COMMISSION OF THE EUROPEAN COMMUNITIES

COM(84) 703 final

Brussels, 14 December 1984

Proposal for a

Council Directive

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

(submitted to the Council by the Commission)

COM (84) 703 final

Com 703

EXPLANATORY NOTE

1. On 21 December 1976 the Council adopted Directive 77/94/EEC on the approximation of the laws of the Member States relating to foodstuffs for particular nutritional uses (1). Article 1(3) of that outline directive provides for the adoption of specific directives applicable to certain groups of products defined th rein. This proposal covers infant formulae and follow-up milks intended for particular nutritional use by infants in good health. Products intended for use by low birth-weight infants and for infants and young children suffering from nutritional or metabolic disorders are excluded from the scope of this proposal.

2. Human milk, when available in sufficient quantities, is the best food for nearly all healthy infants. But when mothers choose or are obliged not to breastfeed, or to do so partially, manufactured preparations provide the best alternative. Such products first appeared about a century ago in response to a need for alternatives to a wet nurse or to cow's milk. Initially the aim was to provide a product free from pathogenic micro organisms. Later, doctors recognised the problems associated with the digestibility of cow's milk and started providing their own blends of diluted cow's milk to which they added sugar and fat. In parallel, the importance of vitamins in the diet was discovered. Manufacturers adopted the idea and started producing accordingly modified preparations. But it was after the second World War that most significant developments in this area started.

3. These products have to respond to the needs of the most vulnerable section of the population. Thus, their evolution followed closely advances in scientific knowledge, in medicine, nutrition and other disciplines as has the evolution of legislation relating to these products.

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(1) O.J. No L 26/55 of 31.1.77

Within the Community, two types of approaches exist. One lays down general legal criteria to which these products have to conform in order to be marketed while the other requires the examination of each individual product and its approval. Directive 77/94/EEC has retained the first approach which forms therefore the basis for this proposal.

4. The nature of the products and the population for which they were intended called for careful assessment of the nutritional and other scientific evidence which should be taken into consideration in laying down their essential composition. The Scientific Committee for Food (SCF) was asked to give its opinion on the matter. The SCF was assisted in its work by eminent experts on the subject. It expressed its opinion on 27 April 1983 (1). This opinion formed the basis for the nutritional and technical specifications of this proposal.

5. In addition, the Commission services, in their preparatory work, had the benefit of the advice of the Advisory Committee on Foodstuffs which is composed of representatives of Agriculture, Commerce, Consumers, Industry and Workers. They also consulted Member States in the usual way.

6. The great majority of infant formulae intended for healthy infants existing presently in the Community market are based on cow's milk protein. A small number of products (7-8 % of the market) is based wholly or partially on other protein sources, mainly soya protein. The latter are currently used for infants which are allergic to cow's milk protein, suffer from diarrhoea or other conditions. These preparations though can be used for healthy infants. However, additional scientific and technological considerations have to be taken into account in laying down specific rules for these products. The Commission feels that more time is needed for the evaluation

(1) Report of SCF 14th Series.

of the data related to these products and intends to specify their essential composition at a later date. The problem does not arise with follow-up milks since these products are exclusively manufactured from cow's milk protein.

7. At birth some physiological processes involved in the digestion, absorption, hepatic functions and renal clearance are not fully developed. The neonate therefore has a limited tolerance with respect to certain nutrients during its first few months of life. The essential composition of infant formulae based on cow's milk laid doown in Annex I, Part A, takes this into account as well as the fact that this product being the sole source of nourishment for the infant has to supply him with all the nutrients and the energy necessary for growth and for the development of various tissues.

8. In the words of the SCF, "after the age of about 4 months, the mechanisms that ensure homeostasis are sufficiently developed to cope with much wider variations in the concentration of nutrients". In addition, usually between the age of 3 and 6 months, infants are gradually introduced to a variety of foods. Thus, the milk preparation, when used, becomes a component of a progressively diversified diet and has to supply only part of the materials necessary for growth. Manufacturers in the Community have therefore developed a distinct product, followup milk, which can be fed to infants after the age of 4-6 months. For the above reasons the essential requirements for the latter product, which are laid down in Annex II, have more flexibility, especially with regard to vitamins and mineral substances, than those for the former. It must be stressed, however, that infant formula is also suitable for use by infants above the age of 4-6 months.

9. The essential requirements laid down in Annexes I and II refer to the products ready for use. In order that these are fulfilled a number of mineral substances, vitamins, amino acids and other nitrogen compounds have to be added. Infant

formulae and followup milks are manufactured from raw materials whose composition may vary according to their source or may fluctuate according to the season. The finished product can be marketed as a powder or as a liquid. Their method of production varies according to the product and the proprietory mark. The list of compounds which can be added, given in Annex III, is wide enough to allow for these factors to be taken into consideration. The criteria used for the inclusion of the compounds in this list have been mainly the absence of any health risk, their good nutritional availability, their correct solubility, their stability and low reactivity with other substances during processing, their lack of colour defects and unacceptable taste effects and their optimal storage stability. The technological needs for the production of these products justifies the use of the additives given in Annex IV, which are acceptable from the point of view of health protection.

10. Scientific and technological advances in the field might necessitate future changes or additions in the provisions of Annexes I, II, III and IV. It is essential that adequately proven, beneficial technical modifications to this directive should be able to be effected with the minimum of delay. The contrary would be a deterrent for investing in research and seeking progress in the area. Article 7 takes account of these facts.

11. The labelling provisions of Article 9 take into account the particular nature of the produts and the relevant provision of the International Code of Marketing of Breast-milk substitutes. These products are specifically formulated to meet the needs of infants and the special conditions of their metabolism. The use of terms such as "humanized", "maternalized", "adapted" and the like which might imply that these products are of an extra quality compared with others is prohibited. On the other hand the specific compositional criteria for which a claim can be made are defined in Annex V.

12. The Commission, with the support of the SCF, is currently examining infant formulae not or not entirely based on cow's milk proteins and other groups of foods for infants and young children with a view to present proposals in these areas in the future.

13. The consultation of the European Parliament and the Economic and Social Committee on this proposal is required under article 100 of the Treaty.

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 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;

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 follow-up milks currently sold in the Community are manufactured exclusively from cows' milk; whereas the scope of this Directive should therefore be restricted to that type of product for the time being;

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

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 need do no more than adopt the additions and exceptions to those general rules;

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, in application of 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 and labelling laid down in this Directive should also take account of 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,

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

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. It shall apply to "infant formulae" and "follow-up milks" intended for particular nutritional use by infants in good health.

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

Member States shall take all necessary steps to ensure that the products referred to in Article 1(2) may be marketed only if they conform to the definitions and rules laid down in this Directive.

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 cows' milk and, where appropriate, other 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 criteria for the compositional criteria for infant formulae that are not or not exclusively manufactured from cows' milk proteins shall be specified at a later date 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.

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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 States shall forward to the other Member States and to the Commission the text of any authorization drawn up pursuant to 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. By way of derogation from 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 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 foreseen 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;

(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 suitable for particular nutritional use by infants over the age of four months and that it should form part of a diversified diet;

(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;

(g) a statement to the effect that it is important for the infant's health that these instructions be followed;

(h) information making possible batch identification.

3. The labelling of infant formulae shall in addition bear the following mandatory particulars:

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

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

4. The labelling of infant formulae and follow-up milks and the methods used must not idealize the use of the products. The use of the terms "humanized", "maternalized", "adapted" or similar terms shall be prohibited.

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 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 prohibitions and restrictions referred to in paragraphs 4 and 5 shall also apply to:

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(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.

7. This Article shall also apply to infant formulae and follow-up milks for export outside the Community, in so far as this is not precluded by provisions in the importing country.

Article 10

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.

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Article 11

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, by 1 January 1986 at the latest, trade in products complying with this Directive,
- prohibit, on 1 July 1987, trade in products which do not comply with this Directive.

Article 12

This Directive is addressed to the Member States.

Done at

For the Council

The President

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.

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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 ∝ - TE)[3]	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 10 µg = 400 i.u. of vitamin D.

[3] ∝-TE = d-∝ -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

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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

A VC

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

REPORT ON
INFANT FEEDING AND THE IMPLEMENTATION OF THE INTERNATIONAL CODE OF MARKETING OF BREAST-MILK SUBSTITUTES

1. Introduction

The Commission of the European Communities has for some time now been studying the subject of infant feeding. In this the Commission was prompted by international interest and by the fact that the Community is competent to regulate on the qualitative aspects of foodstuffs intended for the particular nutritional use of infants and young children.

1.1. In the late 1970s the subject of infant and young child feeding received much attention. At the origin of this interest there were reports compiled by various non-governmental organisations describing the marketing practices for the promotion of breast milk substitutes to the detriment of breast-feeding and denouncing the effects these practices had on the health of infants particularly in the developing countries. In October 1979 WHO and UNICEF organised a joint meeting on the subject in Geneva. Representatives of industrialised and developing countries, of the relevant sector of industry, of non-governmental organisations, of the Commission of the European Communities and experts in related disciplines participated. The discussions were organised on five main themes: the encouragement and support of breast-feeding; the promotion and support of appropriate and timely complementary feeding practices with the use of local food resources; the strengthening of education, training and information on infant and young child feeding; the promotion of the health and social status of women in relation to infant and young child health and feeding and the appropriate marketing and distribution of breast-milk substitutes.

In this meeting a series of recommendations relating to infant feeding were formulated among which that "there should be an international code of marketing of infant formula and other products used as breast-milk substitutes"(1).

In May 1981 the final draft of the International Code was presented to the 34th World Health Assembly in the alternative forms of a regulation and a recommendation. It was adopted as a recommendation by 118 votes in favour,1 against and 3 abstentions. During the debate at that meeting the Community and its Member States stated (Annex 1) that they were in favour of the code as a recommendation and that they fully subscribed to its aims. With regard to its implementation they pointed out that in the past action had already been taken to achieve several of these aims within the Community. For other parts of the Code it was stated that the Community and its Member States, as appropriate, would endeavour to give effect to the principles and goals set out therein, having regard to their constitution, laws and social structures. A second statement, to the same effect, was made at the 36th World Health Assembly. (Annex II).

1.2. With two resolutions, in October 1981 (2) and April 1983 (3), the European Parliament called on the Commission to submit to the Council a proposal for a directive on the application of the International Code and to make all reasonable efforts to ensure that companies based in Member States and operating in developing countries comply with the provisions of the International Code or local legislation and codes in developing countries.

2. <u>The situation of infant feeding in the Community in relation to the aims of the International Code</u>

Apart from these cases where medical or other imperative circumstances remove all element of choice the decision whether

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(1)Resolution WHO 33.32 Infant and young child feeding. 8

(2)OJ No C 287/75 of 15.10.81.

(3)OJ No C 128/16 of 16.5.83.

to breast-feed or not is an intensely personal one taken by each mother usually before birth. In the Community the high degree of development of the health services, the activities of voluntary groups and extensive public debate in the media ensures that the majority of mothers are aware of and are able to appreciate the considerable advantages of breast feeding before making their decision. Amongst the factors which can influence their choice are, health status, whether the mother works or not, her working conditions, her level of education, information, advice and assistance she receives during pregnancy and during her stay in the maternity clinic after birth by health professionals, opinions expressed by the close environment (relatives, friends). Marketing and distribution of breast milk substitutes is another factor but in an informed society by no means the most important. It should be noted here that studies and research are currently under way to assess the level of contamination of human milk by various chemicals and in different settings, and to assess the health significance of these levels of contamination.

The aim of the International Code as spelt out in its first article is to contribute to the provision of safe and adequate nutrition for infants, firstly by the protection and promotion of breast-feeding and secondly, by ensuring the proper use of breast-milk substitutes of appropriate quality, when these are necessary.

The main areas dealt with in the International Code can be identified as

- the education and information of the general public, mothers and health workers,
- the conduct of health care systems
- the marketing practices for breast-milk substitutes and
- their labelling and quality.

2.1. Education, information and the conduct of health care systems

Measures concerning information and education on the particular subject and the conduct of health care services are essentially the responsibility of National Authorities of Member States. The latter have recognised the importance of breast-feeding long before the development of the International Code and they have undertaken active campaigns for its protection and promotion.

Social measures, which are not covered by the International Code, include special maternity leave which, in many cases, is flexible and its greater part can be taken after the birth. In some countries this leave can be extended without pay with guarantee of the post of employment and financial assistance is provided by the State during this period of leave.

In some countries mothers of infants and young children have reduced working hours or are allowed breaks during work to give them the possibility to continue to breast-feed their babies. The provision of breast-feeding breaks, together with the provisions of creches in the places of employment is under consideration by other Member States.

Most of the efforts, though, have been concentrated in the field of education and information. Such action has been directed at health care systems and the public.

In the U.K., for example, the attention of health care systems and health workers had been drawn to the benefits of breast feeding in the past by publications such as "Reducing the risk" (1977), "Breast Feeding" (1978),"Eating for Health" (1978) and "Present day Practice in Infant feeding" (1980), to cite as an example the United Kingdom.

Health circulars reaffirming the Member States Authorities' commitment to the promotion of breast feeding have been circulated to health care systems following the publication of the WHO Code. In these the responsibilities of health care personnel, covered by specific provisions of the WHO Code, are stressed. The importance of the advice given to mothers regarding infant feeding practices is underlined. The aim is to enable mothers to make an informed choice about the method of feeding their babies. Maternity clinics are encouraged to put into practice, whenever possible, current concepts which will help the establishment of breast-feeding such as immediate contact between the mother and the baby after delivery, "rooming in" of mothers and babies and the possibility of feeding the baby "on demand" if the mother so wishes. Guidelines for the distribution of samples of breast milk substitutes, when necessary, are also provided.

In order that the health workers are best able to carry out their duties, measures are taken or are under study to include in the curricula of health personnel, as priority subjects, principles of nutrition, nutritional needs of mothers and infants, the advantages of breast feeding over artificial feeding and the appropriate use of breast milk substitutes when these are necessary.Further measures aim at the provision of in-service training and refresher courses for improving the continuous education of doctors, health visitors and midwives. This formal training is supplemented by leaflets and posters containing appropriate information, which are published by the Health Authorities. Education and information of future mothers and mothers is extremely important. They are, after all, the ones to make the final decision. The importance attached to it is well illustrated by the fact that certain Member States have carried out or are in the process of carrying out surveys on the frequence of breast-feeding, its duration, the physiological, socio-economic and enviromental factors affecting breast-feeding. In Ireland one of these surveys has identified also the media preferred by mothers for receiving information on nutrition. The results of these surveys provide baseline information for planning further

public education programmes.

At present primary sources of education are the health personnel of ante- and post-natal clinics and of maternity clinics. Their responsibilities and their importance have been outlined above.

Another equally important source are booklets, leaflets and posters produced by Health Authorities and made available through the health care systems free of charge. These publications contain comprehensive information on maternal nutrition, infant nutrition, the superiority and benefits of breast-feeding, how to establish and maintain breast-feeding, the proper use of breast milk substitutes when these are necessary and other information on baby care.

Special attention is given to particular population groups such as ethnic minorities, where these exist. In Germany, for example, a 60-page publication, "Das Baby", is published also in Greek, Italian, Portuguese, Serbo-Croatian, Spanish and Turkish. In the United Kingdom the Government's Asian Mother and Baby Project has the responsibility of informing this special group.

The Authorities in Member States provide various means of assistance, including financial support, to a number of voluntary organisations which promote breast-feeding. The contribution of these organisations towards this goal is indeed considerable. They diffuse a plethora of information through leaflets, lectures, etc.

Regarding the education and information of the public at large, professional bodies and non-governmental organisations publish articles in the Press which cover certain needs in this field. The Health Circular to Health Authorities in the United Kingdom notes that health education officers, school doctors, health visitors and school nurses will have a role to play in spreading appropriate information among young people in the context of preparation for parenthood. This may mark a trend in developments in the area of health education of the public in general.

2.2. Marketing practices

Marketing according to the International Code means product promotion, distribution, selling, advertising, product public relations and information services. Marketing campaigns are planned by manufacturers. But because of the nature of these products there is a close link between the health policies and the organisation of health care systems in this area in the various Member States and the way in which these products are marketed. Thus national authorities exercise control over the marketing practices for these products. But apart from differences in traditions and customs there are other differences which influence marketing practices. For example a total ban on advertising, as advocated by the International Code, would be contrary to the constitution of several Member States.

All Member States are in favour of voluntary agreements for the control of the marketing practices for breast-milk substitutes. National Federations of Manufactures have expressed their willingness to set up such voluntary codes of practice for implementing the aims and principles of the WHO Code in a way which is appropriate to national circumstances. In Ireland, the United Kingdom and Denmark such voluntary codes were developed in consultation with the responsible authorities and they are already in operation. In other Member States consultations are still going on.

At Community level manufacturers have been making considerable efforts to elaborate a voluntary code of conduct. The Association of Dietetic Foods of the EEC (ICACE) sent to the Commission in April 1982 a first draft of a voluntary code of practice for the marketing of breast milk substitutes agreed by the manufacturers of the Community, which was followed by a new draft in December 1982. The Commission felt that it would be very useful for the Member States and other parties concerned within the Community to be able to comment on the IDACE draft voluntary code. This was done in meetings with Member States and within the Advisory Committee for Food, which took place in

March/April 1983 and October 1983. During these meetings the Member Sates expressed firm support for voluntary measures for the regulation of the marketing practices of breast milk substitutes. However, they made numerous comments and suggestions for the improvement of the IDACE proposals. The four of the five groups represented in the Advisory Committee for Food, namely Agriculture, Commerce, Industry and Workers, were also in favour of the voluntary approach and thought that the IDACE draft was a good basis for discussions. The other group, Consumers, expressed their opposition in principle to voluntary measures, but participated fully in the discussions, made most of the suggestions for the improvement of the IDACE code and were generally satisfied with the final compromise. IDACE communicated the final version of their voluntary code to the Commission in January 1984 (Annex III).

The IDACE code relates to the marketing practices of infant formulae, which are the only ones marketed as a breast milk substitute for the first few months of life. It takes into account the individual constitutions, laws, social structures and relevant policies of Member States and therefore represents a general requirement for the Community area, not excluding specific national measures existing or being adopted. The IDACE code covers the conduct of manufacturers only. However, the manufacturers undertake not to infringe this code indirectly by inciting third parties or by providing them the means for doing so. After careful consideration of all the factors which influence the marketing practices for breast-milk substitutes in the Member States, the Commission is convinced that the flexibility offered by a voluntary agreement is the best way to control these practices. The Commission will consider again this position in the light of experience gained from the operation of the IDACE code.

The Commission is strongly in favour of the principle of monitoring the operating of the IDACE code which is unlikely to inspire sufficient confidence unless it is seen to be under independent scrutiny. However, the responsibility of setting up and the composition of a monitoring committee are

still under consideration and the text of Article 11.2 of the IDACE code should therefore be considered provisional.

2.3. Quality and labelling

The composition and labelling of infant foods, is covered by Article 9 and 10 of the International Code. This matter can be regulated through Article 1(3) of Council Directive 77/94/EEC on the approximation of the laws of the Member States relating to foodstuffs for particular nutritional uses, which states that the Council shall, by means of directives, adopt the provisions applicable to certain groups of products, among which are foodstuffs for particular nutritional use of infant and young children in good health.

The Commission asked the Scientific Committee for Food to give its opinion on the essential composition of infant formulae and follow-up milks. On the basis of this opinion, which was expressed in April 1983, and in consultation with Member States Government experts and the Advisory Committee for Food, the Commission drafted a proposal for a Council Directive on the composition, labelling and certain aspects of advertising of infant formulae and follow-up milks which is submitted to the Council together with this report.

3. The implementation of the International Code in developing countries

The Commission considered carefully the request of the European Parliament to make all reasonable efforts to ensure that companies based in Member States and operating in developing countries comply with the provision of the International Code or local legislation and codes in developing countries.

It agrees with the points of view expressed by the European Parliament that real problems of malnutrition of bottle-fed babies exist essentially in developing countries where the limited purchasing power of parents does not permit the regular provision of sufficient quantities of breast milk substitutes and where the hygienic conditions necessary for

the correct preparation of these substitutes are more difficult to obtain.

It is very important that marketing practices in developing countries should not discourage mothers from breastfeeding. It is the responsibility of the competent authorities of these countries to make sure that this principle is respected. The Commission in its effort to offer them effective support proposes the adoption of a Council Resolution on the subject (Annex 4). The system envisaged therein is both flexible and efficacious. At the same time, extra-territorial measures which are legally doubtful are avoided.

The Commission, on the other hand proposes that certain labelling requirements concerning the products covered by the attached proposal for a directive should also apply for products being exported.

The Commission finally draws attention to the fact that the IDACE industries have agreed to observe voluntarily that "all exported infant formulae will meet internationally recognised standards of quality, unless the recipient countries have specific national standards or particular nutritional requirements which have to be complied with".

4. Conclusions

In conclusion the Commission believes that the response of the Community to the International Code has to be a balanced one which makes the most effective use of the different means available to achieve the objectives of the Code. The variety of interrelationships between education, information and health care systems in the Member States reflect the different social traditions in a question in which personal contact and relationships are extremely important. The Commission is pleased to note the achievements of the various authorities and voluntary bodies and considers that discussion and exchange of experience at Community level can provide a useful stimulus to further progress.

The cooperation of industry both in respect of the voluntary code within the Community and their engagement of the quality of exported products has enabled a solution to be achieved much more rapidly than it could have if the Community had proceeded by using mandatory instruments. The effectiveness of this public commitment by industry is reinforced by their declared willingness to keep the operation of the code under continuous review in cooperation with public authorities and consumer bodies.

Finally the directive on the composition, labelling and certain aspects of advertising of infant formula and follow-up milk will give added assurance to the consumer that the product concerned is of appropriate quality whilst removing barriers to trade in an important area of foodstuffs.

ANNEX 1

European Community

Press Release

Geneva, 20 May 1981

STATEMENT BY THE NETHERLAND PRESIDENCY
ON BEHALF OF THE EUROPEAN ECONOMIC COMMUNITY AND ITS MEMBER STATES
ON THE DRAFT INTERNATIONAL CODE OF MARKETING OF BREAST MILK SUBSTITUTES
PRESENTED BY THE WORLD HEALTH ORGANIZATION

The Community and its Member States are in favour of the draft Code presented in the form of a recommendation of the World Health Organization.

1. We have examined the Code very closely and it is clear that we subscribe fully to its aims, namely the "provision of safe and adequate nutrition for infants". We also consider that breastfeeding must be encouraged as an unequalled way of contributing to the achievement of this aim. On the other hand, where breastfeeding cannot be ensured, it is essential that breastmilk substitutes should be used under optimum conditions.

2. We should also like to emphasize that the Code, which, as I have just said, is essenti should be seen in a more general and broader context. It should be recognized as being one of a variety of features of the policy carried out by the WHO, the aim of which is to improve the health situation of mothers and young children throughout the world.

3. As regards the implementation of the Code, it should firstly be pointed out that withi the Community, several of the aims of the Code have in the past reached the stage of being put into practice. As regards other parts of the Code, the Community and its Member States, as the case may be, will endeavour to give effect to the principles and aims expressed as appropriate to their constitutional and legislative framework as well as their social situations. It goes without saying that the World Health Organization will be kept informed of further action taken on the Code by the Community and its Member States.

4. In conclusion, I should like to reiterate our commitment to the guiding principles expressed in the Code and to thank the WHO and UNICEF on behalf of the Community and its Member States for the initiative they have taken. We must now proceed with the phase of practical implementation and gain more experience. After a few years, it will in any case be necessary to meet again and, in the light of the experience gained in the meanwhile, to revise and improve one or other section of the Code. As far as we are concerned, I can confirm here and now that you may be assured of our collaboration when that occasion arises.

Press and Information Office of the EC Commission – 37-39, rue de Vermont, case 195, 1211 Geneva 20
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European Community

Press Release

WHO - 34th World Health Assembly

STATEMENT OF THE DELEGATION OF THE FEDERAL REPUBLIC OF GERMANY ON BEHALF OF THE EUROPEAN COMMUNITY AND ITS MEMBER STATES

(10 May 1983)

On behalf of the European Community and its Member States I have the honour to make the following statement:

1. At the 34th World Health Assembly the European Economic Community and its Member States fully endorsed the aims pursued by the International Code of Marketing of Breast-Milk Substitutes. With regard to its implementation, they pointed out that in the past action had already been taken to achieve several of these aims within the Community. For other parts of the Code, it was stated that the Community and its Member States, as appropriate, would endeavour to give effect to the principles and goals set out therein, having regard to their constitution, laws and social structures.

2. Broadly speaking, the provisions of the International Code concerned with information and education, health care systems, health workers and persons employed by the industry are primarily the responsibility of the Member States.

2.1. As a general rule enforcement of the provisions relevant to these points does not necessarily call for the adoption of laws or regulations by the Member States but can be done through non-legislative measures. In several Member States voluntary agreements have already been or are about to be developed.

.../...

2.2. It should also be noted that the Commission of the European Communities is examining a draft voluntary code of practice for the marketing of breast-milk substitutes which was prepared by the Association of Dietetic Foods Industries of the European Economic Community. This draft is still under consideration.

3. The Community as an entity is responsible for regulating under the international Code:

(a) the composition of breast-milk substitutes,

(b) their labelling and certain aspects concerning advertising.

3.1. As far as the composition of breast-milk substitutes is concerned, the Scientific Committee for Food has been asked to make recommendations to serve as the basis for future Community regulations. The Commission of the European Communities will of course send the WHO any texts drafted in this respect.

3.2. The future Community regulations must also cover the labelling of breast-milk substitutes. For this, the International Code will serve as a reference document.

It should be noted that any labelling or advertising likely to be misleading is already prohibited by Community regulations.

4. In summary, the European Economic Community and its Member States welcome this comprehensive report by the Director General and share his view, that it would be premature, at this stage, to propose any amendments to the Code.

ANNEX 3

I D A C E

83/200 (1)
15/12

INDUSTRY CODE OF PRACTICE FOR THE MARKETING OF BREAST MILK SUBSTITUTES IN THE EEC

PREAMBLE

The National Associations of manufacturers of dietetic foods, including manufacturers of foods for infants and young children, constituting IDACE, agree to establish the following Code of Practice concerning the marketing of breast-milk substitutes, following consultation with the European Commission, and the EEC Advisory Committee on Foodstuffs representing the various sectors concerned.

The pre-eminent role of breast-feeding is recognized, and it is in the interest of mothers to breast-feed their babies.

It is considered that mothers should not be discouraged from breast-feeding their babies and that any promotional activity which may be of a nature to suggest that feeding babies with a breast-milk substitute is in any way preferable to breast-feeding, should be avoided.

When mothers do not breast-feed, or only do so partially, there is a need for nutritionally adequate breast-milk substitutes formulated in accordance with EEC or national standards.

The development of nutritionally adequate breast-milk substitutes has resulted from traditional co-operation between manufacturers, universities, paediatricians, maternity hospitals, clinics and governments ; and such co-operation must continue to play an important role in the research, formulation, and recommendation of these products in order to ensure the supply of high quality products backed by a guarantee of maximum safety.

(1) replaces 82/130 and 83/150

.../...

IDACE, representing the dietetic food industries in the Member States of the European Community, its constituent National Associations, and their individual member companies, is convinced that it must continue to have the obligation to act in accordance with the recommendations of the medical profession, and the needs and interests of the users and final consumers of breast-milk substitutes, and in compliance with the national legislation in force in each Member State of the EEC.

It is with these principles in mind that IDACE has drawn up the following voluntary Code of Practice for the Marketing of Breast-Milk Substitutes in the EEC.

This voluntary code is intended to give effect to the principles and aims of the WHO International Code of Marketing of Breast-milk Substitutes, as appropriate to the constitutional and legislative framework and the social structures of the EEC Member States, and relevant to the needs of mothers and babies. It relates to the marketing practices mentioned in the WHO Code which are applicable in the EEC and over which manufacturers have direct control. It does not include those elements of the WHO Code which are the responsability of health services.

The Code applies to breast-milk substitutes as defined in article 3, i.e. infant formulae only, because the latter are the only products nutritionally suitable to replace breast-milk before weaning and are consequently the sole products marketed for this purpose within the social and legislative framework of the EEC.

It is recognized that this voluntary code is a minimum requirement, which does not exclude specific national measures existing or being adopted. This Code does not take precedence over national or EEC legislation.

CODE

The National Associations of Manufacturers of Dietetic Foods of the EEC, constituting IDACE, hereby agree the following articles as a Code of Practice within the EEC, for all manufacturers marketing breast-milk substitutes in the EEC.

ARTICLE 1 : AIM OF THE CODE

The aim of this Code is to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breast-feeding, and by ensuring the proper use of breast-milk substitutes when these are necessary, on the basis of adequate information and through appropriate marketing and distribution.

ARTICLE 2 : SCOPE OF THE CODE

The Code applies to the marketing in the EEC, and practices related thereto, of breast milk substitutes marketed as suitable for the sole source of nourishment for an infant during the first months of life. It also applies to information concerning their use.

ARTICLE 3 : DEFINITIONS

"Breast-milk substitute " means : an infant formula formulated industrially in accordance with EEC standards or appropriate national standards, as suitable for use as the sole source of nourishment and to satisfy the normal nutritional requirements of infants from birth on and during the first months of life, and adapted to their physiological characteristics. It does not include weaning foods or follow up milks when marketed for use as a part of a mixed diet during the time when breast-feeding or feeding with breast-milk substitutes begins to be replaced.

"Health services" means : governmental or private institutions or organizations engaged, directly or indirectly, in health care for mothers, infants and pregnant women, nurseries and child-care institutions.

"Health professional" means : a professionally qualified person working in a component of the health services.

"Manufacturer" means : a person, corporation or any other entity engaged in the business or function (whether directly or through an agent or through an entity controlled by or under contract with it) of manufacturing breast-milk substitutes.

"Marketing" means : breast-milk substitutes promotion, distribution, selling advertising, product public relations, and information services.

"Marketing Personnel" means : any person whose functions involve the marketing of breast-milk substitutes.

"Monitoring Committee" means : the committee established in accordance with the annexe of this Code.

"Public Mass Media" means : television, radio, cinema, national or local newspapers, billboards and magazines intended for the general public. It does not include professional journals.

"Samples" means : single or small quantities of breast-milk substitutes provided without cost to the recipient.

"Labelling" : the definition according to the labelling directive (79/112/EEC).

ARTICLE 4 : INFORMATION AND EDUCATION

4.1 Information on the characteristics and use of breast milk-substitutes may be provided by manufacturers for use by families and others responsible for the care of infants, when in conformity with the policies of the health services and/or the national legislation.

4.2 Informational and educational materials whether written, audio or visual dealing with the characteristics and use of breast-milk substitutes should always :

a) state the superiority of breast-feeding,

b) avoid using terms which might discourage breast-feeding,

c) avoid using terms which could cause concern to mothers who are unable or unwilling to breast-feed,

d) provide explicitly worded and illustrated instructions to guide mothers on the appropriate and correct use of breast-milk substitutes,

e) stress the importance for the baby's health of following feeding instructions carefully,

f) clearly identify the product concerned.

4.3 Any information or educational material provided by manufacturers in accordance with articles 4.1 and 4.2, should be available to members of the health professions and to those members of the public who request it.

ARTICLE 5 : THE GENERAL PUBLIC AND MOTHERS

5.1 **Public mass media** should not be used for product advertising of breast-milk substitutes to the general public. Product advertising of breast-milk substitutes is permitted in specialized consumer publications dealing with baby care, and should be in conformity with the requirements of article 4.2 a), b), c) and e).

5.2 Point of sale advertising dealing with the characteristics and the use of breast-milk substitutes should state the superiority of breast-feeding, avoid using terms which might discourage breast-feeding or cause concern to mothers who do not breastfeed and should stress the importance of following feeding instructions carefully. This does not apply to point of sale advertising consisting of the company logo, product identification, company or brandname and price indication.

5.3 Samples of breast-milk substitutes should not be distributed by manufacturers to pregnant women, mothers of infants below the age of 3 months or their families.

5.4 Utensils, equipment, or other articles used in the preparation of breast-milk substitutes, or other gifts used to promote breast-milk substitutes, may not be given by manufacturers to pregnant women, mothers of infants below the age of 3 months or their families.

5.5 Marketing personnel, in their business capacity, should not seek direct contact with pregnant women or with mothers of infants except when requested by a health professional or when information is specifically requested by a consumer. Information provided by marketing personnel must conform to the requirements of article 4, where appropriate.

ARTICLE 6 : INFORMATION TO HEALTH PROFESSIONALS AND HEALTH SERVICES

6.1 Information and educational materials published by manufacturers in conformity with the requirements of article 4 may be provided to the health services for use at the discretion of health professionals.

6.2 Information about breast-milk substitutes provided by manufacturers to health professionals should be restricted to scientific, factual and practical matters and should accurately reflect current knowledge. Such information should not imply or create a belief that feeding with a breast-milk substitute is equivalent or superior to breast-feeding. Information designed for use by health professionals in instructing mothers must conform to the requirements of article 4. Assistance may be provided by appropriately trained personnel employed by manufacturers only if requested by the health services concerned.

6.3 No financial or material inducement to promote breast-milk substitutes should be offered by manufacturers to health professionals or members of their families. However, inexpensive articles of general utility for their professional use may be provided.

6.4 Breast milk-substitutes and utensils, equipment or other articles used in the preparation of breast-milk substitutes may be supplied to health professionals for use at their discretion in accordance with national health policies or legislation, notwithstanding the provisions of article 5.3 and 5.4.

6.5 Manufacturers of breast-milk subsitutes may donate equipment and materials or support scientific activities including fellowships, study tours, research grants, attendance at professional conferences, provided that such donations are not conditional on the recommendation of breast-milk substitutes to the detriment of breast-feeding. Requests for support and the decision to grant support must be made and confirmed in writing. Such donations may only be made if permitted under the national health policies or national legislation.

ARTICLE 7 : MARKETING PERSONNEL

7.1 Manufacturers should apprise persons employed by them who are engaged in the marketing of breast-milk substitutes of the provisions of this code and of their responsibilities under it.

7.2 Persons engaged in marketing breast-milk substitutes should not as part of their job responsabilities perform educational functions in relation to pregnant woment or mothers of infants except as provided for under article 5.5.

ARTICLE 8 : LABELLING

8.1 Labelling of breast-milk substitutes must comply with the relevant EEC Directives as implemented into national legislation.

ARTICLE 9 : QUALITY

9.1 Breast-milk substitutes must conform to the quality requirements of the relevant EEC Directives or national legislation.

9.2 Foods which do not conform to these quality requirements should not be labelled or marketed as a breast-milk substitute.

ARTICLE 10 : APPLICATION

10.1 No manufacturers will infringe this code directly or indirectly by inciting third parties or by providing them the means for doing so.

ARTICLE 11 : MONITORING

11.1 The National Associations of manufacturers in each Member State of the EEC commit themselves to set up a national monitoring committee in accordance with rules and customs relevant to each country. The sanctions will be established in accordance with the legislation in force in each Member State.

11.2 For alleged infringements involving the activities of a manufacturer or manufacturers in more than one Member State, IDACE proposes to the EEC Authorities that they set up a supranational monitoring committee made up of 7 members :

- a person recommended by the EEC Commission,
- a person recommended by the European Court of Justice,
- a person recommended by the Consumer Consultative Committee,
- a paediatrician,
- the President of IDACE or his representative, and two other representatives of IDACE of the Member States concerned.

The rules of operation of this supra-national monitoring committee will be established with the mutual agreement of the EEC Authorities. The Committee will elect its own chairman.

ANNEX 4

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.