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SECOND REPORT

drawn up on behalf of the Committee on the Environment, Public Health and Consumer Protection

on the proposal from the Commission of the European Communities to the Council (COM(84) 703 final - Doc. 2-1530/84) on the approximation of the laws of the Member States relating to infant formulae and follow-up milks

Rapporteur: Mr B. van der LEK

WG(VS1)/2885/2886E

PE 101.909/fin. 2
Or. Fr.

By letter of 23 January 1985, the President of the Council of the European Communities requested the European Parliament, pursuant to Article 100 of the EEC Treaty, to deliver an opinion on the proposal from the Commission of the European Communities to the Council for a directive on the approximation of the laws of the Member States relating to infant formulae and follow-up milks.

On 11 February 1985 the President of the European Parliament referred this proposal to the Committee on the Environment, Public Health and Consumer Protection as the committee responsible. On 10 May 1985 the proposal was also referred to the Committee on Development and Cooperation.

At its meeting of 28 February 1985 the Committee on the Environment, Public Health and Consumer Protection appointed Mr van der LEK rapporteur.

At its sittings of 11 March 1985 and 10 July 1985, the European Parliament referred the motion for a resolution tabled by Mr BOCKLET and others on the approximation of the laws of the Member States relating to infant formulae and follow-up milks (Doc. 2-1608/84) and the motion for a resolution tabled by Mr ROELANTS du VIVIER and others on the approximation of the laws of the Member States relating to baby foods (Doc. B 2-528/85), pursuant to Rule 47 of the Rules of Procedure, to the Committee on the Environment, Public Health and Consumer Protection as the committee responsible.

The committee decided to consider these motions for resolutions in conjunction with the proposal for a directive referred to it earlier.

The committee considered the Commission's proposal and a working document at its meetings of 25 April 1985 and 25 June 1985. It considered the draft report at its meetings of 27 November 1985 and 22 January 1986.

At the last meeting the committee decided by 26 votes to none, with one abstention, to recommend to Parliament that it approve the Commission's proposal, subject to the following amendments.

The committee then adopted the motion for a resolution as a whole by 21 votes to none with six abstentions.

The following took part in the vote : Mrs Weber, chairman; Mrs Schleicher, vice-chairman; Mrs Bloch von Blottnitz, vice-chairman; Mr van der Lek, rapporteur; Mr Bandres Molet (deputizing for Mr Roelants du Vivier), Mr Barral Agesta, Mr Bombard, Mr Elliot (deputizing for Mr Collins), Mr Falconer (deputizing for Mr Muntingh), Mr Fitzsimmons (deputizing for Mrs Dupuy), Mr Garcia (deputizing for Mrs Veil), Mr Hughes, Mr Ippolito (deputizing for Mr Iversen), Mrs C. Jackson, Mr Lambrias (deputizing for Mr Alber), Mrs Lentz-Cornette, Mr Ligios (deputizing for Mr Mertens), Mrs Llorca Viliplana, Mrs S. Martin (deputizing for Mr Nordmann), Mr Novelli (deputizing for Mr Moravia), Mr V. Pereira, Mrs Renau I Manen, Mr Schmid, Mr Sherlock, Mrs Squarcialupi, Ms Tongue and Mr Vittinghof.

At its sitting of 11 March 1986, the European Parliament decided to refer the report back to the Committee on the Environment, Public Health and Consumer Protection, pursuant to Rule 85 of the Rules of Procedure.

At its meeting of 19 March 1986 the committee unanimously decided to retable the report without amendment.

The committee also decided to request the European Parliament to adopt the report without debate, pursuant to Rule 34 of the Rules of Procedure.

The following took part in the vote: Mrs Weber, chairman; Mrs Schleicher, vice-chairman; Mr Collins, vice-chairman; Mr van der Lek, rapporteur; Mr Avgerinos (deputizing for Mr Barral Agesta), Mrs Banotti, Mr Barros Moura (deputizing for Mr Iversen), Mr Bombard, Mr Garcia (deputizing for Mr Nordmann), Mrs Gredal (deputizing for Mr Tognoli), Mr Hughes, Mrs C. Jackson, Mrs Lentz-Cornette, Mrs Llorca Vilaplana, Mr Muntingh, Mr V. Pereira, Mrs Peus, Mrs Renau i Manen, Mr Roelants du Vivier, Mr Schmid, Mr Sherlock, Mrs Squarcialupi, Ms Tongue and Mr Verbeek (deputizing for Mrs Bloch von Blottnitz).

The report was tabled on 21 March 1986.

The deadline for tabling amendments to this report will be indicated in the draft agenda for the part-session at which it will be debated.

C O N T E N T S

The Committee on the Environment, Public Health and Consumer Protection hereby submits to the Euroepan Parliament the following amendments to the Commission's proposal and motion for a resolution together with explanatory statement.

Proposal for a Council directive on the approximation of the laws of the Member States relating to infant formulae and follow-up milks

Text proposed by the Commission of the European Communities	Amendments tabled by the Committee on the Environment, Public Health and Consumer Protection
	Amendment No. 1
Title	Title
Proposal for a Council Directive on the approximation of the laws of the Member States relating to infant formulae and follow-up milks.	Proposal for a Council Directive on the approximation of the laws of the Member States relating to breast-milk substitutes and follow-up milks.
	Amendment No. 2
1st Recital	1st Recital
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 breast-milk substitutes and follow-up milks intended for particular nutritional use by infants in good health, in those cases in which breastfeeding is not possible or the mother chooses not to breastfeed, form a very important group within the category of foodstuffs for particular nutritional uses;
	Amendment No. 3
4th Recital	4th Recital
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 or protein; whereas specific rules for such products will therefore have to be adopted at a later date;	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 or protein; whereas specific rules for the composition of such products will therefore have to be adopted at a later date, but not later than 1 July 1987;

Text proposed by the Commission of the European Communities	Amendments tabled by the Committee on the Environment, Public Health and Consumer Protection
	Amendment No. 4
10th Recital	10th Recital
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, 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;
	Amendment No. 5
Article 1	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.	1. This Directive is a specific Directive within the meaning of Article 1(3) of Directive 77/94/EEC. It shall apply to 'breast-milk substitutes' and 'follow-up milks' intended for particular nutritional use by infants in good health.
	Amendment No. 6
2. For the purposes of this Directive,	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;	(a) 'breast-milk substitutes' shall mean infant formulae and any other food products marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breast-milk; (b) unchanged (a)

Text proposed by the Commission of the European Communities	Amendments tabled by the Committee on the Environment, Public Health and Consumer Protection
	Amendment No. 7
(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.	(c) 'follow-up milks' shall mean artificially prepared milk-based products, adhering to guidelines established by WHO/UNICEF, FAO and intended for particular nutritional use by infants aged over 6 months as part of a progressively diversified diet;
	Amendment No. 8
	(d) In the provisions applying to marketing, 'equipment specially designed and manufactured for use with breast-milk substitutes' shall mean teats, specially designed bottles and bottle-heaters and other specially designed material for the feeding of breast-milk substitutes.
	Amendment No. 9
Article 2	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.	Member States shall take all necessary steps to ensure that the products referred to in Article 1(2) may be marketed only if their composition and the marketing practices employed, conform to the definitions and rules laid down in this Directive.
	Amendment No. 10
	New Article 2(a)
	2(a) This Directive shall also apply to all the products which fall within the scope of this Directive and are exported to countries outside the Community, insofar as this is not precluded by provisions in the importing country.

Text proposed by the Commission of the European Communities	Amendments tabled by the Committee on the Environment, Public Health and Consumer Protection
	Amendment No. 11
Article 3, paragraph 2	Article 3, paragraph 2
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.	Delete cows' milk and, where appropriate, other ...
	Amendment No. 12
Article 4, paragraph 1	Article 4, paragraph 1
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 exclusively manufactured from cows' milk proteins shall be specified at a later date in accordance with Article 100 of the Treaty.	1. Infant formulae must comply with the compositional criteria specified in Annex I. However, the compositional criteria for infant formulae that are not exclusively manufactured from cows' milk proteins shall be laid down in a Council Directive not later than 1 July 1987 in accordance with Article 100 of the Treaty.
	Amendment No. 13
Article 8, paragraph 1	Article 8, paragraph 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.	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 laid down in a Council Directive not later than 1 July 1987 in accordance with Article 100 of the Treaty.
	Amendment No. 14
Article 9, paragraph 2	Article 9, paragraph 2
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 :	2. The labelling of breast-milk substitutes and follow-up milks shall bear, in addition to those foreseen in Article 3 of Directive 79/112/EEC, the following mandatory particulars :

Text proposed by the Commission of the European Communities	Amendments tabled by the Committee on the Environment, Public Health and Consumer Protection
	Amendment No. 15
(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;	(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 where breastfeeding is not possible or the mother chooses not to breastfeed;
(b) unchanged	
	Amendment No. 16
(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;	(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 six months of age and that it should form only part of a diversified diet, and that it is not to be used as a breast-milk substitute;
(d) and (e) unchanged	
	Amendment No. 17
(f) instructions for appropriate preparation;	(f) instructions for appropriate preparation, and a warning against the health hazards of inappropriate preparation;
	Amendment No. 18
(g) a statement to the effect that it is important for the infant's health that these instructions be followed;	(g) deleted
(h) unchanged	

Text proposed by the Commission of the European Communities	Amendments tabled by the Committee on the Environment, Public Health and Consumer Protection
	Amendment No. 19
	(i) information about the storage conditions required and the date before which the product is to be consumed, taking into account the climatic and storage conditions of the country concerned.
	Amendment No. 20
Article 9, paragraph 3	Article 9, paragraph 3
3. The labelling of infant formulae shall in addition bear the following mandatory particulars :	3. The containers in which breast-milk substitutes are marketed, shall in addition have a clear, conspicuous, and easily readable and understandable message printed on them, or on labels which cannot readily become separated from them, in an appropriate language, which includes all the following points :
	Amendment No. 21
	(a) the words 'Important Notice' or their equivalent;
(a) a statement concerning the superiority of breastfeeding;	(b) unchanged (a)
	Amendment No. 22
(b) a statement recommending that the product be used only on the advice of persons having qualifications in medicine, nutrition or pharmacy.	(c) a statement recommending that the product be used only on the advice of a health worker as to the need for its use and the proper method of use;
	(d) a warning concerning the negative effect on breastfeeding of introducing partial bottle-feeding;
	(e) a warning concerning the difficulty of reversing the decision not to breastfeed;
	(f) instructions for appropriate preparation, and a warning against the health hazards of inappropriate preparation.

Text proposed by the Commission of the European Communities	Amendments tabled by the Committee on the Environment, Public Health and Consumer Protection
	Amendment No. 23
Article 9, paragraph 4	Article 9, paragraph 4
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.	4. Labels shall be designed to provide the necessary information about the appropriate use of the product, and so as not to discourage breastfeeding. The use of the terms 'humanized', 'maternalized', 'adapted', or similar terms shall be prohibited. Neither the container nor the label shall have pictures of infants, nor shall they have other pictures or text which may idealize the use of the product as a breast-milk substitute. They may however have graphics for easy identification of the product as a breast-milk substitute 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.	Unchanged
	Amendment No. 24
Article 9, paragraph 6	Article 9, paragraph 6
6. The prohibitions and restrictions referred to in paragraphs 4 and 5 shall also apply to :	6. The requirement, the prohibitions and the 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;	(a) the presentation of breast-milk substitutes 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.	(b) advertising.

Text proposed by the Commission of the European Communities	Amendments tabled by the Committee on the Environment, Public Health and Consumer Protection
	Amendment No. 25
Article 9, paragraph 7	Article 9, paragraph 7
7. This Article shall also apply to infant formulae and follow-up milks for export outside the Community, insofar as this is not precluded by provisions in the importing country.	7. This Article shall also apply to breast-milk substitutes and follow-up milks for export outside the Community, insofar as this is not precluded by provisions in the importing country. The labelling shall be in the most appropriate language(s) of the country concerned, as determined by the government of that country.
	Amendment No. 26
	New Article 9(a)
	9(a) The labelling and marketing of equipment specially designed and manufactured for use with breast-milk substitutes and all advertising for this equipment shall refer to breast-milk substitutes in the same way as stated in Article 9, paragraphs 3 and 4. This Article shall also apply to equipment for export outside the Community, insofar as this is not precluded by provisions in the importing country.
	Amendment No. 27
	New Article 9(b)
	9(b) Member States shall take the necessary measures to ensure that all aspects of the International Code of Marketing of Breast-Milk Substitutes of the World Health Organization, dealing with marketing, information and responsibilities of health authorities, are implemented in their territories. In particular this responsibility shall cover the points stated in the remainder of this Article and in Articles 9(c) and (d).

Text proposed by the Commission of the European Communities	Amendments tabled by the Committee on the Environment, Public Health and Consumer Protection
	1. Member States shall have the responsibility 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. This responsibility shall cover either the planning, provisions, design and dissemination of information, or their control.
	2. 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 and other breast-milk substitutes. Such material shall not use any pictures which may idealize the use of breast-milk substitutes.

Text proposed by the Commission of the European Communities	Amendments tabled by the Committee on the Environment, Public Health and Consumer Protection
	3. 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 government authority or within guidelines given by governments for this purpose. Such equipment or materials may bear the donating company's name or logo, but shall not refer to a proprietary product that is within the scope of this Directive, and shall be distributed only through the health care system.
	Amendment No. 28
	New Article 9(c)
	1. Manufacturers and distributors of breast-milk substitutes and follow-up milks 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.
	2. Donations or low-price sales to institutions or organizations of supplies of infant formulae or other products within the scope of this Directive, whether for use in the institutions or for distribution outside them, may be made. Such supplies shall only be used or distributed for infants who have to be fed on breast-milk substitutes for as long as needed, and following guidelines established by WHO/UNICEF.

Text proposed by the Commission of the European Communities	Amendments tabled by the Committee on the Environment, Public Health and Consumer Protection
	Amendment No. 29
	New Article 9(d)
	1. Information on products within the scope of this Directive shall be subject to the conditions laid down in Article 9, paragraphs 3, 4, 5 and 6(b), and appear only in publications available exclusively to doctors and professional health workers, and is to be restricted to scientific and factual matters. Such information must not imply or create a belief that bottle-feeding is equivalent or superior to breastfeeding. There shall be no advertising or other forms of promotion to the general public or to pregnant women, mothers or members of their families.
	2. There should be no point-of-sale advertising, giving of samples, or any other promotion device to induce sales directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales for products within the scope of this Directive.
	Amendment No. 30
Article 11	Article 11
Member States shall take the necessary measures to comply with this Directive. They shall forthwith inform the Commisison thereof. Those measures shall be applied in such a way as to :	Member States shall take the necessary measures to comply with this Directive. They shall forthwith inform the Commisison 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,	- permit, by 1 July 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.	- prohibit, on 1 January 1988, trade in products which do not comply with this Directive.

A

MOTION FOR A RESOLUTION

embodying the opinion of the European Parliament on the proposal from the Commission of the European Communities to the Council for a Council Directive on the approximation of the laws of the Member States relating to infant formulae and follow-up milks.

The European Parliament,

- having regard to the proposal from the Commission to the Council[1],

- having been consulted by the Council pursuant to Article 100 of the EEC Treaty (Doc. 2-1530/84),

- having regard to the motion for a resolution tabled by Mr BOCKLET and others on the approximation of the laws of the Member States relating to infant formulae and follow-up milks (Doc. 2-1608/84),

- having regard to the motion for a resolution tabled by Mr ROELANTS du VIVIER and others on the approximation of the laws of the Member States relating to baby foods (Doc. B 2-528/85),

- having regard to the motion for a resolution tabled by Mrs DALY and Mr C. JACKSON at the ACP-EEC Joint Assembly in Inverness on breast-milk substitutes (Doc. ACP-EEC 20/85),

- having regard to the report of the Committee on the Environment, Public Health and Consumer Protection (Doc. A 2-218/85),

- having regard to the second report of the Committee on the Environment, Public Health and Consumer Protection (Doc. A 2-16/86),

- having regard to the result of the vote on the Commission's proposal,

A. whereas it is extremely important that suitable and high quality breast-milk substitutes should be available for cases in which breastfeeding is impossible or inappropriate,

B. whereas the basic composition of such preparations should comply with the nutritional needs of infants, as determined by generally accepted scientific data,

C. whereas it is desirable that legislation in the Member States concerning the composition, labelling and marketing of breast-milk substitutes should be harmonized and governed by a specific directive,

D. having regard to the opinion of the World Health Organization (WHO) that 'breastfeeding is an unequalled way of providing ideal food for the healthy growth and development of infants; that it forms a unique biological and emotional basis for the health of both mother and child; that the anti-infective properties of breast-milk help to protect infants against disease; and that there is an important relationship between breastfeeding and child-spacing',

E. whereas there is an increasing amount of scientific data to support the superiority of breastfeeding, particularly as regards protection against disease, in the case of all infants including those in industrialized countries such as the Member States of the European Community,

[1] OJ No. C 28, 30.1.1985, p. 3

F. considering therefore that it is extremely important that breastfeeding should be kept up, supported and encouraged during the first four to six months,

G. whereas the practice of breastfeeding has increased during recent years in most countries of the Community, although still to a limited extent and often only for a very short period,

H. believing that this trend should be encouraged in the interests of public health and that the sale and marketing of breast-milk substitutes should be controlled to ensure that they do not discourage breastfeeding, while safeguarding the principle of freedom of choice for the consumer,

I. recalling the view expressed by the World Health Organization (WHO) that 'the marketing of breast-milk substitutes requires special treatment, which makes usual marketing practices unsuitable for these products',

J. whereas for these reasons the WHO adopted at its 34th assembly in May 1981 an 'International Code of Marketing of Breast-Milk Substitutes' which was supported by virtually all the WHO Member States, including all the Member States of the European Community,

K. whereas the European Parliament in its resolutions of 15 October 1981 (Doc. 1-541/81)[1] and 11 April 1983 (Doc. 1-962/82)[2] called clearly for the drawing up of a Council directive based on the WHO International Code,

L. convinced of the need for such a directive, both in the interests of public health in the Community and to fulfil the commitments entered into by the Member States in the context of the WHO,

1. Notes that the Commission's proposal meets only some of the demands made by the European Parliament in the resolutions referred to above;

2. Nevertheless approves the Commission's proposal as a basis for the harmonization of legislation in the Member States of the Community, provided that the provisions on labelling and marketing contained in the Directive are worded in such a way that they comply with the recommendations of the International Code, as indicated in the preceding amendments;

3. Considers that the scope of the directive should be extended to cover all breast-milk substitutes;

4. Regrets that the proposal for a directive contains no provisions for preparations not based on cows' milk or regarding the maximum permitted levels of contaminants or bacteriological criteria;

5. Considers that such provisions should be adopted as soon as possible and by 1 July 1987 at the latest;

6. Calls for a clear distinction to be made between infant formulae and follow-up milks, and for it to be clearly specified in all cases that follow-up milks cannot be used as a substitute for breastfeeding;

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[1] OJ No. C 287, 9.11.1981, p. 73
[2] OJ No. C 128, 16.5.1983, p. 15

7. Considers that the directive should also include provisions on the marketing of bottles, teats and other articles specifically designed for use with breast-milk substitutes;

8. Endorses the Commission's proposal that the provisions on labelling and marketing should also apply to products exported from the Community to third countries, insofar as this is not precluded by provisions in the importing country;

9. Calls on the Member States to ensure that the sections of the International Code which have not been incorporated into the directive - policy in hospitals, maternity units, clinics, etc. - are dealt with at national level, in accordance with the recommendations made in the International Code;

10. Believes that, if its amendments are adopted, full account will have been taken of the reservations expressed by the Committee on Development and Cooperation;

11. Calls on the Council to incorporate the attached amendments in its decision;

12. Reserves the right to invoke Rule 36 of the Rules of Procedure should its amendments not be adopted;

13. Reserves the right to open the conciliation procedure should the Council propose to depart from this opinion;

14. Instructs its President to forward to the Council, as Parliament's opinion, the Commission's proposal as voted by Parliament and the corresponding resolution.

B

EXPLANATORY STATEMENT

Introduction

1. Concern over the impact of artificial infant feeding on infant health began to escalate in the late 1960s. Medical studies noted the difference in health between bottle-fed and breast-fed infants. At the same time it was noted that artificial infant feeding was on the increase in many areas of the world. Especially in Third World countries this had led to dramatic situations : undernourishment, morbidity, and a high mortality. It was clear that a major public health problem was occuring, and that action was required to halt the decline in breastfeeding.

2. Discussions about the subject in the World Health Organization (WHO) led to the approval during the World Health Assembly in 1974 of a resolution calling on Member States to : 'review sales promotion activities on baby foods and to introduce remedial measures, including advertisement codes and legislation where necessary.' A second resolution in 1978 reiterated this call for action. These resolutions, however, had little effect, either on Member States or on manufacturers of infant food and bottles. Therefore, an international meeting on infant and young child feeding was convened by WHO and UNICEF in 1979. As a result of this meeting a code was worked out which was approved at the 34th World Health Assembly in May 1981 by 118 out of the 121 Member States. There were two abstentions and only the USA voted against.

The World Health Code

3. The main elements of the 'International Code of Marketing of Breast-Milk Substitutes' are :

A. The obligation of Governments to ensure that objective and consistent information is provided on infant and young child feeding. Informational and educational materials should include clear information on

   (a) the benefits and superiority of breastfeeding,

   (b) maternal nutrition and the preparation for and the maintenance of breastfeeding,

   (c) the negative effect on breastfeeding of introducing partial bottle-feeding,

   (d) the difficulty of reversing the decision not to breastfeed, and

   (e) where needed, the proper use of infant formulae.

   Attention should be given to the social and financial implications of the use of infant formulae and the health hazards of inappropriate or unnecessary use of it (Article 4).

B. The exclusion of all advertising or other forms of promotion to the general public of all breast-milk substitutes and related products (bottles and teats). Manufacturers and distributors should not provide samples of any such products to the general public, either directly or indirectly (Article 5).

C. The obligation of the health authorities to encourage and protect breastfeeding, and to act within the principles of the Code. No facility of a health care system should be used for the promotion of infant formulae or other products within the scope of the Code. The use of 'professional service representatives' or 'mothercraft nurses' provided or paid for by manufacturers or distributors should be prohibited. Distribution of information and samples by manufacturers to health care systems should be for scientific and research purposes only and not be disseminated to the general public (Articles 6 and 7).

D. Incentives for marketing personnel should not be linked to the amount of sales (Article 8).

E. Detailed labelling prescriptions, including under the heading 'Important Notice' a statement of the superiority of breastfeeding, and a warning against the health hazards of inappropriate preparation. No pictures of infants or any other pictures or text idealizing the use of infant formulae. 'Follow-up' or weaning products should bear a warning that the unmodified product should not be the sole source of nourishment of an infant. The exclusion of sweetened products (Article 9).

F. The obligation of governments to take action to give effect to the principles and aim of the Code, 'including the adoption of national legislation, regulations or other suitable measures'. Such measures, including laws and regulations, should be publicly stated and should apply on the same basis to all those involved in the manufacture and marketing of products within the scope of the Code.

Implementation and monitoring is an obligation on governments. Manufacturers, distributors, NGO's, professional groups and consumer organizations should collaborate.

Individual Member States are to communicate annually to the Director-General of the WHO information on action taken. The Director-General shall, on request, provide technical support to Member States preparing national legislation or regulations or other appropriate measures (Article 11).

The European Parliament

4. In October 1981 the European Parliament approved, by a large majority, a resolution (Castellina report, Doc. 1-541/81) endorsing the International WHO Code, and calling for a Community Directive to ensure application of the Code within the Member States of the Community. Referring to the fact that both the Community and the individual Member States had endorsed and accepted the Code during the World Health Assembly, the resolution asked explicitly for measures, including legislation, to ensure the entire application of the code both within the Member States themselves and for the export of the products involved.

5. In April 1983 a further debate took place in the European Parliament. On the basis of a resolution tabled by Mr Collins and many others (Doc. 1-1093/81), Mrs Castellina had prepared another report (Doc. 1-962/82). Also included in the debate were oral questions from Mrs Maij-Weggen and others, and Mrs Krouwel-Vlam and others (Doc. 1-1142/82 and Doc. 1-40/83). In this discussion nearly all the speakers insisted on the need for full implementation of the WHO Code. They referred to the apparent infringement of

the Code both in Europe and elsewhere (e.g. Mrs Maij-Weggen referred to a report by IBFAN citing 2 250 infringements by 54 undertakings from 37 countries) and concluded from this that a voluntary code did not work and legislative regulations were needed. Mr Narjes, on behalf of the Commission, defended the Commission's approach saying that a voluntary producers' agreement would be better than a Community directive, and that enforcing the code for export would be 'paternalistic'. However, he also stated : 'If a voluntary agreement cannot be reached, or cannot be reached in time, we will of course immediately issue a directive, making it as extensive as possible and more comprehensive than the labelling provision mentioned above.' Although he suggested that the Commission would continue on the line of a voluntary code for producers and a restricted directive on labelling alone, he concluded by stating that the request made in the resolution was entirely acceptable. (Debates of the EP, No. 1-297, pp. 10-17).

The resolution (Doc. 1-962/82) was adopted by Parliament by 136 votes to 23 with 11 abstentions. In this resolution the Commission is again requested 'without further delay to issue a draft directive on the application of the rules of the WHO Code'.

The Commission Proposal

6. The Commission draft now tabled (COM(84) 703, 14 December 1984) consists of two separate parts :

A. A directive on the composition and labelling of 'infant formulae' and 'follow-up milks'. This directive includes some regulations on advertising and marketing but far fewer than are called for in the International WHO Code.

B. A report and a proposal for a decision of the Council of Ministers, which states that the Council is willing to assist third countries in monitoring the application of 'appropriate marketing practices for breast-milk substitutes in developing countries'. The Commission will instruct its delegations in the developing countries to serve as contact points for the competent authorities. Complaints can be notified there, and the Commission will be ready to examine such cases and to assist in the search for a satisfactory solution for all parties concerned.

7. The Committee on the Environment, Public Health and Consumer Protection does not consider that this proposal goes far enough to meet the repeated requests of the European Parliament. In the committee's view the Member States of the Community should observe the rules laid out in the WHO International Code and that the latter should be incorporated into a directive, for the following reasons :

A. The International Code is a compromise solution and is regarded by experts as the minimum code of conduct required to prevent a further decline in breastfeeding.

B. The Code as such has been endorsed by all the Member States of the Community, with the proviso that each of the Member States will give effect to the Code 'in its own way' and implement the regulations 'as appropriate to its constitutional and legislative framework as well as its social situation'. The committee regards this as so obvious that no separate mention was required. However, in its view this does not by any means exclude the possibility of the principles of the International Code being implemented by the Member States and, where necessary, incorporated into legislation.

C. The rules contained in the International Code cannot be implemented effectively in the countries of the Third World unless they also apply to the countries from which breast-milk substitutes are exported. The impression would otherwise be created that the countries of Western Europe apply one set of standards to themselves and another to third countries. The moral authority of the Commission in offering assistance in monitoring observance of the code in the Third World would be seriously undermined. Furthermore, it would make it difficult to monitor observance of the code in practice.

D. It is also important for the public in the Member States that breastfeeding should be encouraged as much as possible and that mothers should not only be free to choose between breastfeeding and bottle-feeding but also able to make an objective choice. This is precisely the intention of the regulations laid down in the International Code. It is therefore important that they should also be enforced in the Member States.

8. The committeee therefore considers that the proposal put forward by the Commission of the European Communities should be supplemented with the missing provisions of the International Code, as indicated in the preceding amendments. The substance of these amendments is explained briefly below (paragraphs 11-20).

9. The committee has also studied the annexes on composition, with which it is in broad agreement. However, it has one objection, namely that the directive fails to cover a number of matters, for example provisions on raw materials other than cows' milk, the limit values for contaminants and bacteriological criteria. The committee considers that the directive should at least stipulate the deadline by which regulations must be drawn up to deal with these matters. Articles 4 and 8 have been amended accordingly.

10. 'Follow-up milks' raise a special problem. The committee regards it as extremely doubtful whether such products serve any useful purpose since a number of other cheaper, home-prepared products can be used in weaning. The major objection to follow-up milks is that they are marketed in such a way that they can easily be confused with infant formulae when the two are quite different things. However, since follow-up milks are to be included by the FAO in the new Codex Alimentarius, the committee did not feel able to exclude them from the European directive completely. It does however consider that it is extremely important that it should be indicated clearly on all packaging that the product cannot be used instead of infant formulae (Article 9(2)(c)). It is also proposed that in this article the age limit of four months should be replaced by the new limit of six months recommended by the FAO.

Clarification of amendments

11. In the title of the directive, the committee has opted for the broader term 'breast-milk substitutes'. This is also the term used by the World Health Organization and rules out the possibility of products other than the recognized 'infant formulae' being brought on to the market with the suggestion that they may be used as a partial or total replacement for breastfeeding. It follows on from this that the definition of breast-milk substitutes given in the WHO Code should be included in Article 1 (Amendment No. 5). This term is used throughout the directive where the general concept of 'breast-milk substitutes' is appropriate. However, it is not used where the specific product 'infant formulae' is concerned, for example in Article 9(2)(a) and (b).

12. The International Code also covers equipment designed for use with breast-milk substitutes (bottles, teats and other articles). It is obvious that the way in which these articles are marketed, sold or distributed as free gifts has a part to play in promoting the sale of breast-milk substitutes. Consequently, the amendments include a new article seeking to make the regulations contained in the directive also apply to such equipment (new Article 9(1)(a)). It is of course clear that the composition and design of such products should not be covered by this directive, the amendment merely seeks to ensure that the rules on sales, marketing and the donation of free samples also apply to such products. For the purposes of this article, a definition of the 'equipment specially designed and manufactured for use with breast-milk substitutes' has been added to Article 1.

13. It is proposed that a new Article 2(a) should be added stating that the directive also applies to all products which fall within the scope of the directive and are exported to countries outside the Community. The proposal to insert this article is primarily a question of logic. Such a provision appeared in the Commission's original proposal, in Article 9(7), where it applied to the requirements and provisions on labelling, advertisements and publicity. The Commission can therefore be assumed to have no objection to the insertion of such a provision. The Committee on the Environment, Public Health and Consumer Protection shares this view but sees no good reason why the provision should not also apply to the rules on composition and the other regulations on breast-milk substitutes.

14. In Article 3, the first paragraph defines the composition of infant formulae in general and paragraph 2 defines follow-up milks. In the first case the definition reads 'food ingredients whose suitability for particular nutritional use ..... has been established by generally accepted scientific data'. However, in the second instance the directive reads 'cows' milk and, where appropriate, other food ingredients whose suitability ....' In the opinion of the committee, there is no valid reason why cows' milk should be referred to specifically in the second case whereas a different definition is given in the first. If the Commission considers that follow-up milks must be recognized as a distinct product, the committee would prefer a general definition covering every conceivable ingredient.

15. The proposed amendments to Articles 4 and 8 have been dealt with in paragraph 9.

16. Follow-up milk is a product which can give rise to confusion. The committee is not totally convinced that this product serves any useful purpose. However, since it is produced and marketed in a number of Member States, regulation is required. Such regulations must therefore stipulate quite clearly that the product is NOT to be confused with infant formulae or any other product designed as a breast-milk substitute. This must be clearly indicated on the label (Article 9(2)(c)). The age limit of four months has been replaced by six months (see paragraph 10).

17. The original Article 9 has been amended to bring it into line with the provisions of the International Code. The message that breastfeeding is superior should be printed conspicuously and preceded by the words 'important notice' or their equivalent (Article 9(3)). The wording of a number of warnings and instructions has also been brought into line with the International Code (amendments to paragraphs 3 and 4).

18. The new Article 9(a) seeks to ensure that the directive's provisions on labelling and marketing also apply to equipment specially designed for use with breast-milk substitutes, such as bottles, teats and other specially designed utensils (see paragraph 12).

19. The new Articles 9(b), 9(c) and 9(d) contain the most important provisions regarding information, marketing, the distribution of gifts, free samples, etc. The articles specify in detail the rules that should be observed, stipulates that the Member States have the responsibility to take the necessary measures to ensure that they are observed and lays down the minimum restrictions imposed on the manufacturers of breast-milk substitutes.

20. On practical grounds, the deadlines laid down in Article 11 have been extended by six months.

MOTION FOR A RESOLUTION

pursuant to Rule 47 of the Rules of Procedure

tabled by Mr BOCKLET, Mrs RABBETHGE, Mr WAWRZIK, Mrs SCHLEICHER, Mr MERTENS, Mr ALBER and Mrs LENTZ-CORNETTE

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

The European Parliament,

A. having regard to the statement made by the Commission during the European Parliament's plenary sitting of 11 April 1983 (Official Journal 1983, Annex No. 1-297, pp. 15 et seq.),

B. having regard to the report on infant feeding and the implementation of the International Code of Marketing of Breastmilk Substitutes of 14 December 1984,

C. endorsing its aim, which 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 breastmilk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution,

1. Calls on the Commission to ensure that the solution which it indicated for the purpose of achieving the aims of the WHO International Code is implemented as soon as possible;

2. Calls on the Commission, in particular, to bring its influence to bear so that the industry's voluntary agreement (the IDACE Code) a flexible instrument for the achievement of these aims which takes account of the social and legal structures of the Member States of the Community, comes into force as soon as possible;

3. Calls on the Commission, in this connection, to make its contribution to the setting-up and composition of the supranational monitoring committee referred to in Article 11(2) of the IDACE Code;

4. Instructs its President to forward this resolution to the Commission, the Council and the governments of the Member States.

ANNEX II

MOTION FOR A RESOLUTION

pursuant to Rule 47 of the Rules of Procedure

tabled by Mr ROELANTS du VIVIER, Mrs DURY and Mrs VAN HEMELDONCK

on the approximation of the laws of the Member States relating to baby foods

The European Parliament,

A. whereas the European Parliament adopted a resolution in October 1981 in favour of the International Code of Marketing of Breastmilk Substitutes adopted by the World Health Assembly (OJ No. C 287, 9.11.1981, p.75),

B. stressing the importance of this code for babies' health and its worldwide relevance,

C. emphasizing the Commission's undertaking to Parliament to draw up a proposal for a directive to ensure uniform application of the WHO Code throughout the Member States,

D. having regard to the document COM(84) 703 final of 14 December 1984 setting out a proposal for a Council directive on the approximation of the laws of the Member States relating to infant formulae and follow-up milks,

E. approving the declared aim of helping to provide for healthy, adequate food for babies by protecting and encouraging breastfeeding and by making rational use, if necessary, of breastmilk substitutes on the basis of adequate information and an appropriate marketing and distribution system,

1. Calls on the Commission to review its proposed solution without delay so as to make it truly correspond to its declared objective and previous undertakings;

2. Calls on the Commission to draft another directive that will incorporate all the WHO recommendations on the marketing of breastmilk substitutes;

3. Calls on the Commission to take particular account of the problems caused by direct advertising and free samples and gifts for mothers and the staff of maternity hospitals;

4. Calls on the Commission in this connection not to endorse the voluntary code drawn up by the baby food industry (IDACE), which can in no way be compared with the WHO Code or serve as a substitute for it;

5. Calls on the Commission to act in accordance with the wishes of the delegations from all the EEC Member States present at the World Health Assembly in May 1981, at which the International Code was adopted;

6. Instructs its President to forward this resolution to the Commission, the Council and the governments of the Member States.

MOTION FOR A RESOLUTION

tabled by Mrs Margaret DALY and Mr Christopher JACKSON

on breast-milk substitutes

The ACP-EEC Joint Assembly

A. Noting that the European Parliament has twice asked the European Commission to submit to the Council of Ministers a proposal for a directive to implement the World Health Organization International Code of Marketing of Breast-milk Substitutes (the WHO code);

B. Noting that the proposed Council directive (Com(84)73 final) on the approximation of the laws of the Member States relating to infant formulae and follow-up milks is weaker than the WHO code despite the fact that the Community voted 'en bloc' for the WHO code as a minimum standard;

C. Aware of the importance of adequate and healthy feeding for all children, particularly at a time of major food crisis;

D. Aware of the need to encourage the promotion and protection of breastfeeding in Europe and in ACP states;

E. Wishing to see effective controls placed on the use of artificial breastmilk substitutes through the use of adequate information and appropriate marketing and distribution;

1. Calls on all signatories of the Lomé Convention to fully implement the WHO code to protect the health of their children,

2. Draws attention to the shortcomings of the IDACE voluntary code upon which the Commission's proposals are based, in particular the following omissions:

   a) the need to prevent misleading advertising based on misinformation or emotional promotion in both ACE and EEC states,

   b) the need for governments to oblige the manufacturers to provide objective information and education on the dangers of bottle feeding as well as the monitoring of company literature,

c) the need for education and information on the possible negative effects of bottle feeding and the health risks involved,

d) the need to control the distribution and promotion of baby-milk products in hospitals and clinics,

3. Stresses the need to control the promotion and marketing of breast-milk substitutes in both Community and ACP countries,

4. Calls on the Commission to strengthen their proposals to cover the operations of Community companies operating in ACP states, and help ACP states with the drafting of the legislation needed to bring current practices into line with the WHO code, and in the monitoring of the WHO code,

5. Recommends that a Working Party of the ACP Assembly examines ways in which intra ACP-EEC co-operation may be enhanced in support of the WHO code,

6. Calls on the Joint Presidents to forward this resolution to the Commission, the ACP-EEC Council of Ministers and all ACP and EEC Member States.