COMMISSION OF THE EUROPEAN COMMUNITIES

COM(86) 564 final
Brussels, 20 October 1986

Modified proposal for a

COUNCIL DIRECTIVE

on the approximation of the laws of the Member States relating to infant formulae and follow-up milks

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(submitted to the Council by the Commission pursuant to the second paragraph of Article 149 of the EEC Treaty)

COM(86) 564 final

Com 564 f.

EXPLANATORY NOTE

In December 1984 the Commission submitted to the Council a proposal for a directive on the approximation of the laws of the Member States relating to infant formulae and follow-up milks [1], the reasons for which were set out in the accompanying Explanatory Note. The proposal was furthermore a ccompanied by a Report on Infant Feeding and the Implementation of the International Code of Marketing of Breast-milk Substitutes and by a proposal for a Council Resolution on the marketing practices for breast-milk substitutes in developing countries by Community-based manufacturers.

In the course of the proceedings of the European Parliament, to whom the proposal had been referred for opinion by the Council, it became clear that the Parliament wished the Commission to have gone further in transposing into the framework of a directive the principles and aims of the International Code of Marketing of Breast-milk substitutes. In the light of these views the Commission reconsidered its approach and agreed, in March 1986, to propose a strengthening of the Community comittment to the International Code, first enunciated by the Presidency at the time of the approval of the instrument in 1981.

The strengthening proposed is found in the areas of marketing generally, the responsibilities of health care authorities and advertising. In the first two of these areas the provisions set out in the attached proposal follow the principles of the International Code, whereas in the third the Commission was unwilling to propose a prohibition on the advertising to the general public of infant formulae, as contained in the International Code. It preferred, in the light of the constitutional, legal, social and other considerations applicable within the Community and its Member States, a solution consisting of confining advertising to media specializing in baby care.

Given the scope of the amendments involved, the text of the proposal has been revised in its entirety.

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[1] COM (84) 703 final

Modified Proposal for
a COUNCIL DIRECTIVE
on the approximation of the laws of the Member States
relating to infant formulae and follow-up milks

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,

Having regard to Council Directive 77/94/EEC of 21 December 1976 on the approximation of the laws of the Member States relating to foodstuffs for particular nutritional uses[1], and in particular Article 1(3) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas infant formulae and follow-up milks intended for particular nutritional use by infants in good health, in those cases in which breastfeeding is not advised, sufficient or possible, or the mother chooses not to breastfeed, form a very important group within the category of foodstuffs for particular nutritional uses ;

Whereas a specific Directive within the meaning of Article 1(3) of Directive 77/94/EEC should therefore be adopted for this group of products ;

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

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[1] OJ No L 26, 31.1.1977, p. 55.

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

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 all follow-up milks currently sold in the Community are manufactured from cows' milk; whereas, should follow-up products not or not exclusively based on cows' milk later appear on the market, the advisability of adopting common rules for them would have to be examined;

Whereas pursuant to Article 5(1) of Directive 77/94/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[1]; 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 breastfeeding;

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), point 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;

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[1] OJ No L 33,8.2.1979, p. 1.

Whereas, in an effort to provide better protection for the health of infants, the rules of composition, labelling and marketing 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 the adaptation of this Directive to scientific and technical progress is an implementing measure that should be delegated to the Commission; whereas it is nevertheless advisable to allow the Member States to help find a Community solution by adopting temporary measures; whereas the procedure laid down in Article 9 of Directive 77/94/EEC is appropriate for this purpose since it offers close cooperation between the Member States and the Commission,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive is a specific Directive within the meaning of Article 1(3) of Directive 77/94/EEC and lays down compositional and labelling requirements for infant formulae and follow-up milks. It also provides for Member States to give effect to those 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) "infant formulae" shall mean 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;

(b) "follow-up milks" shall mean foodstuffs intended for particular nutritional use by infants aged over four months and constituting the milk element in a progressively diversified diet of this category of persons.

Article 2

1. Member States shall take all necessary steps to ensure that the products referred to in Article 1(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 infants during the first four to six months of life.

2. The provisions of Articles 2 to 9(5)shall also apply to the products referred to in Article 1(2) which are intended for export to third countries, except insofar as precluded by provisions applicable in the third country of import.

Article 3

1. Infant formulae shall be manufactured from food ingredients whose suitability for particular nutritional use by infants from birth has been established by generally accepted scientific data.

2. Follow-up milks shall be manufactured from food ingredients 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.

However, the compositional criteria for infant formulae that are not or not exclusively manufactured from cows' milk proteins shall be specified at a later date, but not later than 1 July 1988, in accordance with Article 100 of the Treaty.

2. Follow-up milks must comply with the compositional criteria specified in Annex II.

3. In order to make infant formulae and follow-up milks ready for use, nothing more, as the case may be, than the addition of water shall be required.

Article 5

Only the substances listed in Annex III may be used for the enrichment of infant formulae and follow-up milks with:

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

Article 6

For the manufacture of infant formulae and follow-up milks, only the additives listed in Annex IV may be used, provided the conditions laid down therein are met.

Article 7

1. To take account of scientific or technical developments subsequent to the adoption of this Directive, a Member State may authorize within its territory:

- the observance of essential compositional criteria that are new or differ from those in Annexes I and II,
- the use of substances not mentioned in Annexes III and IV,
- the widening of the conditions of use in Annex IV,

subject to the following conditions:

(a) the authorization must be limited to a maximum period of three years;
(b) the Member State must carry out an official check of products manufactured in accordance with the authorization;

(c) products thus manufactured must bear a distinctive indication which is to be defined in the authorization.

2. The Member State shall forward to the other Member States and to the Commission the text of any authorization drawn up by virtue of paragraph 1 within two months of the date of its taking effect.

3. Before the expiry of the three-year period provided for in paragraph 1, the Member State may submit to the Commission a request for the admission in this Directive of the elements that are the subject of national authorization in accordance with paragraph 1. At the same time it shall supply supporting documents setting out the grounds on which it deems such admission justified.

Within 18 months of the submission of the request, a decision shall be taken on the basis of technical data and information relating to public health, where necessary after consulting the Scientific Committee for Food, and in accordance with the procedure laid down in Article 9 of Directive 77/94/EEC as to whether the elements in question may be admitted in this Directive or whether the national authorization should be revoked. Notwithstanding paragraph 1(a), the national authorization shall remain in force until a decision is taken on the request for admission in this Directive.

Should it be decided pursuant to the preceding subparagraph that the national authorization should be revoked, this decision shall apply simultaneously to any authorizations given by another Member State for the same subject.

Article 8

1. Infant formulae and follow-up milks shall not contain any substance in such quantity as to endanger the health of infants. The maximum levels of any such substances shall be stipulated at a later date in accordance with Article 100 of the Treaty.

2. Microbiological standards shall be established according to the procedure referred to in paragraph 1.

Article 9

1. The name under which the products covered by Article 1 are sold shall be, respectively, "infant formula" and "follow-up milk".

2. The labelling of infant formulae and follow-up milks 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 generally, a statement to the effect that the product is suitable for particular nutritional use by infants from birth in cases in which breastfeeding is not advised, sufficient or possible, or the mother chooses not to breastfeed;

(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 six months, their total iron requirements must be met from other additional sources;

(c) in the case of follow-up milks, a statement to the effect that the product is only suitable 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 replacement for breast milk during the first four months of life;

(d) 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) the average quantity of each mineral substance and of each vitamin mentioned in Annex I and Annex II respectively, and where applicable of choline, per 100 ml of the product ready for use;

(f) instructions for appropriate preparation of the product and a warning against the health hazards of inappropriate preparation;

(g) information to enable batch identification.

3. 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 breastfeeding;

(b) a statement recommending that the product be used only on the advice of persons having qualifications in medicine, nutrition or pharmacy;

(c) a warning concerning the negative effect on breastfeeding of introducing partial bottle-feeding;

(d) a warning concerning the difficulty of reversing a decision not to breastfeed.

4. The labelling of infant formulae and follow-up milks shall be designed to provide the necessary information about the appropriate use of the products and so as not to discourage breastfeeding. The use of the terms "humanized", "maternalized", "adapted" or similar terms shall be prohibited.

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

The implementing provisions for this paragraph shall be adopted, where necessary, in accordance with the procedure laid down in Article 9 of Directive 77/94/EEC.

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

Any amendments that have to be made to that Annex in line with scientific and technical progress shall be adopted in accordance with the procedure laid down in Article 9 of Directive 77/94/EEC.

6. The requirements, prohibitions and restrictions referred to in paragraphs 3, 4 and 5 shall also apply to:

(a) the presentation of infant formulae and follow-up milks, in particular their shape, appearance or packaging, the packaging materials used, the way in which they are arranged and the setting in which they are displayed;

(b) advertising.

Article 10

The labelling, marketing and advertising of articles for use in conjunction with infant formulae, such as teats, feeding-bottles, bottle-heaters and other specially-designed feeding equipment, when referring to infant formulae, shall comply with the requirements of Article 9, paragraphs 3 and 4.

The labelling of such articles intended for export to third countries shall likewise comply with the requirements of Article 9, paragraphs 3 and 4, except insofar as precluded by provisions applicable in the third country of import.

Article 11

1. Advertising of infant formulae shall be restricted to publications specializing in baby care.

2. Advertisements for infant formulae shall be subject to the conditions laid down in Article 9, paragraphs 3, 4, 5 and 6(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 breastfeeding.

3. 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.

4. 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 12

1. Member States shall take the necessary measures to 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, provisions, design and dissemination of information and their control.

2. Member States shall take the necessary measures to 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 breastfeeding;
(b) maternal nutrition and the preparation for and maintenance of breastfeeding;
(c) the negative effect on breastfeeding of introducing partial bottle-feeding;
(d) the difficulty of reversing the decision not to breastfeed;
(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 unnecessary or improper use of infant formulae. Such material shall not use any pictures which may idealize the use of infant formulae.

3. Member States shall take the necessary measures to ensure that donations of informational or educational equipment or materials by manufacturers or distributors shall be made only at the 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 formula and shall be distributed only through the health care system.

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

Article 13

1. Where a Member State, as a result of new information or of a reassessment of existing information made since this Directive was adopted, has detailed grounds for establishing that the use in infant formulae or follow-up milks of one of the substances listed in Annexes III and IV or the maximum permissible concentration thereof endangers human health although it complies with this Directive, that Member State may temporarily suspend or restrict application of the provisions in question within its territory. It shall immediately inform the other Member States and the Commission thereof and give reasons for its decision.

2. The Commission shall examine as soon as possible the grounds given by the Member State concerned and consult the Member States within the Standing Committee for Foodstuffs, and shall then deliver its opinion forthwith and take the appropriate measures.

3. If the Commission considers that amendments to this Directive are necessary in order to resolve the difficulties mentioned in paragraph 1 and to ensure the protection of human health, it shall initiate the procedure laid down in Article 9 of Directive 77/94/EEC with a view to

adopting those amendments; in such cases, any Member State which has adopted safeguard measures may in that event retain them until the date on which the amendments are to be applied.

Article 14

Member States shall take the necessary measures to comply with this Directive. They shall forthwith inform the Commission thereof. Those measures shall be applied in such a way as to:

- permit trade in products complying with this Directive, by ...[1];

- prohibit trade in products which do not comply with this Directive, with effect from ...[2].

Article 15

This Directive is addressed to the Member States.

Done at

For the Council

The President

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[1] 18 months after the notification.

[2] 36 months after the notification.

ANNEX I

ESSENTIAL COMPOSITION OF INFANT FORMULAE

N.B.: The values given refer to the products ready for use.

PART A

FORMULAE MANUFACTURED ENTIRELY FROM COWS' MILK PROTEINS

1. Energy

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

2. Proteins (Protein content = nitrogen content x 6.38)

2.1 Formulae manufactured from unmodified cows' milk proteins

Minimum	Maximum
0.56g/100 kJ (2.25g/100 kcal)	0.7g/100 kJ (3g/100 kcal)

- The chemical index of the proteins present shall be equal to at least 80% of that of the reference protein (human milk, as defined in Part I of 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 amino acids of the proteins present and the corresponding amino acids of the reference protein.

2.2 Formulae manufactured from modified cows' milk proteins (alteration of the casein/whey protein ratio)

Minimum	Maximum
0.45g/100 kJ	0.7g/100 kJ
(1.8g/100 kcal)	(3g/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 (human milk as defined in Part I of Annes VI).

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

3. Lipids

Minimum	Maximum
0.8g/100 kJ	1.5g/100 kJ
(3.3g/100 kcal)	(6.5g/100 kcal)

3.1 The use of the following substances is prohibited:

- sesame oil;
- cotton 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)	285 mg/100 kJ (1200 mg/100 kcal)

4. Carbohydrates

Minimum		Maximum
1.7 g/100 kJ (7 g/100 kcal)	3.4 g/100 kJ	(14 k/100 kcal)

4.1 Only the following carbohydrates may be used:

- lactose;
- Maltose;
- sucrose;
- malto-dextrins;
- pre-cooked starch
- gelatinised starch

} Naturally free of gluten

4.2 Lactose

Minimum	Maximum
0.85 g/100 kJ (3.5 g/100 kcal)	-

4.3 Sucrose:

Minimum	Maximum
-	20% of the total carbohydrate content

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4.4 Pre-cooked starch and/or gelatinised starch:

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

5. Mineral substances

	per 100 kJ		per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Sodium (mEq)	0.25	0.6	1	2.6
Potassium (mEq)	0.4	0.9	1.6	3.8
Chloride (mEq)	0.35	0.8	1.4	3.5
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)	0.07	-	0.3	-
Copper (µg)	4.8	19	20	80
Iodine (µg)	1.2	-	5	-

The calcium/phosphorus ratio shall not be less than 1.2 nor greater than 2.0.

[1] Limit applicable to formulae with added iron.

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6. Vitamins

	per 100 kJ		per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamin A (µg RE)[1]	14	43	60	180
Vitamin D (µg)[2]	0.25	0.5	1	2
Thiamine (µg)	10	-	40	-
Riboflavin (µg)	14	-	60	-
Nicotinamide (µg-NE)[3]	60	-	250	-
Pantothenic acid (µg)	70	-	300	-
Vitamin B_6 (µg)	9	-	35	-
Biotin (µg)	0.4	-	1.5	-
Folic acid (µg)	1	-	4	-
Vitamin B_{12} (µg)	0.025	-	0.1	-
Vitamin C (mg)	1.9	-	8	-
Vitamin E (mgα-TE)[4]	0.5/g of poly unsaturated fatty acids expressed as linoleic acid but in no case less than 0.1 mg/100 available kJ	-	0.5/g of poly unsaturated fatty acids expressed as linoleic acid but in no case less than 0.5 mg/100 available kcal	-

[1] RE = all-trans retinol equivalent.

[2] In the form of cholecalciferol, of which 10µg = 400 i.u. of vitamin D.

[3] NE = Niacin equivalent = mg nicotinic acid + mg tryptophan/60.

[4] α-TE = d-α-tocopherol equivalent.

A I

PART B

FORMULAE NOT OR NOT EXCLUSIVELY MANUFACTURED FROM COWS' MILK PROTEINS

(To be completed later in accordance with the second paragraph of Article 4(1)).

ANNEX II

ESSENTIAL COMPOSITION OF FOLLOW-UP MILKS

N.B.: The values given refer to the products ready for use.

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1. Energy

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

2. Proteins (Protein content = nitrogen content x 6.38)

Minimum	Maximum
0.5 g/100 kJ	1g/100 kJ
(2.25g/100 kcal)	(4.5g/100 kcal)

- The chemical index of the proteins present shall be at least equal to 85% of that of the reference protein (casein as defined in Part II of Annex VI).

- The "chemical index" shall mean the lowest of the ratios between the amino acids of the proteins present and the corresponding amino acids of the reference protein.

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

3. Lipids

Minimum	Maximum
0.8g/100 kJ	1.5g/100 kJ
(3.3g/100 kcal)	(6.5g/100 kcal)

3.1 The use of the following substances is prohibited:

- sesame oil;
- cotton 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-up milks containing vegetable oils	-

4. Carbohydrates

Minimum	Maximum
1.7 g/100 kJ (7 g/100 kcal)	3.4 g/100 kJ (14 g/100 kcal)

4.1 The use of ingredients containing gluten is prohibited.

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4.2 Lactose:

Minimum	Maximum
0.45 g/100 kJ (1.8 g/100 kcal)	-

4.3 Sucrose, Fructose, Honey:

Minimum	Maximum
-	Separately or as a whole 20% of the total carbohydrate content

5. Mineral substances

5.1 Iron:

Minimum	Maximum
0.25 mg/100 kJ (1 mg/100 kcal)	0.5 mg/100 kJ (2 mg/100 kcal)

5.2 Zinc:

Minimum	Maximum
0.12 mg/100 kJ (0.5 mg/100 kcal)	-

5.3 Other mineral substances:

The concentrations normally found in cows' milk, reduced, where appropriate, in the same ratio as the protein concentration of the follow-up milk to that of cows' milk. The typical composition of cows' milk is given, for guidance, in Annex VII.

5.4 The calcium/phosphorus ratio shall not exceed 2.0.

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6. Vitamins

	per 100 kJ		per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamins A (µg RE)[1]	14	43	60	180
Vitamin D (µg)[2]	0.25	0.5	1	2
Vitamin C (mg)	1.9	-	8	-
Vitamin E (mg α - TE)[3]	0.5/g of of poly unsaturated fatty acids expressed as linoleic acid but in no case less than 0.1 mg/100 available kJ	-	0.5/g of of poly unsaturated fatty acids expressed as linoleic acid but in no case less than 0.5 mg/100 available kcal	-

[1] RE = all trans retinol equivalent.

[2] In the form of cholecalciferol, of which 10 µg = 400 i.u. of vitamin D.

[3] α-TE = d-α-tocopherol equivalent.

ANNEX III

SUBSTANCES WITH A SPECIFIC NUTRITIONAL PURPOSE THAT MAY BE USED IN INFANT FORMULAE AND FOLLOW-UP MILKS

PART I - MINERAL SALTS

Mineral substances	Permitted salts
1. Calcium (a)	Calcium carbonate
	Calcium chloride
	Calcium citrate
	Calcium gluconate
	Calcium glycerophosphate
	Calcium lactate
	Calcium phosphate, monobasic
	Calcium phosphate, dibasic
	Calcium phosphate, tribasic
	Calcium hydroxide
2. Phosphorus (P)	Calcium phosphate, monobasic
	Calcium phosphate, dibasic
	Calcium phosphate, tribasic
	Magnesium phosphate, dibasic
	Magnesium phosphate, tribasic
	Potassium phosphate, monobasic
	Potassium phosphate, dibasic
	Sodium phosphate, dibasic
3. Magnesium (Mg)	Magnesium carbonate
	Magnesium chloride
	Magnesium oxide
	Magnesium phosphate, dibasic
	Magnesium phosphate, tribasic
	Magnesium sulphate
	Magnesium gluconate

A III

4. Iron (Fe)	Ferrous citrate
	Ferrous gluconate
	Ferrous lactate
	Ferrous sulphate
	Ferric ammonium citrate
5. Copper (Cu)	Cupric citrate
	Cupric gluconate
	Cupric sulphate
	Copper Lysine Complex
	Copper carbonate
6. Iodine (I)	Potassium iodide
	Sodium iodide
	Potassium iodate
7. Zinc (Zn)	Zinc acetate
	Zinc chloride
	Zinc lactate
	Zinc sulphate
	Zinc citrate
8. Manganese (Mn)	Manganese carbonate
	Manganese chloride
	Manganese citrate
	Manganese sulphate
	Manganese gluconate
9. Sodium (Na)	Sodium bicarbonate
	Sodium chloride
	Sodium citrate
	Sodium gluconate
	Sodium carbonate
	Sodium lactate
	Sodium phosphate, monobasic
	Sodium phosphate, dibasic
	Sodium phosphate, tribasic
	Sodium hydroxide

10. Potassium (K)	Potassium bicarbonate
	Potassium carbonate
	Potassium chloride
	Potassium citrate
	Potassium gluconate
	Potassium lactate
	Potassium phosphate, monobasic
	Potassium phosphate, dibasic
	Potassium phosphate, tribasic
	Potassium hydroxide

PART II - VITAMINS

Vitamin	Vitamin formulation[1]
1. Vitamin A	Vitamin A acetate Vitamin A palmitate Beta-carotene (Provitamin A)
2. Vitamin D	Vitamin D_2 (Ergocalciferol) Vitamin D_3 (Cholecalciferol) Vitamin D_3- Cholesterol
3. Vitamin B_1	Thiamine hydrochloride Thiamine mononitrate
4. Vitamin B_2	Riboflavin Riboflavin 5'-phosphate sodium
5. Nicotinamide	Niacinamide Nicotinic acid (niacin)
6. Vitamin B_6	Pyridoxine hydrochloride Pyridoxal-5'-phosphate
7. Folic acid	Folic acid
8. Pantothenic acid	D-calcium pantothenate D-sodium pantothenate D-panthenol
9. Vitamin B_{12}	Cyanocobalamin Hydroxocobalamin

10. Vitamin H	d-Biotin
11. Vitamin C	l-ascorbic acid Sodium-l-ascorbate Calcium-l-ascorbate l-ascorbyl-6-palmitate Potassium ascorbate
12. Vitamin E	d-alpha-tocopherol dl-alpha-tocopherol d-alpha-tocopherol acetate dl-alpha-tocopherol acetate
13. Vitamin K	Vitamin K_1

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[1] The following substances may be added to vitamin formulations, for technological reasons.

- edible substances
- gelatine
- the additives listed in Annex IV
- gum arabic
- silicon dioxide (maximum concentration: 10 g/kg)

A III

PART III - AMINO ACIDS AND OTHER NITROGEN COMPOUNDS

L arginine and its hydrochloride
L cystine and its hydrochloride
L histidine and its hydrochloride
L isoleucine
L leucine
L lysine
L and DL methionine
L phenylalanine
L threonine
L tryptophan
L tyrosine
L valine

taurine

PART IV - OTHER SUBSTANCES

Choline (choline chloride)

ANNEX IV

ADDITIVES

N.B.: The limits given refer to the products ready for use.

Additives		Conditions of use
- L-ascorbic acid	(E 300)	
- Sodium-L-ascorbate	(E 301)	
- Calcium-L-ascorbate	(E 302)	
- Ascorbyl palmitate	(E 304)	
- Tocopherol-rich extracts of natural origin	(E 306)	In a concentration, taken either separately or together, of not more than 1mg/100 ml in infant formulae and follow-up milks
- Synthetic Alpha-tocopherol	(E 307)	
- Synthetic Gamma-tocopherol	(E 308)	
- Synthetic Delta-tocopherol	(E 309)	
- Lecithin	(E 322)	In a concentration of not more than 0.5g/100 ml in infant formulae and follow-up milks[1]
- Mono- and diglycerides of fatty acids	(E 471)	In a concentration of not more than 0.4g/100 ml in infant formulae and follow-up milks[1]

[1] Where substances E 322 and E 471 are used together, the amount of each of them actually used shall represent only part of the maximum concentration and shall be such that the sum of the two fractions does not exceed one.

- Carrageenan	(E 407)	In a concentration of not more than 0.03g/100 ml in follow-up milks[1]
- Locust bean gum	(E 410)	In a concentration of not more than 0.1g/100 ml in follow-up milks[1]
- Guar gum	(E 412)	In a concentration of not more than 0.1g/100 ml in follow-up milks[1]
- Citric acid		
- L(+) lactic acid		
- Cultures producing L(+) lactic acid		

[1] Where substances E 407, E 410 and E 412 are used together, the amount of each of them actually used shall represent only part of the maximum concentration and shall be such that the sum of the fractions does not exceed one.

ANNEX V

CLAIMS CONCERNING A SPECIFIC COMPOSITIONAL CRITERION FOR INFANT FORMULAE

Compositional criterion	Conditions warranting a claim
- Proteins	The protein content is lower than 0.6g/100 kJ (2.5g/100 kcal) and the whey protein/casein ratio is not less than 1.0.
- Sodium	The sodium content is lower than 0.4mEq/100 kJ (1.7 mEq/100 kcal)
- Sucrose	No sucrose is present
- Lactose	Lactose is the only carbohydrate used
- Iron	The iron is added

ANNEX VI

REFERENCE PROTEINS

PART I - HUMAN MILK

	mg/100 kJ	mg/100 kcal	g/100g of protein
Arginine	16	69	3.8
Cystine	6	24	1.3
Histidine	11	45	2.5
Isoleucine	17	72	4.0
Leucine	37	156	8.5
Lysine	29	122	6.7
Methionine	7	29	1.6
Phenylalanine	15	62	3.4
Threonine	19	80	4.4
Tryptophan	7	30	1.7
Tyrosine	14	59	3.2
Valine	19	80	4.5

PART II - CASEIN

	g/100g of protein
Arginine	3.7
Cystine	0.3
Histidine	2.9
Isoleucine	5.4
Leucine	9.5
Lysine	8.1
Menthionine	2.8
Phenylalanine	5.2
Threonine	4.7
Tryptophan	1.6
Tyrosine	5.8
Valine	6.7

ANNEX VII

CONCENTRATIONS OF MINERAL ELEMENTS IN COWS' MILK

For guidance, the concentrations of mineral elements in cows' milk are as follows:

	per 100g of fat-free dry matter	per 1g of proteins
Sodium (mEq)	24	0.65
Potassium (mEq)	43	1.10
Chloride (mEq)	30	0.80
Calcium (mg)	1350	35
Phosphorus (mg)	1070	28
Magnesium (mg)	135	3.5
Copper (µg)	225	6
Iodine	Not specified	Not specified

COUNCIL RESOLUTION

on the marketing practices for breast-milk substitutes in developing countries by Community-based manufacturers

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Whereas the Commission has submitted a report on infant feeding and the implementation of the International Code of Marketing of Breast-milk Substitutes and a draft proposal for a Council directive on the approximation of the laws of the Member States relating to infant formulae and follow-up milks;

Whereas in May 1981 the 34th World Health Assembly adopted as a recommendation the International Code of Marketing of Breast-milk Substitutes;

Whereas a considerable volume of these products are sold to developing countries by Community-based manufacturers;

Whereas it is considered very important that marketing practices in developing countries should not discourage mothers from breastfeeding;

Whereas the application of the International Code provides without doubt an excellent way to achieve this in these countries;

Whereas the Community cannot legislate for these countries;

Whereas the Community can offer an effective support to the competent authorities of these countries in their efforts to apply the International Code in their territory,

HAS ADOPTED THE FOLLOWING RESOLUTION:

1. The Community will contribute, in so far as it is able, to the application of appropriate marketing practices for breast-milk substitutes in developing countries.

2. For the implementation of point 1, the Commission will instruct its delegations in the developing countries to serve as contact points for the competent authorities. Any complaints or criticisms with respect to the marketing practices of a manufacturer based in the Community could be notified to them.

3. The Commission will be ready to examine such cases and to assist in the search for a satisfactory solution for all parties concerned.

4. This resolution shall be communicated by the Commission to the countries concerned through the official channels.