein/whey protein ratio) Minimum Maximum 0,45 g/100 kJ 0,7 g/100 kJ (1,8 g/100 kcal) (3 g/100 kcal) For an equal energy value, the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex V). 2.3. Formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins Minimum Maximum 0,56 g/100 kJ 0,7 g/100 kJ (2,56 g/100 kcal) (3 g/100 kcal) Only soya protein isolates must be used in manufacturing these formulae. The chemical index shall be equal to at least 80 % of that of the reference protein (breast milk, as defined in Annex VI). For an equal energy value the formula must contain an available quantity of methionine at least equal to that contained in the reference protein (breast milk, as defined in Annex V). The L-carnitine content shall be at least equal to 1,8 μ moles/100 kJ (7,5 μ moles/100 kcal). 2.4. In all cases, the addition of amino acids is permitted solely for the purpose of improving the nutritional value of the proteins, and only in the proportions necessary for that purpose. 3. Lipids Minimum Maximum 0,8 g/100 kJ 1,5 g/100 kJ (3,3 g/100 kcal) (6,5 g/100 kcal) 3.1. The use of the following substances is prohibited: - sesame seed oil, - cotton seed oil, - fats containing more than 8 % trans isomers of fatty acids. 3.2. Lauric acid Minimum Maximum - 15 % of the total fat content 3.3. Myristic acid Minimum Maximum - 15 % of the total fat content 3.4. Linoleic acid (in the form of glycerides = linoleates) Minimum Maximum 70 mg/100 kJ 285 mg/100 kJ (300 mg/100 kcal) (1 200 mg/100 kcal) 4. Carbohydrates Minimum Maximum 1,7 g/100 kJ 3,4 g/100 kJ (7 g/100 kcal) (14 g/100 kcal) 4.1. Only the following carbohydrates may be used: - lactose, - maltose, - sucrose, - malto-dextrins, - glucose syrup or dried glucose syrup, - pre-cooked starch - gelatinized starch naturally free of gluten 4.2. Lactose Minimum Maximum 0,85 g/100 kJ - (3,5 g/100 kcal) - This provision does not apply to formulae in which soya proteins represent more than 50 % of the total protein content. 4.3. Sucrose Minimum Maximum - 20 % of the total carbohydrate content 4.4 Pre-cooked starch and/or gelatinized starch Minimum Maximum - 2 g/100 ml, and 30 % of the total carbohydrate content 5. Mineral substances 5.1. Formulae manufactured from cows' milk proteins Per 100 kJ Per 100 kcal Minimum Maximum Minimum Maximum Sodium (mg) 5 14 20 60 Potassium (mg) 15 35 60 145 Chloride (mg) 12 29 50 125 Calcium (mg) 12 - 50 - Phosphorus (mg) 6 22 25 90 Magnesium (mg) 1,2 3,6 5 15 Iron (mg) (1) 0,12 0,36 0,5 1,5 Zinc (mg) 0,12 0,36 0,5 1,5 Copper (ig) 4,8 19 20 80 Iodine (ig) 1,2 - 5 -

(1) Limit applicable to formulae with added iron.

The calcium/phosphorus ratio shall not be less than 1,2 nor greater than 2,0. 5.2. Formulae manufactured from soya proteins, alone or in a mixture with cows' milk proteins All requirements of paragraph 5.1 are applicable except those concerning iron and zinc, which are as follows: Per 100 kJ Per 100 kcal Minimum Maximum Minimum Maximum Iron (mg) 0,25 0,5 1 2 Zinc (mg) 0,18 0,6 0,75 2,4 6. Vitamins Per 100 kJ Per 100 kcal Minimum Maximum Minimum Maximum Vitamin A (ìg-RE) (1) 14 43 60 180 Vitamin D (ìg) (2) 0,25 0,65 1 2,5 Thiamin (ìg) 10 - 40 - Riboflavin (ìg) 14 - 60 - Nicotinamide (ìg-EN) (3) 60 - 250 - Pantothenic acid (ìg) 70 - 300 - Vitamin B6 (ìg) 9 - 35 - Biotin (ìg) 0,4 - 1,5 - Folic acid (ìg) 1 - 4 - Vitamin B12 (ìg) 0,025 - 0,1 - Vitamin C (ìg) 1,9 - 8 - Vitamin K (ìg) 1 - 4 - Vitamin E (mg á-TE) (4) 0,5/g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0,1 mg per 100 available kJ - 0,5/g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0,5 mg per 100 available kcal -

(1) RE = all trans retinol equivalent.

(2) In the form of cholecalciferol, of which 10 ìg = 400 i.u. of vitamin D.

(3) NE = Niacin equivalent = mg nicotinic acid + mg tryptophan/60.

(4) á-TE = d-á-tocopherol equivalent.

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 KJ/100 ml (60 kcal/100 ml) (80 kcal/100 ml) 2. Proteins (Protein content = nitrogen content \times 6,38) for cows' milk proteins. (Protein content = nitrogen content \times 6,25) for soya protein isolates. 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 as defined in Annex VI). The 'chemical index' shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein and the quantity of each corresponding amino acid of the reference protein. For follow-on formulae manufactured from soya proteins, alone or in a mixture with cows' milk proteins, only protein isolates from soya may be used. Amino acids may be added to follow-on formulae for the purpose of improving the nutritional value of the proteins, in the proportions necessary for that purpose. 3. Lipids Minimum Maximum 0,8 g/100 kJ 1,5 g/100 kJ (3,3 g/100 kcal) (6,5 g/100 kcal) 3.1. The use of the following substances is prohibited: - sesame seed oil, - cotton seed oil, - fats containing more than 8 % trans isomers of fatty acids. 3.2. Lauric acid Minimum Maximum - 15 % of the total fat content 3.3. Myristic acid Minimum Maximum - 15 % of the total fat content 3.4. Linoleic acid (in the form of glycerides = linoleates) Minimum Maximum 70 mg/100 kJ - (300 mg/100 kcal): this limit applies only to follow-on formulae containing vegetable oils 4. Carbohydrates Minimum Maximum 1,7 g/100 kJ 3,4 g/100 kJ (7 g/100 kcal) (14 g/100 kcal) 4.1. The use of ingredients containing gluten is prohibited. 4.2. Lactose Minimum Maximum 0,45 g/100 kJ - (1,8 g/100 kcal) This provision does not apply to follow-on formulae in which soya protein isolates represent more than 50 % of the total protein content. 4.3. Sucrose, fructose, honey Minimum Maximum - separately or as a whole: 20 % of the total carbohydrate content 5. Mineral substances 5.1. Per 100 kJ Per 100 kcal Minimum Maximum Minimum Maximum Iron (mg) 0,25 0,5 1 2 Iodine (ìg) 1,2 - 5 - 5.2. Zinc 5.2.1. Follow-on formulae manufactured entirely from cows' milk Minimum Maximum 0,12 mg/100 kJ - (0,5 mg/100 kcal) 5.2.2. Follow-on formulae containing soya protein isolates, or mixed with cows' milk Minimum Maximum 0,18 mg/100 kJ - (0,75 mg/100 kcal) 5.3. Other mineral substances: The concentrations are at least equal to those normally found in cows' milk, reduced, where appropriate, in the same ratio as the protein concentration of the follow-on formulae to that of cows' milk. The typical composition of cows' milk is given, for guidance, in Annex VIII. 5.4. The calcium/phosphorus ratio shall not exceed 2,0. 6. Vitamins Per 100 kJ Per

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

(1) RE = all trans retinol equivalent.

(2) In the form of cholecalciferol, of which 10 ig = 400 u.i. of vitamin D.

(3) á-TE = d-á-tocopherol equivalent.

ANNEX III

NUTRITIONAL SUBSTANCES

1. Vitamins

Vitamin Vitamin formulation Vitamin A Retinyl acetate Retinyl palmitate Beta-carotene Retinol Vitamin D Vitamin D2 (ergocalciferol) Vitamin D3 (cholecalciferol) Vitamin B1 Thalmin hydrochloride Thalmin mononitrate Vitamin B2 Riboflavin Riboflavin-5-phosphate, sodium Niacin Nicotinamide Nicotinic acid Vitamin B6 Pyridoxine hydrochloride Pyridoxine-5-phosphate Folate Folic acid Pantothenic acid D-pantothenate, calcium D-pantothenate, sodium Dexpantenol Vitamin B12 Cyanocobalamin Hydroxocobalamin Biotin D-biotin Vitamin C L-ascorbic acid Sodium L-ascorbate Calcium L-ascorbate 6-palmityl-L-ascorbic acid (ascorbyl palmitate) Potassium ascorbate Vitamin E D-alpha tocopherol DL-alpha tocopherol D-alpha tocopherol acetate DL-alpha tocopherol acetate Vitamin K Phylloquinone (Phytomenadione)

2. Mineral substances

Mineral substances Permitted salts Calcium (Ca) Calcium carbonate Calcium chloride Calcium salts of citric acid Calcium gluconate Calcium glycerophosphate Calcium lactate Calcium salts of orthophosphoric acid Calcium hydroxide Magnesium (Mg) Magnesium carbonate Magnesium chloride Magnesium oxide Magnesium salts of orthophosphoric acid Magnesium sulphate Magnesium gluconate Magnesium hydroxide Magnesium salts of citric acid Iron (Fe) Ferrous citrate Ferrous gluconate Ferrous lactate Ferrous sulphate Ferric ammonium citrate Ferrous fumarate Ferric diphosphate (Ferric pyrophosphate) 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

3. Amino acids and other nitrogen compounds

L-arginine and its hydrochloride

L-cystine and its hydrochloride

L-histidine and its hydrochloride

L-isoleucine and its hydrochloride

L-leucine and its hydrochloride

L-cysteine and its hydrochloride

L-cysteine and its hydrochloride

L-methionine

L-phenylalanine

L-threonine

L-tryptophan

L-tyrosine

L-valine

L-carnitine and its hydrochloride

Taurine

4. Others

Choline

Choline chloride

Choline citrate

Choline bitartrate

Inositol

ANNEX IV

COMPOSITIONAL CRITERIA FOR INFANT FORMULAE, WARRANTING A CORRESPONDING CLAIM

Claim related to Conditions warranting the claim 1. Adapted protein The protein content is lower than 0,6 g/100 kJ (2,5 g/100 kcal) and the whey protein/casein ratio is not less than 1,0. 2. Low sodium The sodium content is lower than 9 mg/100 kJ (39 mg/100 kcal). 3. Sucrose free No sucrose is present. 4. Lactose only Lactose is the only carbohydrate present. 5. Lactose free No lactose is present (1). 6. Iron enriched Iron is added.

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

ANNEX V

ESSENTIAL AND SEMI-ESSENTIAL AMINO ACIDS IN BREAST MILK

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

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

(1) 1 kJ = 0,239 kcal.

ANNEX VI

Amino acid composition of casein and breast milk protein

The amino acid composition of casein and breast milk protein:

(g/100 g of protein)

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

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

ANNEX VII

The mineral elements in cows' milk

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

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

(1) SNF: 'solids-no fats'.

(2) NS: non-specified, varies widely according to season and stock farming conditions.

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1.2,3 //

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

4.3 .

Sucrose

1.2.3 //

Minimum

Maximum //

—

20 % of the total carbohydrate content

1.2,34.4

Pre-cooked starch and/or gelatinised starch

1.2.3 //

Minimum

Maximum //

—

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

1.2,35 .

Mineral substances

5.1 .

Formulae manufactured from cows' milk proteins

1.2,3.4,5 // // // //

Per 100 kJ

Per 100 kcal

1.2.3.4.5Minimum

Maximum

Minimum

Maximum // // // // //

Sodium (mg)

5

14

20

60

Potassium (mg)

15

35

60

145

Chloride (mg)

12

29

50

125

Calcium (mg)

12

—

50

—

Phosphorus (mg)

6

22

25

90

Magnesium (mg)

1,2

3,6

5

15

Iron (mg) (1)

0,12

0,36

0,5

1,5

Zinc (mg)

0,12

0,36

0,5

1,5

Copper (* g)

4,8

19

20

80

Iodine (* g)

1,2

—

5

_ // // // // //

(1) Limit applicable to formulae with added iron .

1.2The calcium/phosphorus ratio shall not be less than 1,2 nor greater than 2,0 .

5.2 .

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

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

1.2,3.4,5 // // // //

Per 100 kJ

Per 100 kcal

1.2.3.4.5Minimum

Maximum

Minimum

Maximum // // // // //

Iron (mg)

0,25

0,5

1

2

Zinc (mg)

0,18

0,6

0,75

2,4 // // // // //

1.26 .

Vitamins

1.2.3.4.5 // // // //

Per 100 kJ

Per 100 kcal

1.2.3.4.5Minimum

Maximum

Minimum

Maximum // // // // //

Vitamin A (* g-RE) (1)

14

43

60

180

Vitamin D (* g) (2)

0,25

0,65

1

2,5

Thiamin (* g)

10

—

40

—

Riboflavin (* g)

14

—

60

—

Nicotinamide (* g-EN) (3)

60

—

250

—

Pantothenic acid (* g)

70

—

300

—

Vitamin B6 (* g)

9

—

35

—

Biotin (* g)

0,4

—

1,5

—

Folic acid (* g)

1

—

4

—

Vitamin B12 (* g)

0,025

—

0,1

—

Vitamin C (* g)

1,9

—

8

—

Vitamin K (* g)

1

—

4

—

Vitamin E (mg *-TE) (4)

0,5/g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0,1 mg per 100 available kJ

—

0,5/g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0,5 mg per 100 available kcal

_ // // // // //

(1) RE = all trans retinol equivalent .

(2) In the form of cholecalciferol, of which 10 *g = 400 i.u . of vitamin D .

(3) NE = Niacin equivalent = mg nicotinic acid + mg tryptophan/60 .

(4) *-TE = d-*-tocopherol equivalent .

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

1.2.31 .

Energy // //

Minimum

Maximum //

250 kJ/100 ml

335 KJ/100 ml //

(60 kcal/100 ml)

(80 kcal/100 ml)

1.2,32 .

Proteins //

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

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

1.2.3 //

Minimum

Maximum //

0,5 g/100 kJ

1 g/100 kJ //

(2,25 g/100 kcal)

(4,5 g/100 kcal)

1.2,3 //

The chemical index of the proteins present shall be at least equal to 80 % of that of the reference protein (casein as defined in Annex VI). //

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

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

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

1.2.33 .

Lipids // //

Minimum

Maximum //

0,8 g/100 kJ

1,5 g/100 kJ //

(3,3 g/100 kcal)

(6,5 g/100 kcal)

1.2,33.1 .

The use of the following substances is prohibited : //

_ sesame seed oil, //

_ cotton seed oil, //

_ fats containing more than 8 % trans isomers of fatty acids .

1.2.33.2 .

Lauric acid // //

Minimum

Maximum //

—

15 % of the total fat content

3.3 .

Myristic acid // //

Minimum

Maximum //

—

15 % of the total fat content

1.2,33.4 .

Linoleic acid (in the form of glycerides = linoleates)

1.2.3 //

Minimum

Maximum //

70 mg/100 kJ

_ //

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

this limit applies only to follow-on formulae containing vegetable oils //

4 .

Carbohydrates // //

Minimum

Maximum //

1,7 g/100 kJ

3,4 g/100 kJ //

(7 g/100 kcal)

(14 g/100 kcal)

1.2,34.1 .

The use of ingredients containing gluten is prohibited .

4.2 .

Lactose

1.2.3 //

Minimum

Maximum //

0,45 g/100 kJ

_ //

(1,8 g/100 kcal) //

1.2,3 //

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

4.3 .

Sucrose, fructose, honey

1.2.3 //

Minimum

Maximum //

—

separately or as a whole : // //

20 % of the total carbohydrate content

1.2,35 .

Mineral substances

5.1 . //

1.2,3,4,5 // // // //

Per 100 kJ

Per 100 kcal

1.2.3.4.5Minimum

Maximum

Minimum

Maximum // // // // // // // // //

Iron (mg)

0,25

0,5

1

2

Iodine (* g)

1,2

—

5

_ // // // // //

1.2.35.2 .

Zinc //

1.2,35.2.1 .

Follow-on formulae manufactured entirely from cows' milk

1.2.3Minimum

Maximum //

0,12 mg/100 kJ

_ //

(0,5 mg/100 kcal) //

1.2,35.2.2 .

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

1.2.3Minimum

Maximum //

0,18 mg/100 kJ

_ //

(0,75 mg/100 kcal) //

1.2,35.3 .

Other mineral substances : //

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

5.4 .

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

6 .

Vitamins

1.2,3.4,5 // // // //

Per 100 kJ

Per 100 kcal

1.2.3.4.5Minimum

Maximum

Minimum

Maximum // // // // // // // // //

Vitamin A (* g-ER) (1)

14

43

60

180

Vitamin D (* g) (2)

0,25

0,75

1

3

Vitamin C (* g)

1,9

—

8

—

Vitamin E (mg *-TE) (3)

0,5/g polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0,1 mg per 100 available kJ

—

0,5/g polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0,5 mg per 100 available kcal

_ // // // // //

(1) RE = all trans retinol equivalent .

(2) In the form of cholecalciferol, of which 10 *g = 400 u.i . of vitamin D .

(3) *-TE = d-*-tocopherol equivalent .

ANNEX III

NUTRITIONAL SUBSTANCES

1 . Vitamins

1.2 Vitamin

Vitamin formulation

Vitamin A

Retinyl acetate //

Retinyl palmitate //

Beta-carotene //

Retinol

Vitamin D

Vitamin D2 (ergocalciferol) //

Vitamin D3 (cholecalciferol)

Vitamin B1

Thalmin hydrochloride //

Thalmin mononitrate

Vitamin B2

Riboflavin //

Riboflavin-5-phosphate, sodium

Niacin

Nicotinamide //

Nicotinic acid

Vitamin B6

Pyridoxine hydrochloride //

Pyridoxine-5-phosphate

Folate

Folic acid

Pantothenic acid

D-pantothenate, calcium //

D-pantothenate, sodium //

Dexpanthenol

Vitamin B12

Cyanocobalamin //

Hydroxocobalamin

Biotin

D-biotin

Vitamin C

L-ascorbic acid //

Sodium L-ascorbate //

Calcium L-ascorbate //

6-palmityl-L-ascorbic acid (ascorbyl palmitate) //

Potassium ascorbate

Vitamin E

D-alpha tocopherol //

DL-alpha tocopherol //

D-alpha tocopherol acetate //

DL-alpha tocopherol acetate

Vitamin K

Phylloquinone (Phytomenadione) // //

2 . Mineral substances

1.2Mineral 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

Mineral substances

Permitted salts

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 // //

3 . Amino acids and other nitrogen compounds

L-arginine and its hydrochloride

L-cystine and its hydrochloride

L-histidine and its hydrochloride

L-isoleucine and its hydrochloride

L-leucine and its hydrochloride

L-cysteine and its hydrochloride

L-cysteine and its hydrochloride

L-methionine

L-phenylalanine

L-threonine

L-tryptophan

L-tyrosine

L-valine

L-carnitine and its hydrochloride

Taurine

4 . Others

Choline

Choline chloride

Choline citrate

Choline bitartrate

Inositol

ANNEX IV

COMPOSITIONAL CRITERIA FOR INFANT FORMULAE, WARRANTING A CORRESPONDING CLAIM

1.2 Claim related to

Conditions warranting the claim

1 . Adapted protein

The protein content is lower than 0,6 g/100 kJ (2,5 g/100 kcal) and the whey protein/casein ratio is not less than 1,0 .

2 . Low sodium

The sodium content is lower than 9 mg/100 kJ (39 mg/100 kcal).

3 . Sucrose free

No sucrose is present .

4 . Lactose only

Lactose is the only carbohydrate present .

5 . Lactose free

No lactose is present (1).

6 . Iron enriched

Iron is added . // //

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

ANNEX V

ESSENTIAL AND SEMI-ESSENTIAL AMINO ACIDS IN BREAST MILK

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

1.2.3 Per 100 kJ (1)

Per 100 kcal // // //

Arginine

16

69

Cystine

6

24

Histidine

11

45

Isoleucine

17

72

Leucine

37

156

Lysine

29

122

Methionine

7

29

Phenylalanine

15

62

Threonine

19

80

Tryptophan

7

30

Tyrosine

14

59

Valine

19

80 // // //

(1) 1 kJ = 0,239 kcal .

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)

1.2.3Casein (1)

Breast milk (1) // // //

Arginine

3,7

3,8

Cystine

0,3

1,3

Histidine

2,9

2,5

Isoleucine

5,4

4,0

Leucine

9,5

8,5

Lysine

8,1

6,7

Methionine

2,8

1,6

Phenylalanine

5,2

3,4

Threonine

4,7

4,4

Tryptophan

1,6

1,7

Tyrosine

5,8

3,2

Valine

6,7

4,5 // // //

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

ANNEX VII

The mineral elements in cows' milk

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

1.2.3Per 100 g SNF (1)

Per g of proteins // // //

Sodium (mg)

550

15

Potassium (mg)

1 680

43

Chloride (mg)

1 050

28

Calcium (mg)

1 350

35

Phosphorus (mg)

1 070

28

Magnesium (mg)

135

3,5

Copper (* g)

225

6

Iodine

NS (2)

NS // // //

(1) SNF : "solids-no fats '.

(2) NS : non-specified, varies widely according to season and stock farming conditions .