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The International Code of Marketing of Breast-Milk Substitutes: Survey of Legislation and Other Measures Adopted (1981-1991)

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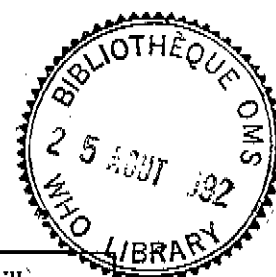
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**THE INTERNATIONAL CODE OF MARKETING OF BREAST-MILK
SUBSTITUTES: SURVEY OF NATIONAL LEGISLATION AND OTHER
MEASURES ADOPTED (1981-1991)**

by

Gillian Lester, LL.B.



Since the adoption of the International Code of Marketing of Breast-milk Substitutes in 1981, Member States of the World Health Organization have responded in varying degree and manner in giving effect to it. WHO has prepared a comprehensive summary, organized on a country-by-country basis, of government action in this regard (document WHO/MCH/NUT/90.1). The present paper complements this summary, and increases its usefulness, by focusing on the Code's individual articles and describing how each has been given expression through national legislation or other measures. Their adoption is one aspect of the wider efforts Member States are making to address the health and nutritional problems of infants and young children, and the related aspects of the health and social status of women and families.

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INTRODUCTION

1. The adoption of the International Code of Marketing of Breast-milk Substitutes¹ on 21 May 1981 marked the culmination of several years of concern within the World Health Organization, and among its Member States and various groups and individuals, about the detrimental effects on infant and child health of the decline of breast-feeding in favour of artificial feeding practices.² Its genesis lay in the recognition that the marketing and distribution of breast-milk substitutes was one of a number of important factors that influence infant-feeding practices, and therefore infant health.³
2. The International Code was adopted by the World Health Assembly in the form of a recommendation, under Article 23 of WHO's Constitution. The intention was that Member States take action to give effect to its principles and aim by adopting legislation or other suitable measures that are appropriate to their social and legislative framework. The aim of the International 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".⁴ In furtherance of this aim, the International Code sets out detailed provisions on the appropriate dissemination of information and provision of education on infant feeding; on the marketing of breast-milk substitutes and related products to the general public and mothers; on measures to be taken in health care systems, and with regard to health workers and employees of manufacturers and distributors; on the labelling and quality of breast-milk substitutes and related products; and on the implementation and monitoring of the Code's provisions.
3. The ten years since the adoption of the International Code have seen Member States respond in varying degree and manner. WHO has prepared a comprehensive summary, organized on a country-by-country basis, of government action in line with, or otherwise giving effect to, the International Code (hereafter referred to as the "Synthesis Document").⁵ The present paper complements this summary, and increases its usefulness, by

¹ World Health Organization. *International Code of Marketing of Breast-milk Substitutes* (hereafter referred to as the "International Code"). Document WHA34/1981/REC/1, Annex 3, Geneva, 1981; and Annex 1 to the present document.

² For an overview of the events leading up to the adoption of the Code, see Shubber, S. "The International Code of Marketing of Breast-milk Substitutes". *International Digest of Health Legislation* (hereafter *IDHL*) 36(4): 879-880 (1985).

³ See, in particular, the preambular paragraphs of the resolutions of the Thirty-third and Thirty-fourth World Health Assemblies, which led to the development and adoption of the International Code, respectively resolution WHA33.32 (1980) and resolution WHA34.22 (1981), and the preamble to the Code itself.

⁴ *International Code, op. cit.*, Article 1.

⁵ *The International Code of Marketing of Breast-milk Substitutes: synthesis of reports on action taken (1981-1990)* (document WHO/MCH/NUT/90.1; available in English, French and Spanish).

focusing on the Code's individual articles and describing how each has been given expression through national legislation and other measures.

4. At the outset, several points should be noted. First, the present text discusses general trends in the measures taken in each of the six WHO regions.¹ Specific national provisions or policies are described only in some cases, for purposes of illustration.² Second, since the information presented is based largely on reporting by Member States, it varies in detail and scope. Third, the International Code urges Member States "to translate [it] into legislation, regulations or other suitable measures" (emphasis added).³ Legislation or regulations are thus neither the only measures, nor necessarily the best measures, for achieving the aim of the International Code in every country. Which measures are most effective, practical and feasible depends on their context and mode of application. This paper should therefore not be seen as evaluating the success or failure of Member States in implementing the aim of the International Code on the basis of the form of the measures they have taken. Such an analysis would require the assessment of different factors, and indeed, is the subject of a separate study undertaken by a number of Member States themselves.⁴ Finally, the adoption of national legislation and other measures to give effect to the International Code is but one aspect of the wider efforts Member States are making to address the health and nutritional problems of infants and young children, and the related aspects of the health and social status of women and families.

ACTION GIVING EFFECT TO THE PRINCIPLES AND AIM OF THE INTERNATIONAL CODE

5. Articles 1-3 of the International Code are entitled, respectively, "Aim of the Code", "Scope of the Code" and "Definitions". These provisions, which serve as a framework within which the other provisions operate, are not addressed directly within this analysis.

Article 4 - Information and education

6. This provision urges governments to "ensure that objective and consistent information is provided on infant and young child feeding" to the public and to health workers. It sets out detailed recommendations as to the content and distribution of informational and educational materials, and discourages donations by manufacturers or distributors except on the basis of a written government request.

7. By and large, national governments have vested health authorities with the responsibility for implementing this provision. In some regions, however, private and volunteer interest groups play an active promotional role. Implementation is generally achieved through policy directives, guidelines or campaigns rather than legislation. Various modes of communication, including the mass media, video, printed materials, and educational curricula are used to disseminate information. In addition, several countries have conducted studies to gather objective information on current feeding practices and public attitudes. A few countries have devised detailed guidelines or strategies for public education.

¹ The six WHO regions are the African Region, the Region of the Americas, the South-East Asia Region, the European Region, the Eastern Mediterranean Region and the Western Pacific Region. See Annex 2.

² For a more detailed account of legislation and other measures, the reader may wish to refer to the numerous texts reproduced in the *IDHL*, cited in the present document where applicable; and to the summary within the Synthesis Document of individual reports of Member States submitted to the World Health Assembly in even years since the adoption of the Code, respectively documents WHA35/1982/REC/1, Annex 5; A36/7; WHA37/1984/REC/1, Annex 5, part II; WHA39/1986/REC/1, Annex 6, part 1; EB81/1988/REC/1, Annex 10; WHA43/1990/REC/1, Annex 1; and WHA45/1992/REC/1, Annex 9.

³ *International Code, op. cit.*, Article 11.

⁴ In 1990-1991 the governments of Brazil, Egypt, Finland, Guatemala, the Islamic Republic of Iran, Kenya, the Netherlands, Nigeria, Papua New Guinea, the Philippines, Poland, Sweden, the United Kingdom of Great Britain and Northern Ireland, and Yemen undertook an in-depth review and evaluation of their own experiences in giving effect to the International Code. A summary of the results of this exercise served as the basis for discussion by representatives of the countries concerned at a technical meeting on the subject held in The Hague (30 September-2 October 1991). The report of the meeting, which includes the background document, is available in document WHO/MCH/NUT/91.2.

8. In the **African Region**, the most prevalent means of implementing this provision has been through information circulars to health educators and health workers requesting that they ensure adequate information is disseminated to mothers. Only six of 34 countries for which information is available have instituted measures to promote the aim of the International Code through public information and education.¹ Three of these have done so through radio and television campaigns,² and in one country five-minute film messages on breast-feeding have been prepared for screening in public cinemas.³

9. In the **Region of the Americas** five countries have established structured programmes for public education, sometimes in collaboration with national breast-feeding promotion associations, such as La Leche League.⁴ These programmes have variously involved workshops in health centres, schools and hospitals, mass media campaigns, and the expansion of health educational curricula. One country has incorporated into its legislation a set of standards for breast-feeding promotion.⁵ The standards set out a strategy, which includes defining and researching the groups targeted so that socioeconomic and cultural factors are taken into account, and designing a simple and clear message, which seeks to awaken interest, encourage acceptance and facilitate active participation in breast-feeding.

10. Little detail is available on specific measures taken in the area of information and education by countries in the **South-East Asia Region**. One country, however, has made an active effort to discourage the notion that bottle-feeding is a status symbol. This campaign also adopted the slogan "from breast to cup and spoon".⁶ In another country, money donated by manufacturers for educational purposes is channelled through the national medical association, to be disbursed as the association sees fit.⁷

11. Five countries in the **European Region** report the provision of consistent and objective information through hospitals, clinics, the mass media and the scientific literature.⁸ A more common practice is to distribute circulars or booklets,⁹ usually to health workers, who are in turn encouraged to teach mothers appropriate feeding techniques (discussed under Article 7, below). One country has placed restrictions on contributions by manufacturers for meetings and the distribution of prizes, bursaries and study travel.¹⁰ The European Commission Directive on infant formulae and follow-on formulae (91/321/EEC) (hereafter referred

¹ *Synthesis Document, op. cit.*, at paras. 16 (Burkina Faso), 26 (Kenya), 28 (Liberia), 38 (Sierra Leone) and 42 (United Republic of Tanzania). South Africa also has such measures.

² *Ibid.* at paras. 28 (Liberia), 38 (Sierra Leone) and 42 (United Republic of Tanzania).

³ *Ibid.* at para. 16 (Burkina Faso).

⁴ *Ibid.* at paras. 52 (Bolivia), 53 (Canada), and 74 (Saint Kitts and Nevis). Paraguay (*ibid.* at para. 72) also recently reported a National Programme for the Promotion of Breast-Feeding to be implemented in 1991-1992. Peru established its programme through legislation, prior to the adoption of the International Code: Ministerial Resolution No. 0041-80-SA/DS of 1 April 1980 [hereafter "Peru, Resolution No. 0041-80-SA/DS"], chap. II, Secs. 8-11. chap. III, Sec. 12. See also Peru, Legislative Decree No. 346 of 6 July 1985 promulgating the National Population Policy Law [hereafter, "Peru, Decree No. 346"], Sec. 32. For *IDHL* citation of this and all subsequent legislation referred to in this paper, see Annex 3.

⁵ Peru, Supreme Decree No. 20-82-SA of 10 September 1982 prescribing regulations on standards for infant feeding [hereafter "Peru, Supreme Decree No. 20-82-SA"], Chap. V.

⁶ *Synthesis Document, op. cit.*, at para. 93 (Maldives).

⁷ *Ibid.* at para. 96 (Sri Lanka).

⁸ *Ibid.* at paras. 101 (Bulgaria), 102 (Czechoslovakia), 107 (France), 125 (Portugal: see Portugal, Code of Ethics for the Marketing of Breast-milk Substitutes, Feeding-bottles and Teats [hereafter "Portugal, Code"]) and 133 (former USSR).

⁹ *Ibid.* at para. 119 (Malta).

¹⁰ Spain, Crown Decree No. 1424 of 18 June 1982 amending item 15 of Section 20 of Crown Decree No. 2685/1976 of 16 October 1976 approving Technical Health Regulations on the preparation and marketing of and trade in food preparations for special dietary uses [hereafter "Spain Crown Decree No. 1424"], item 15.1.5.

to as the "EEC Directive")¹ requires that objective and consistent information be provided on infant and young child feeding for use by families and others concerned.²

12. Four of the seven countries that report implementing Article 4 in the **Eastern Mediterranean Region** have delegated the task to the Minister of Health, who relies on the mass media to conduct public education campaigns. One country has undertaken several studies on infant and child nutrition, with the purpose of raising awareness of the importance of breast-feeding among the general public and mothers, and is also setting up centres to teach mothers to prepare infant foods and encourage breast-feeding rather than the use of breast-milk substitutes.³

13. Countries in the **Western Pacific Region** have been particularly active in implementing Article 4. Nearly two-thirds of countries report the promotion of breast-feeding through such means as the mass media, video and other audiovisual aids, health education in school curricula, workshops, posters, and guidelines and booklets distributed directly to the public. In some cases, special committees have been established to conduct a promotional campaign.⁴ One campaign adopted the accessible theme that if breast-milk substitutes must be used, they should be fed with a cup and spoon.⁵ Another programme, which provides counselling and prenatal classes, has instituted an innovative promotional scheme in which breast-fed infants of mothers in the programme receive T-shirts that read "Mommy loves me - I'm breast-fed".⁶

Article 5 - The general public and mothers

14. This provision discourages advertising and other forms of promotion to the general public. It discourages, in particular, the distribution of manufacturers' samples or gifts to pregnant women, mothers or their families, special sales inducements such as discount pricing, and direct contact between marketing personnel and potential consumers among the general public.

15. This Article has been implemented through such measures as legal prohibitions, non-legislative bans, voluntary suspensions, government requests, and the screening of the content of advertisements. Where measures do exist, their scope is typically limited to advertising in the mass media. Less commonly, measures extend to special sales promotions, the donation of samples, and the other items covered by Article 5.

16. Almost half the countries in the **African Region** report implementation of this provision in some form, for the most part by non-legislative government bans on advertising. Three countries have adopted policies or entered into voluntary agreements that essentially reflect the International Code.⁷ Another requires that promotional materials first obtain clearance from the Government.⁸

17. Countries in the **Region of the Americas** have been most active in implementing Article 5, with 16 of 35 countries reporting some type of action. Six countries have enacted legislation with effects including the virtual

¹ *Official Journal of the European Communities*, No. L 175, 4 July 1991, pp. 35-49. The directive deals solely with the internal Community market; a separate instrument is being drawn up concerning exports to countries outside the Community (see under Articles 9 and 10). The Member States of the European Community are Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, and the United Kingdom of Great Britain and Northern Ireland.

² *Ibid.*, Article 9.

³ *Synthesis Document, op. cit.*, at para. 160 (Qatar).

⁴ *Ibid.* at paras. 184 (Guam), 198 (Philippines) and 201 (Singapore).

⁵ *Ibid.* at para. 202 (Solomon Islands).

⁶ *Ibid.* at para. 184 (Guam).

⁷ *Ibid.* at para. 15 (Botswana); Kenya, Kenya Code for Marketing of Breast Milk Substitutes [hereafter "Kenya Code"], Article 10; Nigeria, Code of Ethics and Professional Standards for Marketing of Breastmilk Substitutes [hereafter "Nigeria, Code"], Articles 4, 5 and 7.

⁸ *Ibid.* at para. 43 (Zaire).

adoption of the provisions of the International Code,¹ the regulated allowance of advertising,² and a prohibition only on donations of samples.³ Other countries report non-legislative measures, which ban,⁴ partially ban,⁵ or discourage⁶ advertising. Three countries rely on voluntary agreements by manufacturers and advertisers to refrain from promoting products within the scope of the International Code.⁷

18. In the **South-East Asia Region**, three countries have legislation prohibiting the advertising and promotion of breast-milk substitutes to the public, in one case modelled on the International Code.⁸ A non-legislative ban on advertising and distributing samples is also in place in one country.⁹ A fourth country has passed a resolution to adopt legislation to implement Article 5.¹⁰

19. No country in the **European Region** reports legislation prohibiting the marketing of breast-milk substitutes to the general public and mothers. However, in two countries, legislation encourages "responsibility" on the part of manufacturers, for example, by stipulating that infant foods "must not be offered for sale in such a way as to influence the feeding of the child and have an adverse effect on the child's health".¹¹ In addition, nine countries report voluntary agreements or policies to prohibit advertising.¹² In another country, the sole manufacturer of breast-milk substitutes, in cooperation with health workers, has prepared and distributed a booklet on proper feeding practices.¹³ The EEC Directive permits advertising of infant formula in

¹ Peru, Supreme Decree No. 20-82-SA of 10 September 1982 prescribing regulations on standards for infant feeding. Part II. Standards for the marketing of breast-milk substitutes and complementary infant foods [hereafter "Peru, Supreme Decree No. 20-82-SA Part II"], Standard IV, Secs. 17-18; Venezuela, Resolution No. 5 of 16 July 1982 of the Ministry of Health and Social Welfare on the requirements to be fulfilled by infant formulas as regards the relevant legal provisions in force and those to be issued in future by the Ministry [hereafter "Venezuela, Resolution No. 5"], Secs. 3, 7 and 8.

² Colombia, Decree No. 1220 of 23 May 1980 regulating the promotion, labelling, and packaging of breast-milk substitutes and supplements [hereafter "Colombia, Decree No. 1220"], Secs. 4 and 5 (this legislation was in place before the adoption of the International Code); Ecuador, Decree No. 2215 of 3 November 1983 promulgating Regulations on the marketing of formulas for infants and young children under one year of age [hereafter "Ecuador, Decree No. 2215"], Chap. V; Nicaragua, Decree No. 912 of 15 December 1981 promulgating the Law for the promotion of breast-feeding [hereafter "Nicaragua, Decree No. 912"], Sec. 3.

³ Guatemala, Decree-Law No. 66-83 of 6 June 1983 on the marketing of breast-milk substitutes [hereafter "Guatemala, Decree-Law No. 66-83"], Sec. 12 (provisions on donation of samples).

⁴ *Synthesis Document, op. cit.*, at paras. 58 (Cuba), and 71 (Panama).

⁵ *Ibid.* at para. 85 (Uruguay).

⁶ *Ibid.* at para. 74 (Saint Kitts & Nevis).

⁷ *Ibid.* at paras. 53 (Canada) and 79 (United States of America). See also Trinidad and Tobago, The International Code of Marketing of Breast-milk Substitutes as applied to Trinidad and Tobago. Dated 1 February 1982 [hereafter "Trinidad and Tobago, Code"], Article 5.

⁸ Bangladesh, The Breast-Milk Substitutes (Regulation of Marketing) Ordinance, 1984 [hereafter "Bangladesh, Ordinance, 1984"], Secs. 3-4; Indonesia, Regulations No. 240/Men.Kes./Per/V/85 of 1 May 1985 of the Minister of Health of the Republic of Indonesia on breast-milk substitutes [hereafter "Indonesia, Regulations No. 240"], Sec. 10; Sri Lanka, Direction No. 44 under Section 6(1)(c) of the Consumer Protection Act, No. 1 of 1979. Dated 3 February 1983 [hereafter "Sri Lanka, Direction No. 44"], Secs. 2-3 (modelled after the International Code). Note also that Thailand reports having a national code, but its text has not been made available.

⁹ *Synthesis Document, op. cit.*, at para. 95 (Nepal).

¹⁰ India, Indian National Code for Protection and Promotion of Breast-feeding. Dated 19 December 1983 [hereafter "India, Code"], Article 5.

¹¹ Norway, Regulations No. 1251 of 8 July 1983 on the production and offer for sale, etc. of foods for infants and young children [hereafter "Norway, Regulations No. 1251"], Sec. 3. See also, Sweden, Regulations No. 21 of 2 May 1983 of the National Board of Health and Welfare for health care and nursing personnel, etc. on the implementation of the International Code of Marketing of Breast-milk Substitutes [hereafter "Sweden, Regulations No. 21"], under the rubric "Aim and Scope".

¹² *Synthesis Document, op. cit.*, at paras. 101 (Bulgaria), 105-106 (Finland), 121-122 (Netherlands), 125 (Portugal), 131 (Switzerland), 133 (former USSR), 134-137 (United Kingdom) and 138-139 (Yugoslavia). Greece also has reported such a policy.

¹³ *Ibid.* at para. 139 (Yugoslavia).

"publications specializing in baby care". However, it also provides that "Member States may further restrict or prohibit such advertising".¹

20. Two countries in the **Eastern Mediterranean Region** have adopted Article 5 as part of their legislation.² Six other countries prohibit advertising as a matter of public policy.³

21. There has been a widespread response to Article 5 in the **Western Pacific Region** by way of voluntary agreements or government policy initiatives. However, only about half of the countries with such agreements prohibit both advertising and samples,⁴ while the others prohibit only advertising⁵ or samples.⁶ Several countries have "vetting committees" made up of representatives of the government and other interested groups, which must approve all advertising before it can be used.⁷ One country has adopted Article 5 as legislation.⁸

Article 6 - Health care systems

22. Article 6 sets out recommendations for public and private institutions, including health workers in private practice, involved in maternal and child health care. This provision vests such institutions with the responsibility to ensure that the appropriate information is disseminated to health workers and patients on the premises. This includes, not surprisingly, a prohibition on the marketing or display of products within the scope of the International Code. It also includes guidelines relating to employees, such as the requirement that the use of infant formulas be demonstrated only by health or community workers (accompanied by a warning as to the hazards of improper use), and a prohibition on the employment of persons paid by manufacturers or distributors. Finally, Article 6 sets out limitations on the use to be made of supplies and equipment donated by manufacturers or distributors: for example, these items are not to be accepted if designed to induce sales, nor if they bear the name of a product falling within the scope of the International Code.

23. The most prevalent response to this provision is a prohibition of the promotion or display of infant formulas in health institutions. Somewhat less common are prohibitions of donations of samples and equipment, employment restrictions, institution-run educational programmes for mothers and health workers, and policies to encourage "rooming-in" (accommodating mothers and infants in the same room). Other techniques devised for discouraging resort to breast-milk substitutes, which do not appear in the International Code, include making substitutes available only by prescription, and setting up breast-milk donor banks.

24. In the **African Region**, three countries have responded to Article 6 through voluntary agreements between government and the infant-food industry.⁹ Other countries have less formal policies to prohibit

¹ *EEC Directive, op. cit.*, Article 8.

² Lebanon, Decree-Law No. 110 of 16 September 1983 on the marketing of breast-milk substitutes [hereafter "Lebanon, Decree-Law No. 110"]; Tunisia, Law No. 83-24 of 4 March 1983 on the quality control, marketing, and information concerning the use of breast-milk substitutes and related products [hereafter "Tunisia, Law No. 83-24"], Secs. 6-9.

³ *Synthesis Document, op. cit.*, at paras. 152 (Egypt), 155 (Jordan), 156 (Kuwait), 161 (Saudi Arabia), 168 (United Arab Emirates) and 169 (Yemen).

⁴ *Ibid.* at paras. 181 (Cook Islands), 183 (French Polynesia), 187 (Kiribati), 189 (Macao), 193-194 (New Zealand) and 195 (Republic of Korea).

⁵ *Ibid.* at paras. 172 (American Samoa), 178 (Brunei Darussalam), 185 (Hong Kong), 186 (Japan), 190-191 (Malaysia) and 204-205 (Vanuatu).

⁶ *Ibid.* at paras. 200 (Samoa) and 203 (Tonga).

⁷ *Ibid.* at paras. 190-191 (Malaysia), 201 (Singapore) and 203 (Tonga). Sec. 12 of the Philippines Code also prescribes advance approval.

⁸ Philippines, Executive Order No. 51 adopting a National Code of Marketing of Breastmilk Substitutes, Breastmilk Supplements and Related Products, penalizing violations thereof, and for other purposes. Dated 20 October 1986 [hereafter "Philippines, Code"], Sec. 6.

⁹ Kenya Code, Articles 11.1-11.2; Nigeria, Code, Article 3; South Africa, Code of Ethics for Infant Food Manufacturers [hereafter "South Africa Code"], 1977, Secs. 9-10 (this Code was drafted prior to the adoption of the International Code).

promotion by manufacturers and distributors of substitutes, or the donation of samples to health institutions.¹ Only one country has established a programme for educating health workers and instructors in health institutions on the principles of the International Code.² One country also restricts the availability of breast-milk substitutes to a prescription basis.³

25. Nearly half the countries in the **Region of the Americas** have responded to Article 6, largely by way of public policy rather than legislation. In general, the policies respond by restricting promotion,⁴ acceptance of donations,⁵ or both.⁶ Some address other parts of Article 6; one country has adopted it fully in the form of a voluntary agreement,⁷ while others provide education within health institutions⁸ or prohibit the employment of persons paid by manufacturers.⁹ Four countries have passed legislation, in two cases entirely adopting the International Code.¹⁰ Finally, health institutions in various countries practice rooming-in¹¹ or human milk-banking,¹² or require prescriptions for distribution of the products covered by the International Code.¹³

26. In the **South-East Asia Region**, one country has passed legislation which adopts Article 6 of the International Code.¹⁴ Another country has resolved to adopt legislation implementing the provision.¹⁵ Other countries' policy measures include creating mother's milk donor units in maternity hospitals and making breast-milk substitutes available on prescription only,¹⁶ and a prohibition against the display or distribution of breast-milk substitutes and related products in health institutions.¹⁷

27. Two countries in the **European Region** have adopted Article 6 via national codes, one in the form of legislation,¹⁸ and the other as a voluntary agreement by manufacturers, traders and distributors of infant foods and related products.¹⁹ Approximately one-third of the countries in the Region have implemented policy

¹ *Synthesis Document, op. cit.*, at paras. 15 (Botswana), 21 (Ethiopia), 33 (Mozambique), and 39 (Swaziland).

² *Ibid.* at para. 42 (United Republic of Tanzania).

³ *Ibid.* at para. 25 (Guinea).

⁴ *Ibid.* at paras. 49 (Belize), 59 (Dominica), 63 (El Salvador), 64 (Grenada) and 69 (Montserrat).

⁵ *Ibid.* at paras. 53-54 (Canada), 56 (Colombia), 67 (Honduras, public institutions only), 71 (Panama) and 74 (Saint Kitts and Nevis).

⁶ *Ibid.* at paras. 51 (British Virgin Islands) and 85 (Uruguay).

⁷ Trinidad and Tobago, Code, Article 6.

⁸ *Synthesis Document, op. cit.*, at paras. 63 (El Salvador), 74 (Saint Kitts and Nevis) and 75 (Saint Lucia).

⁹ Mexico Regulations of 4 January 1988 for the implementation of the General Law on health in the field of the health control of activities, establishments, products and services [hereafter "Mexico, Regulations of 4 January 1988"], Sec. 731.

¹⁰ Ecuador, Decree No. 2215, Chap. V, Secs. 26-29 (deals with promotion and donations only); Guatemala Decree-Law No. 66-83, Secs. 4, 6 and 12; Mexico, Regulations of 4 January 1988, Sec. 731; and Peru, Supreme Decree No. 20-82-SA, Standard XI, and Part II, Standard V.

¹¹ *Synthesis Document, op. cit.*, at paras. 51 (British Virgin Islands), 61 (Dominican Republic), 64 (Grenada), 69 (Montserrat) and 75 (Saint Lucia).

¹² *Ibid.* at para. 61 (Dominican Republic); United States of America (State of New York), An Act to amend the public health law, in relation to the availability of human breast milk for infant consumption. Dated 23 June 1980, Secs. 1-2.

¹³ *Ibid.* at paras. 58 (Cuba), 63 (El Salvador) and 85 (Uruguay). See also Costa Rica, Decree No. 18078-S of 22 March 1988.

¹⁴ Sri Lanka, Direction No. 44, Sec. 4. Thailand also has reported the existence of a national code, though the text has not been made available.

¹⁵ India, Code, Article 6.

¹⁶ *Synthesis Document, op. cit.*, at para. 94 (Mongolia).

¹⁷ *Ibid.* at para. 95 (Nepal).

¹⁸ Sweden, Regulations No. 21, under the rubric "The health and medical care system".

¹⁹ Portugal, Code, under the rubric "The health services".

measures consistent with Article 6, either by prohibiting the promotion¹ or donation of samples² of breast-milk substitutes, introducing educational programmes,³ or creating breast-milk donor banks⁴ in health care institutions. One country has legislation recommending that large maternity departments have a nurse-midwife responsible for providing mothers and personnel with instructions and information on breast-feeding and supervising the collection of human milk.⁵ In two countries, infant formula can be obtained only by prescription or in pharmacies.⁶

28. In the **Eastern Mediterranean Region**, three countries have legislation giving effect to Article 6.⁷ The majority of the remaining countries have responded to Article 6 in one way: by introducing policies to prohibit the promotion of breast-milk substitutes in health institutions.⁸ One country permits obtaining substitutes on prescription only.⁹

29. In the **Western Pacific Region**, one country has adopted legislation giving full effect to Article 6 of the International Code,¹⁰ though others have reported policy measures which also respond to the entire provision.¹¹ Roughly half of the countries in this Region have policy measures addressing some portion of Article 6. Most common are the prohibition of promotion¹² and sample distribution¹³ in hospitals, but there have also been some moves to encourage rooming-in¹⁴ and education¹⁵ in health institutions. Prescriptions are required to obtain infant formula in two countries, one of which dictates it as law.¹⁶

¹ *Synthesis Document, op. cit.*, at paras. 119 (Malta), 120 (Monaco) and 138 (Yugoslavia).

² *Ibid.* at para. 134 (United Kingdom).

³ *Ibid.* at paras. 99 (Austria) and 138 (Yugoslavia).

⁴ *Ibid.* at para. 133 (former USSR). Greece also has reported such measures, and two countries have legislation regulating donor banks: France, Order of 18 August 1983 laying down the conditions for the establishment and operation of breast-milk banks; and Sweden, Regulations No. 8 of 15 April 1987 of the National Board of Health and Welfare on the use of breast milk, etc.

⁵ Sweden, Instructions No. 30 of 18 May 1978 of the National Board of Health and Welfare on the desirability of avoiding the use of human milk substitutes during the first week of life [hereafter "Sweden Instructions No. 30"]. This legislation existed prior to the adoption of the International Code.

⁶ *Synthesis Document, op. cit.* at paras. 102 (Czechoslovakia) and 112 (Hungary). See also France, Orders of 28 April 1988 and 9 June 1988 fixing the characteristics of dietetic milk foods for infants and dietary foods for infants (under 4 months old) that may be sold by retail and supplied in any way to the public only by pharmacists in pursuance of Article L. 512 of the Public Health Code.

⁷ Djibouti, Instructions No. 707/I/MSP/DSP of 19 August 1981 for the promotion of breast-feeding, Secs. 1-3 [hereafter "Djibouti, Instructions No. 707/I/MSP/DSP"; these Instructions only partially reflect the provisions of Article 6]; Egypt, Decision No. 514 of 1980 of the Minister of Health, Secs. 1-2 [this legislation existed prior to the adoption of the International Code]; Lebanon, Decree-Law No. 110.

⁸ *Synthesis Document, op. cit.*, at paras. 156 (Kuwait), 161 (Saudi Arabia), 168 (United Arab Emirates) and 169 (Yemen).

⁹ *Ibid.* at para. 157 (Libyan Arab Jamahiriya).

¹⁰ Philippines, Code, Sec. 7.

¹¹ *Synthesis Document, op. cit.*, at paras. 173-177 (Australia), 178 (Brunei Darussalam) and 193-194 (New Zealand).

¹² *Ibid.* at paras. 185 (Hong Kong [this policy existed prior to the adoption of the International Code]) and 200 (Samoa).

¹³ *Ibid.* at paras. 182 (Fiji), 183 (French Polynesia), 184 (Guam), 185 (Hong Kong [pre-International Code]), 186 (Japan [pre-International Code]) and 204-205 (Vanuatu).

¹⁴ *Ibid.* at paras. 198-199 (Philippines), 203 (Tonga) and 204-205 (Vanuatu).

¹⁵ *Ibid.* at para. 183 (French Polynesia).

¹⁶ *Ibid.* at para. 172 (American Samoa); Papua New Guinea reports legislation in this regard, though it has not been made available.

Article 7 - Health workers

30. Article 7 covers two points. First, it recommends that health workers familiarize themselves with the International Code, particularly Article 4 (information and education), and take responsibility for encouraging and protecting breast-feeding. Second, it recommends restrictions on the nature and extent of contact between health workers and manufacturers or distributors of breast-milk substitutes. Information provided to health workers should be limited to material which is scientific in nature, and there should be no financial inducements for health workers to promote breast-milk substitutes, nor distribution of infant-formula samples unless necessary for professional evaluation or research.

31. To a certain degree, measures taken to implement Article 6 can also address this provision. More specifically, educational programmes and prohibitions on sample donations in health institutions will also affect health workers. Otherwise, the most common response to this provision is the distribution to health workers of either the International Code itself or a circular describing the anticipated role of health workers in implementing the Code. Less common are direct attempts to control contact between health workers and manufacturers or distributors.

32. Fewer than one-quarter of countries in the **African Region** have taken measures aimed at health workers. Among those that have, the majority have done so through circulars informing health workers of their responsibilities under the International Code,¹ though one country has instituted a more structured "five-year plan" on infant and child nutrition, which includes sensitization on Code monitoring for all health workers.² Three countries have placed restrictions on contact between manufacturers or distributors and health workers, in two of which the provisions are part of a voluntary national code.³

33. Roughly half of the countries in the **Region of the Americas** have taken action directed at health workers, though one-third of those identified have gone no further than to distribute the International Code to senior health officers.⁴ Several countries provide seminars or training to health workers through community programmes.⁵ In addition, a number of countries have adopted Article 7 in its entirety, one through a voluntary agreement,⁶ and several through incorporation into national laws or regulations.⁷ One country requires, as a matter of law, that health workers comply with a detailed set of rules for the promotion of breast-feeding.⁸ These rules include ensuring that infants be breast-fed within three hours of birth, encouraging continuance of this practice until the end of the fourth month, strengthening mothers' confidence in their ability to breast-feed, and providing instruction to mothers on the appropriate techniques and nutritional requirements to optimize breast-feeding.

34. In the **South-East Asia Region**, two of nine countries have legislation dealing with health workers, in both cases modelled on the International Code.⁹

¹ *Synthesis Document, op. cit.*, at paras. 15 (Botswana), 29 (Madagascar), 32 (Mauritius) and 45 (Zimbabwe).

² *Ibid.* at para. 42 (United Republic of Tanzania).

³ *Ibid.* at para. 39 (Swaziland), Kenya, Code, Article 11 and Nigeria, Code, Article 6.

⁴ *Ibid.* at paras. 46 (Antigua and Barbuda), 49 (Belize), 53 (Canada), 59 (Dominica), 71 (Panama) and 75 (Saint Lucia).

⁵ *Ibid.* at paras. 48 (Barbados), 52 (Bolivia), 61 (Dominican Republic), 64 (Grenada) and 77 (Trinidad and Tobago).

⁶ Trinidad and Tobago, Code, Article 7.

⁷ Colombia, Resolution No. 5532 of 9 July 1979 of the Minister of Health prescribing rules for the promotion of breast-feeding (this legislation existed prior to adoption of the International Code) and Decree No. 1220, Secs. 2(1), 5(d); Ecuador, Decree No. 2215, Chap. V; Guatemala, Decree-Law No. 66-83, s. 8; Peru, Supreme Decree No. 20-82-SA, Standards XII(1) and (4) and XV(2) and Supreme Decree No. 20-82-SA Part II, Standard VI, Secs. 27-28. Venezuela also has implemented Article 7 through law, but only in part: Venezuela, Resolution No. 5, Sec. 4.

⁸ *Ibid.*, Colombia Resolution No. 5532.

⁹ India, Code, Article 7; Sri Lanka, Directive No. 44, Article 5. Thailand also reports having a national code which includes provisions on health workers, though it has not been made available.

35. Nearly one-half of countries in the **European Region** have developed measures in relation to health workers. Frequently they have been limited to distributing copies of the International Code or a circular to health workers,¹ though some countries have gone further by including information on breast-feeding practices in health workers' educational curricula,² or by prohibiting manufacturers' contact with,³ or giving of samples or gifts⁴ to, health workers. Two countries have voluntary codes which, *inter alia*, vest in health workers the responsibility for actively encouraging breast-feeding.⁵

36. The pattern in the **Eastern Mediterranean Region** is similar to that in Europe. Measures range from distributing circulars,⁶ to issuing legislative guidelines,⁷ to instructing health workers on promoting breast-feeding and proper child nutrition.⁸ One country also has adopted Article 7 into law as part of its national code.⁹

37. Education of health workers through workshops, curriculum modifications and training courses has been the most prevalent response to Article 7 in the **Western Pacific Region**.¹⁰ As an alternative, some countries have issued guidelines instructing health workers to encourage and promote breast-feeding in accordance with the International Code,¹¹ and in one country legislation prohibits health workers from prescribing breast-milk substitutes unless "satisfied that it would be in the best interest of the baby or infant".¹² Three countries have adopted Article 7 as part of a national code, voluntary¹³ or legislative.¹⁴

Article 8 - Persons employed by manufacturers and distributors

38. Article 8 recommends that products within the scope of the International Code be excluded from systems of sales incentives for marketing personnel such as bonuses and quotas. It also recommends against employing marketing personnel to perform educational functions in relation to pregnant women or mothers of infants or young children.

39. This provision has drawn the weakest response of any. Measures aimed at employees of manufacturers and distributors appear primarily in countries that have adopted comprehensive national codes. This is the pattern in the **African Region**¹⁵ and the **South-East Asia Region**.¹⁶ There are minor exceptions elsewhere. In the **Region of the Americas** three of the four countries with such a provision adopted it as part of a national

¹ *Synthesis Document, op. cit.*, at paras. 99 (Austria), 102 (Czechoslovakia), 105 (Finland), 118 (Morocco), 121-122 (Netherlands) and 134 (United Kingdom).

² *Ibid.* at para. 107 (France); Greece has also done so.

³ *Ibid.* at para. 101 (Bulgaria).

⁴ *Ibid.* See also Spain, Crown Decree No. 1424, item 15.1.5.

⁵ Portugal, Code; Sweden, Instructions No. 30.

⁶ *Synthesis Document, op. cit.*, at paras. 149 (Cyprus), 164 (Syrian Arab Republic) and 165-167 (Tunisia).

⁷ Djibouti, Instructions No. 707/I/MSP/DSP.

⁸ *Synthesis Document, op. cit.*, at paras. 155 (Jordan) and 160 (Qatar).

⁹ Lebanon, Decree-Law No. 110, Sec. 7.

¹⁰ *Synthesis Document, op. cit.*, at paras. 178 (Brunei Darussalam), 180 (Commonwealth of the Northern Mariana Islands), 181 (Cook Islands), 183 (French Polynesia), 184 (Guam), 190-191 (Malaysia) and 200 (Samoa).

¹¹ *Ibid.* at paras. 173-177 (Australia) and 182 (Fiji).

¹² *Ibid.* at para. 197 (Papua New Guinea).

¹³ *Ibid.* at paras. 189 (Macao) and 193-194 (New Zealand).

¹⁴ Philippines, Code, Sec. 8.

¹⁵ Kenya, Code, Article 12; Nigeria, Code, Article 6; and South Africa, Code, Articles 7-11. All are voluntary codes.

¹⁶ India, Code, Article 7; Sri Lanka, Direction No. 44, Article 5. Thailand also reports having a code (unavailable) which deals with this subject.

code.¹ Similarly, in the **European Region** two of three countries with such a provision have included it as part of a national code.² In the **Eastern Mediterranean Region**, while Article 8 appears as part of a national code in one country,³ other countries have passed separate legislation requiring that only health workers demonstrate the use of breast-milk substitutes,⁴ or issued circulars discouraging contact between manufacturers and health workers.⁵ Finally, in the **Western Pacific Region** two of three countries reporting these measures have national codes.⁶

Article 9 - Labelling

40. Article 9 is designed to ensure that labels provide information about the product so as not to discourage breast-feeding. It has three parts. First, labels should warn against the disadvantages of infant formula by making a clear statement of the superiority of breast milk, recommending advice from a health worker before its use, providing instructions for preparation and a warning against the health hazards of inappropriate preparation, and excluding any pictures or text, such as pictures of infants, which may idealize the use of substitutes. Second, food products within the scope of the Code which do not meet all the requirements of an infant formula should warn against their use as the sole source of infant nutrition. Finally, labels should specify the ingredients, composition, storage requirements and expiration date.

41. This provision has many elements, and national measures are somewhat fragmented. Many countries have adopted only some of the Code's recommendations, but it is difficult to identify a trend as to which are most prevalent.

42. In the **African Region**, the one country having legislated labelling provisions for breast-milk substitutes requires, among other things, that labels urge mothers to breast-feed and that they state that "the best food for your child is mother's milk ... better than this or any other kind of artificial food".⁷ The non-legislative responses of other countries are in some cases limited to requiring an indication of the superiority of breast milk⁸ and, in the remaining cases, more comprehensive provisions based on the International Code.⁹

43. In contrast, there has been heavy reliance on legal measures to implement Article 9 in the **Region of the Americas**. Eight countries have legislation which effectively codifies the provision.¹⁰ The four other countries with legislation all require that consumers be instructed about proper use, though they otherwise differ in their emphasis: two require that labels warn of the superiority of breast milk but have no special labelling requirements with respect to composition and other product details¹¹ while, conversely, two focus on ensuring

¹ Guatemala, Decree-Law No. 66-83, Secs. 7, 10, 11 and 12; Peru, Resolution No. 0041-80-SA/DS, Chap. I, Secs. 2, 6, Chap. III, Sec. 14 and Supreme Decree No. 20-82-SA, Part II, Standard VII, Secs. 29-30; and Trinidad and Tobago, Code, Article 8. Mexico, however, adopted the provision as part of its national food regulations: Regulations of 4 January 1988, Sec. 731.

² Portugal, Code and Sweden, Regulations No. 21. Spain, Crown Decree No. 1424, item 15.1.6, independently prohibits the giving of contributions or subsidies to, among others, persons employed by manufacturers and distributors.

³ Lebanon, Decree-Law No. 110, Sec. 8.

⁴ Tunisia, Law No. 83-24, Sec. 7.

⁵ *Synthesis Document, op. cit.*, at paras. 157 (Libyan Arab Jamahiriya) and 164 (Syrian Arab Republic).

⁶ *Ibid.*, at paras. 200 (Samoa) and 203 (Tonga) (voluntary national code), and Philippines Code, Sec. 8.

⁷ Zambia, The Food and Drug Regulations, 1978.

⁸ Nigeria, Code, Sec. 7.2; South Africa, Code, Articles 3-6 (this instrument existed before the adoption of the International Code); *Synthesis Document, op. cit.*, at para. 39 (Swaziland).

⁹ Kenya Code, Article 9.1; *Synthesis Document, op. cit.*, at para. 33 (Mozambique).

¹⁰ Chile, Decree No. 60 of 5 April 1982 approving the Health Regulations on foods [hereafter "Chile, Decree No. 60"], Secs. 202-204; Colombia, Decree No. 1220, Secs. 6-8; Ecuador Decree No. 2215, Chap. V, Secs. 21-25; Guatemala, Decree-Law No. 66-83, Sec. 13; Mexico Regulations of 4 January 1988, Sec. 735; Peru, Resolution No. 0041-80-SA/DS, Chap. I, Secs. 1, 7 and Supreme Decree No. 20-82-SA Part II, Standard VIII, Secs. 31-33; Trinidad and Tobago, The Food and Drugs (Amendment) Regulations, 1984.

¹¹ Nicaragua, Decree-Law No. 912, Sec. 4; Venezuela, Resolution No. 5, Sec. 5.

that labels adequately reflect product composition without regard to emphasizing the superiority of human milk.¹

44. More than half the countries in the **South-East Asia Region** have adopted provisions which conform with Article 9, either through a voluntary code,² legislation,³ or government policy.⁴

45. In the **European Region**, four countries have legislation effectively codifying Article 9.⁵ Other countries have adopted laws or policies to implement parts of Article 9, such as prohibiting the product's idealization⁶ or comparison to breast milk,⁷ requiring that the product label state that it is not for infants under four months,⁸ that breast milk is superior,⁹ that medical advice should accompany the product's use,¹⁰ or that it have a particular composition.¹¹ The EEC Directive provides that the labelling of products shall bear, in addition to those provided for in Directive 79/112/EEC,¹² a variety of mandatory particulars including suitability of product use, total iron requirements for infants over the age of four months, energy value of the product, and instructions for appropriate preparation and a warning against the health hazards of inappropriate preparation. Labels are to be designed to provide the necessary information about the appropriate use of the products so as not to discourage breast-feeding.¹³ The proposal for a Council Directive on infant formulae and follow-on formulae intended for export to third countries¹⁴ stipulates that "no product other than infant formulae may

¹ Canada, Food and Drug Regulations, amendment. Dated 9 December 1983, Sec. B.25.057; United States of America, Infant formula; labeling requirements. Parts 105 and 107 of Title 21 (Food and Drugs) of the United States Code of Federal Regulations. Dated 6 December 1984.

² India, Code, Article 9. Thailand also reports having a code with labelling provisions, though the text has not been made available.

³ Bangladesh, Ordinance, 1984, Sec. 5; Indonesia, Regulations No. 240, Chap. III-IV, Secs. 5-10; Sri Lanka, Direction 3 under Section 6(1)(c) of the Consumer Protection Act, No. 1 of 1979. Dated 6 February 1979, Direction 4 under Section 6(1)(c) of the Consumer Protection Act, No. 1 of 1979. Dated 6 February 1979, Direction 28 under Section 6(1)(c) of the Consumer Protection Act, No. 1 of 1979. Dated 2 March 1981; Direction No. 44, Sec. 2.3.

⁴ *Synthesis Document, op. cit.*, at para. 95 (Nepal).

⁵ Belgium, Crown Order of 28 February 1986 amending the Crown Order of 4 August 1983 on foods for special dietary uses [hereafter, "Belgium Crown Order of 28 February 1986"], item 6.4.4; Finland, Decree No. 630 of 10 July 1979 of the National Board of Trade and Consumer Interests concerning the notices on certain retail packaging, Secs. 8-12 and The Infant Foods Ordinance (No. 722) of 29 October 1981, Chap. 4 [hereafter, "Finland, Infant Foods Ordinance No. 722"], Secs. 10-12; Netherlands, the Infant Foods (Agricultural Quality) Regulations. Dated 2 October 1984 [hereafter, "Netherlands, Regulations No. J 5870"], Chaps. 5-6, Secs. 11-19. Israel also reports having adopted the labelling recommendations from the International Code in 1983, though no text of Israel's provisions has been made available.

⁶ *Synthesis Document, op. cit.*, at para. 112 (Hungary).

⁷ Spain, Crown Decree No. 2685 of 16 October 1976 approving Technical Health Regulations on the preparation and marketing of and trade in food preparations for special dietary uses, Title VI (this legislation existed prior to the adoption of the International Code); policies are described in *Synthesis Document, op. cit.*, at paras. 125 (Portugal) and 132 (Turkey).

⁸ *Ibid.* at para. 112 (Hungary).

⁹ *Ibid.* at paras. 101 (Bulgaria) and 112 (Hungary).

¹⁰ France, Decree No. 78-278 of 9 March 1978 for the implementation of the Law of 1 August 1905 on fraudulent practices and misbranding with regard to products or services, in respect of partly or wholly dehydrated preserved milk for human consumption.

¹¹ Denmark, Order No. 598 of 28 November 1978 on foods for special dietary uses, Sec. 3 (pre-International Code) and Order No. 75 of 20 February 1981 amending the Order on breast-milk substitutes [hereafter, "Denmark, Order No. 75"], Sec. 11(a); Hungary, Joint Ordinance No. 10 of 30 June 1988 of the Minister of Agriculture and Food and the Minister of Social Affairs and Health for the implementation of Law No. IV of 1976 on foods; Norway, Regulations No. 1251 of 8 July 1983 on the production and offer for sale, etc. of foods for infants and young children [hereafter, "Norway Regulations No. 1251"], Sec. 6. The former USSR also reported having legislation in this regard, though it has not been made available.

¹² Of 18 December 1978.

¹³ *EEC Directive, op. cit.*, Article 7.

¹⁴ *Official Journal of the European Communities*, No. C 124, 16 May 1992, p. 14, as amended (*ibid.*, No. C 155, 20 June 1992, pp. 18-19).

be represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first four to six months of life". The proposal also provides that products "must be in conformity" with relevant labelling provisions of the EEC Directive "or with applicable world standards established by the Codex Alimentarius", and "shall be labelled in such a way as to avoid any risk of confusion between infant formulae and follow-on formulae".

46. Two countries in the **Eastern Mediterranean Region** have legislation fully adopting Article 9.¹ In addition, three countries have policies implementing Article 9, in whole² or in part.³

47. In the **Western Pacific Region**, one country has a national code containing comprehensive labelling provisions.⁴ In some cases, where there are no domestic producers, importers are also required to conform fully to the requirements.⁵ A few countries have legislation in partial conformity with Article 9, requiring either the appropriate product information,⁶ or the statement that breast milk is superior to infant formula.⁷ Several countries have voluntary codes which partially conform to the International Code's recommendations.⁸

Article 10 - Quality

48. Article 10 notes that ensuring that food products are of a high recognized standard of quality is an essential element for protecting the health of infants. It states that products should meet the applicable standards recommended by the Codex Alimentarius Commission and the Codex Code of Hygienic Practice for Foods for Infants and Children.

49. It is somewhat misleading to summarize national measures regarding product quality as if they were responses to the International Code as such. Many countries had food quality regulations well before the adoption of the Code, and their applicability to infant foods is largely incidental. Where countries have adopted special infant food standards, this is specified. Ultimately, of course, what matters is the adequacy of the standards rather than the date of their enactment. A second qualifier called for here is that it is often difficult to judge whether a country's legislation meets the standards recommended by the International Code. Many countries clearly have careful and detailed standards, but make no reference to those of the Codex Alimentarius Commission or to the Codex Code of Hygienic Practice for Foods for Infants and Children. This summary lists all known measures.

50. In the **African Region**, five of 33 countries report laws regulating the quality of infant foods, some as a special category of food and drug standards,⁹ others as occasional exceptions to general laws.¹⁰ Three other

¹ Lebanon, Decree-Law No. 110; Tunisia, Law No. 83-24, Chap. 3, Secs. 10-11.

² *Synthesis Document, op. cit.*, at para. 161 (Saudi Arabia).

³ *Ibid.* at paras. 155 (Jordan) (requirement that labels indicate the superiority of breast milk) and 156 (Kuwait) (product information requirements).

⁴ Philippines, Code, Sec. 10.

⁵ *Synthesis Document, op. cit.*, at paras. 183 (French Polynesia) and 185 (Hong Kong).

⁶ *Ibid.* at para. 196 (Republic of Palau) (requirement that labels be in the English language). The State of South Australia also reports this requirement.

⁷ *Ibid.* at para. 186 (Japan). This legislation, which also requires instructions to mothers to seek advice from a health professional, has existed since 1975.

⁸ *Ibid.* at paras. 184 (Guam), 189 (Macao) (only prohibits favourable comparisons between breast milk and breast-milk substitutes) and 193-194 (New Zealand) (contains nothing on the superiority of breast milk or idealization of the formula-fed infant).

⁹ Botswana, The Public Health Regulations, 1983, Part X; Kenya, Code, Articles 3 and 5.1; Nigeria, Code, Article 8.

¹⁰ Mauritius, The Food and Drugs (Phytopharmaceutical Residues) Regulations 1980, Sec. 3(3) and The Food and Drugs (Antioxidants in Food) Regulations 1982, Sec. 4(e); Sudan, The Food Additives (Control of Circulation) Regulations, 1977, Reg. 11; Zambia, The Food and Drug Regulations, 1978, Regs. 27, 396 and 406.

countries report policy measures designed to increase scrutiny of infant food quality (for example reducing their number and increasing the controls on brands available).¹

51. Roughly one-quarter of the countries in the **Region of the Americas** report regulation of infant food quality, either through special infant-food standards,² treating infant foods as a medicament,³ or based on the Codex Alimentarius Commission's recommended standards.⁴

52. Two countries in the **South-East Asia Region** have legislation specifying that infant foods must meet national quality control standards.⁵ Another country makes a similar specification in its voluntary national code.⁶ One country requires that infant foods meet Codex Alimentarius standards.⁷

53. Food quality is highly regulated in the **European Region** and over half the countries have legislation dictating the composition of infant formula. Some have legislation pertaining expressly to infant foods,⁸ while

¹ *Synthesis Document, op. cit.*, at paras. 13 (Algeria), 16 (Burkina Faso) and 21 (Ethiopia).

² Brazil (São Paulo), Decree No. 12486 of 20 October 1978 approving special technical standards for foods and beverages, standard 87; Canada, Food and Drug Regulations, amendment. Dated December 1983, Division B25; Chile, Decree No. 60 of 5 April 1982 approving the Health Regulations on foods, Title XVII, Secs. 200-210; Mexico, Regulations of 4 January 1988, Secs. 733-734; United States of America, Infant formulas: interim guidelines for nutrient composition; notice to manufacturers, packers, and distributors. Notice of the Food and Drug Administration. Dated 11 March 1980; The Infant Formula Act of 1980; Part 246 (Special Supplemental Food Program for Women, Infants, and Children) of Title 7 (Agriculture) of the United States Code of Federal Regulations [hereafter, "WIC Program Regulations"]. Revised version dated 3 November 1980, Sec. 246.8; Enforcement policy: infant formula recalls, Part 7 (Enforcement Policy) of Title 21 (Food and Drugs) of the United States Code of Federal Regulations. Dated 12 April 1982, Sec. 7.71; Nutrient requirements for infant formulas. Part 107 (Infant Formula) of Title 21 (Food and Drugs) of the United States Code of Federal Regulations. Dated 7 October 1985; Infant formula recall requirements, Part 107 of Title 21 (Food and Drugs) of the United States Code of Federal Regulations. Dated 22 December 1988.

³ Nicaragua, Decree No. 912, Sec. 6.

⁴ Ecuador, Decree No. 2215, Chap. IV, Secs. 15-16; Paraguay, *Synthesis Document, op. cit.*, at para. 72; Peru, Supreme Decree No. 20-82-SA, Standard VII, Sec. 2(3) and Annex 2; United States of America, *ibid.*

⁵ Indonesia, Regulations No. 240/Men.Kes./Per/V/85, Chap. II; Thailand, Notification No. 34 of 1979 of the Ministry of Public Health declaring modified milk for infants to be a specially controlled food and prescribing provisions on quality standards and the manufacturing process. Dated 13 September 1979; and Notification No. 66 of 1982 of the Ministry of Public Health amending Notification No. 55 of 1981 of the Ministry of Public Health. Dated 11 January 1982.

⁶ India, Code, Article 10.

⁷ Sri Lanka, Direction No. 44, Secs. 7.4-7.6.

⁸ Belgium, Crown Order of 4 August 1983 on foods for special dietary uses, Sec. 1; Crown Order of 28 February 1986, item 6.1.2.2; Finland, Infant Foods Ordinance No. 722; Decree No. 450 of 28 January 1983 of the National Board of Health on the composition of infant foods and of breast-milk substitutes and on instructions for their use, and amendment of 27 January 1988, Secs. 1, 9, 11; France, Order of 1 July 1976 on foods for special dietary uses, and amendment of 5 January 1981; Decree No. 81-574 of 15 May 1981 for the implementation of the Law of 1 August 1905 on fraudulent practices and misbranding with regard to products or services, in respect of foods and beverages for special dietary uses, Sec. 10; Orders of 4 August 1986 and 14 December 1988 on the use of additives in the production of foods for special dietary uses; Italy, *Synthesis Document, op. cit.*, at para. 117; Netherlands, Regulations No. J 5870, Chap. 4; Norway, Regulations No. 1251, Secs. 4-5; Portugal, Code (refers to regulations); Spain, Crown Decree No. 2685 of 16 October 1976 approving Technical Health Regulations on the preparation and marketing of and trade in food preparations for special dietary uses, and amendment of 18 January 1980; Sweden, Order No. 17 of 25 May 1978 of the National Food Administration on infant foods, Annexes 1 and 2; Order No. 36 of 10 November 1989 of the National Food Administration amending Order No. 17 of 1978 on infant foods; Switzerland, Ordinance on foods. Amendment of 4 November 1987; former USSR, *Synthesis Document, op. cit.*, at para. 133; Yugoslavia, Regulations No. 3463 of 29 October 1979 on conditions governing the wholesomeness of marketed foods for special dietary uses.

others include infant foods as part of a list of foods subject to particular restrictions.¹ One country reports compliance with the Codex Alimentarius standards.² The EEC Directive also covers questions of quality and composition in considerable detail.³ The proposal for a Council Directive on infant formulae and follow-on formulae intended for export to third countries⁴ provides that products "must be in conformity" with relevant provisions covering composition of the EEC Directive.

54. In the **Eastern Mediterranean Region**, two countries legally require compliance with Article 10,⁵ while two others have adopted the policy of having public health authorities randomly sample infant-food products to test their quality.⁶

55. In the **Western Pacific Region**, three countries report quality control legislation specially for infant foods.⁷ Two countries comply with the Codex Alimentarius standards.⁸

Article 11 - Implementation and monitoring

56. Article 11 states that national governments, in collaboration with WHO, manufacturers and distributors, and concerned organizations and individuals, are responsible for implementing and monitoring the application of the Code. To this end, it recommends that governments adopt legislation, regulations or other suitable measures, as appropriate to their particular social and legislative framework.

57. In contrast to earlier portions of this paper which elaborate on the various ways, article by article, in which national governments have implemented the International Code, this final section describes overarching institutional measures or, in some cases, preliminary steps (e.g. workshops, draft codes) taken to facilitate compliance with the Code's recommendations.

58. There was considerable activity in the **African Region** shortly after the International Code was adopted. About two-thirds of countries took preliminary steps toward implementing the Code. This was done through the creation of national committees⁹ or by conducting workshops or surveys, often in consultation with WHO and the United Nations Children's Fund (UNICEF), which in many cases led to recommendations or draft

¹ Austria, The Colouring Matters in Foods Ordinance. Dated 4 May 1979, Sec. 6 (on food colouring); Denmark, Order No. 51 of 10 February 1986 on dummies and teats for infant-feeding bottles; and Order No. 447 of 5 September 1985 on the limit values applicable to certain metals in foods; Federal Republic of Germany, The Nitrosamines in Consumer Goods Ordinance. Dated 15 December 1982; Greece, Decision No. 3507/79 of 23 November 1982 on the use of nitrates and nitrites in foods; Finland, Decree No. 1023 of 18 December 1984 of the Food Directorate on the criteria of microbiological quality for infant foods; Decree No. 84 of 28 January 1986 of the Food Directorate on food additives; Hungary, Ordinance No. 8 of 21 October 1985 of the Minister of Health amending Ordinance No. 4 of 25 June 1978 on the control of hazardous chemical contamination of foods (Annex 2); Ordinance No. 9 of 17 September 1986 of the Minister of Health amending Ordinance No. 6 of 14 July 1978 on the control of the microbiological contamination of food (Annex II, and Annex III, Part C); Luxembourg, Ministerial Regulations of 27 November 1987 determining the permissible levels of radioactivity in food products; United Kingdom, The Miscellaneous Additives in Food (Amendment) Regulations 1982; The Skimmed Milk with Non-Milk Fat (Amendment) Regulations 1981; The Sweeteners in Food Regulations 1983; The Colouring Matter in Food (Amendment) Regulations 1987.

² *Synthesis Document, op. cit.*, at para. 126 (Romania).

³ *EEC Directive, op. cit.*, Articles 4-5 and Annexes I and III.

⁴ *Official Journal of the European Communities*, No. C 124, 16 May 1992, p. 14, as amended.

⁵ Lebanon, Decree-Law No. 110; Tunisia, Law No. 83-24, Chap. 1, Sec. 5.

⁶ *Synthesis Document, op. cit.*, at paras. 156 (Kuwait) and 161 (Saudi Arabia).

⁷ Australia (South Australia), The Food and Drugs Regulations 1978, Reg. 55; Malaysia, The Food Regulations 1985, Reg. 389, and Amendment. Dated 11 April 1988. New Zealand, the Food Regulations 1984, Regs. 237-243.

⁸ *Synthesis Document, op. cit.*, at para. 185 (Hong Kong); Philippines, Code, Sec. 11.

⁹ *Ibid.*, at paras. 13 (Algeria), 16 (Burkina Faso), 22 (Gabon), 23 (Gambia), 28 (Liberia), 31 (Mali), 33 (Mozambique), 39 (Swaziland), 42 (United Republic of Tanzania), 44 (Zambia) and 45 (Zimbabwe).

provisions.¹ Similarly, one country took the initial measure of amending public health legislation to enable the competent minister to issue regulations pertaining to infant-feeding practices and infant-food marketing.² Three countries have national codes with voluntary, rather than legislative enforcement mechanisms.³ Eight countries report draft national codes, in various stages of development.⁴

59. Countries in the **Region of the Americas** have taken a range of measures to facilitate implementation of the Code. The most common actions have been surveys,⁵ national programmes,⁶ workshops,⁷ and committees or task forces⁸ devoted to the task of finding ways to adapt the Code to local circumstances. The Caribbean Community has also held intergovernmental conferences, in cooperation with WHO and UNICEF, to recommend ways and means for member countries to implement the Code.⁹ One country has passed enabling legislation to permit the Secretariat of Health to establish appropriate measures for the promotion of breast-feeding.¹⁰ Though not expressly mentioned by the International Code, several countries have adopted or proposed legislation which facilitates implementation of the Code by accommodating breast-feeding in the workplace.¹¹ Finally, several countries have adopted national codes which provide for legislative enforcement of their provisions¹² or voluntary codes devised by manufacturers,¹³ or are working on draft national codes.¹⁴

60. In the **South-East Asia Region**, some countries have worked towards implementation of the International Code by conducting surveys¹⁵ or striking committees to make recommendations.¹⁶ A few countries have

¹ *Synthesis Document, op. cit.*, at paras. 18 (Central African Republic), 19 (Congo), 21 (Ethiopia), 24 (Ghana), 27 (Lesotho), 30 (Malawi), 32 (Mauritius), 35 (Rwanda), 37 (Senegal), 40 (Togo), 41 (Uganda) and 43 (Zaire).

² Zimbabwe, The Public Health Amendment Act, 1985.

³ Kenya Code, Article 8; Nigeria, Code, Article 9; and South Africa, Code, Article 12. Zambia also reports a voluntary code, which is not yet available; see *Synthesis Document, op. cit.*, at para. 44.

⁴ *Synthesis Document, op. cit.*, at paras. 17 (Cameroon), 20 (Cote d'Ivoire), 24 (Ghana), 27 (Lesotho), 28 (Liberia), 29 (Madagascar), 38 (Sierra Leone) and 45 (Zimbabwe).

⁵ *Ibid.*, at paras. 48 (Barbados), 58 (Cuba), 59 (Dominica) and 67 (Honduras).

⁶ *Ibid.* at paras. 49 (Belize), 53 (Canada), 61 (Dominican Republic), 64 (Grenada), 74 (Paraguay) and 75 (Saint Lucia). In some countries, the programme was created by legislation: Brazil, Order No. 042 of 10 February 1981 of the Office of the Minister of Health, Sec. 1; Peru, Legislative Decree No. 346 of 6 July 1985, Sec. 32; United States of America, The Child Nutrition Amendments Act of 1978, 3; and WIC Program Regulations, dated 7 February 1985 (some of these programmes existed prior to the adoption of the International Code).

⁷ *Ibid.* at paras. 70 (Nicaragua) and 76 (Suriname).

⁸ *Ibid.* at paras. 50 (Brazil), 51 (British Virgin Islands), 52 (Bolivia), 57 (Costa Rica), 63 (El Salvador), 66 (Haiti), 70 (Nicaragua), 77 (Trinidad and Tobago), 78-84 (United States of America); see also Costa Rica, Decree No. 17965-S, of 4 February 1988.

⁹ Members of the Conference of Ministers Responsible for Health in the Caribbean Community (CARICOM), in 1989, were Antigua and Barbuda, Bahamas, Barbados, Belize, Dominica, Grenada, Guyana, Jamaica, Montserrat, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, and Trinidad and Tobago; see *ibid.* at para. 87. In addition, the health authorities from Dominica, Grenada, Saint Vincent and the Grenadines, and the Turks and Caicos Islands, in collaboration with the Pan American Health Organization/World Health Organization, met in 1982; see *ibid.* at para. 60.

¹⁰ Mexico, Regulations of 4 January 1988, Sec. 730.

¹¹ *Synthesis Document, op. cit.*, at paras. 61 (Dominican Republic) (proposed), and Peru, Supreme Decree No. 20-82-SA, Standard IX, Sec. 3. Panama and Saint Kitts and Nevis have more recently reported such legislation to WHO.

¹² Ecuador, Decree No. 2215, Chap. VI, Secs. 30-32; Guatemala, Decree-Law No. 66-83, Sec. 14; Nicaragua Decree No. 912, Secs. 7-9; Peru Resolution No. 0041-80-SA/DS, Chap. III, Sec. 15 and Supreme Decree No. 20-82-SA (Part II), Standard X, Secs. 36-40; Trinidad and Tobago, Code, Article 11; Venezuela, Resolution No. 5, Secs. 1, 6, 9-10. Some countries also report having adopted national codes, though they have not been made available: see *Synthesis Document, op. cit.*, at paras. 47 (Argentina), 50 (Brazil) and 52 (Bolivia).

¹³ *Ibid.* at paras. 78-84 (United States of America).

¹⁴ *Ibid.* at para. 57 (Costa Rica).

¹⁵ *Ibid.* at paras. 88 (Bangladesh) and 89 (Bhutan).

¹⁶ *Ibid.* at paras. 92 (Indonesia) and 96-97 (Sri Lanka).

adopted national codes, both voluntary¹ and legally enforceable.² One country has made the selected aspects of the Code that it has adopted enforceable by law.³

61. The most prevalent implementation mechanism in the **European Region** is voluntary codes of conduct between manufacturers, consumer groups and government,⁴ though one country also has a legislated code of conduct.⁵ In addition to codes, some countries also have set up working groups,⁶ conducted surveys on breast-feeding practices⁷ or marketing techniques,⁸ or developed labour legislation to accommodate lactating mothers.⁹ Finally, the EEC Directive requires Member States to enact laws, regulations and administrative provisions in compliance (with minor deviations) with the International Code by June 1994.¹⁰ Member States of the European Community are called upon to "bring into force the laws, regulations and administrative provisions necessary to comply" with the Directive.¹¹

62. In the **Eastern Mediterranean Region**, half the countries have set up committees to examine ways to implement the International Code.¹² One country held a seminar and meeting among representatives of pertinent groups to devise policy recommendations.¹³ Several countries have also developed draft codes, independently¹⁴ or within the framework of the Council of Health Ministers of the Arab Countries of the Gulf Area.¹⁵ Two countries have adopted national codes which can be legally enforced.¹⁶ As in some other regions, certain countries also report having adopted flexible labour legislation to accommodate breast-feeding by working mothers.¹⁷

¹ India, Code, Article 11. Thailand also reports having a national code, but its text has not been made available, and Nepal reports the creation of a draft national code in 1985.

² Sri Lanka, Direction No. 44.

³ Indonesia, Regulations No. 240/Men.Kes./Per/V/85, Chap. V.

⁴ *Synthesis Document, op. cit.*, at paras. 99 (Austria), 103 (Denmark), 105 (Finland), 107 (France), 109 (Federal Republic of Germany), 113 (Ireland), 121 (the Netherlands), 123 (Norway), 125 (Portugal), 128-130 (Sweden), 131 (Switzerland) and 134-137 (United Kingdom).

⁵ *Ibid.*, Sweden.

⁶ *Ibid.*, Denmark, Finland, Ireland and Portugal.

⁷ *Ibid.*, Sweden.

⁸ *Ibid.*, Ireland.

⁹ Austria, Notice of 17 April 1979 (Serial No. 221) of the Federal Government promulgating a consolidated version of the Maternal Protection Law (pre-Code); France, Circular DH/8D/87 No. 210 of 7 October 1987 on maternity or adoption leave for and authorized absences by career and non-career employees of the establishments referred to in Section 2 of Law No. 86-33 of 9 January 1986 laying down regulations applicable to staff in the public service in the hospital sector.

¹⁰ *EEC Directive, op. cit.*

¹¹ *Ibid.*, Article 10.

¹² *Synthesis Document, op. cit.*, at paras. 148 (Bahrain), 149 (Cyprus), 152 (Egypt), 153 (Islamic Republic of Iran), 154 (Iraq), 155 (Jordan), 156 (Kuwait), 159 (Pakistan), 164 (Syrian Arab Republic); and Tunisia, Decree No. 84-1314 of 3 November 1984 determining the functions, composition, and working procedures of the National Commission for the Promotion of Infant and Child Feeding.

¹³ *Ibid.* at para. 147 (Afghanistan).

¹⁴ *Ibid.* at paras. 159 (Pakistan), 168 (United Arab Emirates) and 169 (Yemen).

¹⁵ *Ibid.*, at paras. 170-171. The draft law devised by this regional body bears close resemblance to the International Code. The Member States are Bahrain, Iraq, Kuwait, Oman, Qatar, Saudi Arabia, and the United Arab Emirates.

¹⁶ Lebanon, Decree-Law No. 110, Scs. 11-12; Tunisia, Law No. 83-24, Chap. 4, Sec. 12.

¹⁷ *Synthesis Document, op. cit.*, at paras. 155 (Jordan) and 158 (Oman).

63. Common initiatives to bring about implementation of the International Code in the **Western Pacific Region** include surveys,¹ the creation of working groups² (including an intergovernmental group),³ monitoring committees⁴ and national programmes.⁵ Other measures include labour laws to permit breast-feeding on the worksite,⁶ import duties on breast-milk substitutes⁷ and bans on commercial availability of products.⁸ One country has an enforceable national code.⁹ Several others have voluntary¹⁰ or draft codes.¹¹

SUMMARY AND CONCLUSION

64. This survey of national legislation and other measures adopted to give effect to the International Code during the last 10 years displays a diverse array of approaches. As stressed in the Introduction, there can be no rigid prescription for responding most effectively to the Code. Rather, the legislative and other measures selected by countries reflect their particular economic, social, political and geographical context. It is hoped that the survey will provide governments, and other interested groups and individuals, with some insight into the approaches used in different countries and regions, thereby increasing available options as they continue to build comprehensive legal and policy regimes in support of appropriate infant-feeding practices.

65. In the light of the information summarized above, the most obvious general trend since the International Code's adoption has been the tailoring of country-specific approaches to fit country-specific situations. Specific patterns may be summarized as follows:¹²

(1) The health authorities in many countries have issued, and updated and re-issued, memoranda of guidance to health personnel, often accompanied by copies of the International Code,¹³ to inform them of its provisions and to call attention to their responsibilities under it, in keeping with their national social and legislative framework.

(2) Ad hoc and permanent committees responsible for implementing the Code have been constituted. Such bodies have frequently included representatives of various government offices (e.g. health, agriculture, social affairs, education, and trade and industry), health workers' associations, consumer (including women's) groups, infant-food manufacturers and, in some cases, WHO and UNICEF.

(3) Working groups have been established to review existing legislation and relevant practices relating to the marketing and distribution of breast-milk substitutes, and to recommend amendments or new

¹ *Synthesis Document, op. cit.*, at paras. 204-205 (Vanuatu).

² *Ibid.* at paras. 173 (Australia), 179 (China), 192 (Federated States of Micronesia) and 200 (Samoa).

³ *Ibid.* at para. 207. Representatives of nine countries and territories met in 1981: Cook Islands, Fiji, Kiribati, Papua New Guinea, Solomon Islands, Tonga, Tuvalu, Vanuatu, and Western Samoa.

⁴ *Ibid.* at paras. 182 (Fiji), 190-191 (Malaysia), 193-194 (New Zealand), 198-199 (Philippines) and 201 (Singapore).

⁵ *Ibid.* at para. 184 (Guam).

⁶ *Ibid.* at paras. 180 (Commonwealth of Northern Mariana Islands), 183 (French Polynesia), 188 (Lao People's Democratic Republic) and 198-199 (Philippines).

⁷ *Ibid.* at paras. 204-205 (Vanuatu).

⁸ *Ibid.* at para. 206 (Vietnam).

⁹ Philippines Code, Secs. 12-13.

¹⁰ *Synthesis Document, op. cit.*, at paras. 173-174 (Australia), 178 (Brunei Darussalam), 189 (Macao), 190-191 (Malaysia), 193-194 (New Zealand), 195 (Republic of Korea), 201 (Singapore), and 203 (Tonga).

¹¹ *Ibid.* at paras. 182 (Fiji), 179 (China) and 188 (Lao People's Democratic Republic).

¹² *Synthesis Document, op. cit.*, adapted from para. 220.

¹³ In one of the official languages of WHO (Arabic, Chinese, English, French, Russian and Spanish) or in non-official language translations, whether prepared by the national health authorities themselves, health workers' associations, consumer groups, or infant-food manufacturers. The latter include Catalan and Czech (in press), Dari and Pushtu (Afghanistan), Danish, Dutch, German, Italian, Japanese, Korean, Norwegian, Portuguese, Somali, Swedish and Vietnamese.

legislation to give effect to the International Code. Existing legislation has been updated, while much new legislation has been adopted, covering various provisions of the Code.

(4) Governments have negotiated voluntary agreements with the infant-food industry and, occasionally, with health workers' organizations, to implement all or part of the Code. National codes of ethics, or of marketing and advertising of products within the scope of the Code, have also been developed or revised, in consultation with interested parties.

(5) Governments have reviewed, in the light of experience, their various national measures initially adopted to give effect to the Code. They have re-negotiated with the infant-food industry earlier voluntary agreements, or modified existing legislation or administrative arrangements to take account of new developments.

(6) A number of industrialized countries, where major manufacturers and worldwide exporters of infant formula are based, have investigated the implications of their export trade in the light of the International Code, to ensure that manufacturers operating within their territories adhere to its provisions when marketing internationally.

(7) In some countries the manufacture or importation of breast-milk substitutes, and their distribution, are subject to direct state control based on central licensing and marketing arrangements. In a number of these, infant formula is subsidized or distributed free of charge to mothers of infants who have to be fed on breast-milk substitutes.

(8) National authorities in some countries have made the supply of breast-milk substitutes contingent upon the prior obtainment by the mother, or other family member, of the advice of a health worker as to the need for their use, and the proper method of use. A prescription for this purpose is required for obtaining them at designated retail outlets.

(9) Some countries permit manufacturers or distributors to provide donations or low-price sales of supplies of infant formula directly to institutions or organizations, but closely monitor the practice by requiring detailed reporting by the institutions or organizations and manufacturers concerned on the amount of supplies, the number of infants, and the duration for which the supplies are provided. Other countries welcome such supplies provided they are channelled through an official central distribution point, and that institutions or organizations have no direct contact with manufacturers, but request supplies only from the central point. Still other countries have entirely disallowed the practice of donations or low-price sales of supplies of infant formula.

INTERNATIONAL CODE OF MARKETING OF BREAST-MILK SUBSTITUTES¹

The Member States of the World Health Organization:

Affirming the right of every child and every pregnant and lactating woman to be adequately nourished as a means of attaining and maintaining health;

Recognizing that infant malnutrition is part of the wider problems of lack of education, poverty, and social injustice;

Recognizing that the health of infants and young children cannot be isolated from the health and nutrition of women, their socioeconomic status and their roles as mothers;

Conscious that breast-feeding 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 breast-feeding and child spacing;

Recognizing that the encouragement and protection of breast-feeding is an important part of the health, nutrition and other social measures required to promote healthy growth and development of infants and young children; and that breast-feeding is an important aspect of primary health care;

Considering that when mothers do not breast-feed, or only do so partially, there is a legitimate market for infant formula and for suitable ingredients from which to prepare it; that all these products should accordingly be made accessible to those who need them through commercial or non-commercial distribution systems; and that they should not be marketed or distributed in ways that may interfere with the protection and promotion of breast-feeding;

Recognizing further that inappropriate feeding practices lead to infant malnutrition, morbidity and mortality in all countries, and that improper practices in the marketing of breast-milk substitutes and related products can contribute to these major public health problems;

Convinced that it is important for infants to receive appropriate complementary foods, usually when the infant reaches four to six months of age, and that every effort should be made to use locally available foods; and convinced, nevertheless, that such complementary foods should not be used as breast-milk substitutes;

Appreciating that there are a number of social and economic factors affecting breast-feeding, and that, accordingly, governments should develop social support systems to protect, facilitate and encourage it, and that they should create an environment that fosters breast-feeding, provides appropriate family and community support, and protects mothers from factors that inhibit breast-feeding;

Affirming that health care systems, and the health professionals and other health workers serving in them, have an essential role to play in guiding infant feeding practices, encouraging and facilitating breast-feeding, and providing objective and consistent advice to mothers and families about the superior value of breast-feeding, or where needed, on the proper use of infant formula, whether manufactured industrially or home-prepared;

Affirming further that educational systems and other social services should be involved in the protection and promotion of breast-feeding, and in the appropriate use of complementary foods;

¹ *International Code of Marketing of Breast-milk Substitutes*, Geneva, World Health Organization, 1981; published by WHO in Arabic, Chinese, English, French, Russian and Spanish.

Aware that families, communities, women's organizations and other nongovernmental organizations have a special role to play in the protection and promotion of breast-feeding and in ensuring the support needed by pregnant women and mothers of infants and young children, whether breast-feeding or not;

Affirming the need for governments, organizations of the United Nations system, nongovernmental organizations, experts in various related disciplines, consumer groups and industry to cooperate in activities aimed at the improvement of maternal, infant and young child health and nutrition;

Recognizing that governments should undertake a variety of health, nutrition and other social measures to promote healthy growth and development of infants and young children, and that this Code concerns only one aspect of these measures;

Considering that manufacturers and distributors of breast-milk substitutes have an important and constructive role to play in relation to infant feeding, and in the promotion of the aim of this Code and its proper implementation;

Affirming that governments are called upon to take action appropriate to their social and legislative framework and their overall development objectives to give effect to the principles and aim of this Code, including the enactment of legislation, regulations or other suitable measures;

Believing that, in the light of the foregoing considerations, and in view of the vulnerability of infants in the early months of life and the risks involved in inappropriate feeding practices, including the unnecessary and improper use of breast-milk substitutes, the marketing of breast-milk substitutes requires special treatment, which takes usual marketing practices unsuitable for these products;

THEREFORE:

The Member States hereby agree the following articles which are recommended as a basis for action.

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, and practices related thereto, of the following products: breast-milk substitutes, including infant formula; other milk products, foods and beverages, including bottle-fed complementary foods, when marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breast milk; feeding bottle and teats. It also applies to their quality and availability, and to information concerning their use.

Article 3. Definitions

For the purposes of this Code:

"Breast-milk substitute"	means	any food being marketed or otherwise represented as a partial or total replacement for breast milk, whether or not suitable for that purpose.
"Complementary food"	means	any food, whether manufactured or locally prepared, suitable as a complement to breast milk or to infant formula, when either becomes insufficient to satisfy the nutritional requirements of the infant. Such food is also commonly called "weaning food" or "breast-milk supplement".

"Container"	means	any form of packaging of products for sale as a normal retail unit, including wrappers.
"Distributor"	means	a person, corporation or any other entity in the public or private sector engaged in the business (whether directly or indirectly) of marketing at the wholesale or retail level of a product within the scope of this Code. A "primary distributor" is a manufacturer's sales agent, representative, national distributor or broker.
"Health care system"	means	governmental, nongovernmental or private institutions or organizations engaged, directly or indirectly, in health care for mothers, infants and pregnant women; and nurseries or child-care institutions. It also includes health workers in private practice. For the purposes of this Code, the health care system does not include pharmacies or other established sales outlets.
"Health worker"	means	a person working in a component of such a health care system, whether professional or non-professional, including voluntary, unpaid workers.
"Infant formula"	means	a breast-milk substitute formulated industrially in accordance with applicable Codex Alimentarius standards, to satisfy the normal nutritional requirements of infants up to between four and six months of age, and adapted to their physiological characteristics. Infant formula may also be prepared at home, in which case it is described as "home-prepared".
"Label"	means	any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to, a container (see above) of any product within the scope of this Code.
"Manufacturer"	means	a corporation or other entity in the public or private sector 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 a product within the scope of this Code.
"Marketing"	means	product promotion, distribution, selling, advertising, product public relations, and information services.
"Marketing personnel"	means	any persons whose functions involve the marketing of a product or products coming within the scope of this Code.
"Samples"	means	single or small quantities of a product provided without cost.
"Supplies"	means	quantities of a product provided for use over an extended period, free or at a low price, for social purposes, including those provided to families in need.

Article 4. Information and education

4.1 Governments should 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 should cover either the planning, provision, design and dissemination of information, or their control.

4.2 Informational and educational materials, whether written, audio, or visual, dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children, should include information on all the following points: (a) the benefits and superiority of breast-feeding; (b) maternal nutrition, and the preparation for and maintenance of breast-feeding; (c) the negative effect on breast-feeding of introducing partial bottle-feeding; (d) the difficulty of reversing the decision not to breast-feed; and (e) where needed, the proper use of infant formula, whether manufactured industrially or home-prepared. When such materials contain information about the use of infant formula, they should 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 formula and other breast-milk substitutes. Such materials should not use any pictures or text which may idealize the use of breast-milk substitutes.

4.3 Donations of informational or educational equipment or materials by manufacturers or distributors should 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 should not refer to a proprietary product that is within the scope of this Code, and should be distributed only through the health care system.

Article 5. The general public and mothers

5.1 There should be no advertising or other form of promotion to the general public of products within the scope of this Code.

5.2 Manufacturers and distributors should not provide, directly or indirectly, to pregnant women, mothers or members of their families, samples of products within the scope of this Code.

5.3 In conformity with paragraphs 1 and 2 of this Article, 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 Code. This provision should not restrict the establishment of pricing policies and practices intended to provide products at lower prices on a long-term basis.

5.4 Manufacturers and distributors should not distribute to pregnant women or mothers of infants and young children any gifts of articles or utensils which may promote the use of breast-milk substitutes or bottle-feeding.

5.5 Marketing personnel, in their business capacity, should not seek direct or indirect contact of any kind with pregnant women or with mothers of infants and young children.

Article 6. Health care systems

6.1 The health authorities in Member States should take appropriate measures to encourage and protect breast-feeding and promote the principles of this Code, and should give appropriate information and advice to health workers in regard to their responsibilities, including the information specified in Article 4.2.

6.2 No facility of a health care system should be used for the purpose of promoting infant formula or other products within the scope of this Code. This Code does not, however, preclude the dissemination of information to health professionals as provided in Article 7.2.

6.3 Facilities of health care systems should not be used for the display of products within the scope of this Code, for placards or posters concerning such products, or for the distribution of material provided by a manufacturer or distributor other than that specified in Article 4.3.

6.4 The use by the health care system of "professional services representatives", "mothercraft nurses" or similar personnel, provided or paid for by manufacturers or distributors, should not be permitted.

6.5 Feeding with infant formula, whether manufactured or home-prepared, should be demonstrated only by health workers, or other community workers if necessary; and only to the mothers or family members who need to use it; and the information given should include a clear explanation of the hazards of improper use.

6.6 Donations or low-price sales to institutions or organizations of supplies of infant formula or other products within the scope of this Code, whether for use in the institutions or for distribution outside them, may be made. Such supplies should only be used or distributed for infants who have to be fed on breast-milk substitutes. If these supplies are distributed for use outside the institutions, this should be done only by the institutions or organizations concerned. Such donations or low-price sales should not be used by manufacturers or distributors as a sales inducement.

6.7 Where donated supplies of infant formula or other products within the scope of this Code are distributed outside an institution, the institution or organization should take steps to ensure that supplies can be continued as long as the infants concerned need them. Donors, as well as institutions or organizations concerned, should bear in mind this responsibility.

6.8 Equipment and materials, in addition to those referred to in Article 4.3, donated to a health care system may bear a company's name or logo, but should not refer to any proprietary product within the scope of this Code.

Article 7. Health workers

7.1 Health workers should encourage and protect breast-feeding; and those who are concerned in particular with maternal and infant nutrition should make themselves familiar with their responsibilities under this Code, including the information specified in Article 4.2.

7.2 Information provided by manufacturers and distributors to health professionals regarding products within the scope of this Code should be restricted to scientific and factual matters, and such information should not imply or create a belief that bottle-feeding is equivalent or superior to breast-feeding. It should also include the information specified in Article 4.2.

7.3 No financial or material inducements to promote products within the scope of this Code should be offered by manufacturers or distributors to health workers or members of their families, nor should these be accepted by health workers or members of their families.

7.4 Samples of infant formula or other products within the scope of this Code, or of equipment or utensils for their preparation or use, should not be provided to health workers except when necessary for the purpose of professional evaluation or research at the institutional level. Health workers should not give samples of infant formula to pregnant women, mothers of infants and young children, or members of their families.

7.5 Manufacturers and distributors of products within the scope of this Code should disclose to the institution to which a recipient health worker is affiliated any contribution made to him or on his behalf for fellowships, study tours, research grants, attendance at professional conferences, or the like. Similar disclosures should be made by the recipient.

Article 8. Persons employed by manufacturers and distributors

8.1 In systems of sales incentives for marketing personnel, the volume of sales of products within the scope of this Code should not be included in the calculation of bonuses, nor should quotas be set specifically for sales of these products. This should not be understood to prevent the payment of bonuses based on the overall sales by a company of other products marketed by it.

8.2 Personnel employed in marketing products within the scope of this Code should not, as part of their job responsibilities, perform educational functions in relation to pregnant women or mothers of infants and young children. This should not be understood as preventing such personnel from being used for other functions by the health care system at the request and with the written approval of the appropriate authority of the government concerned.

Article 9. Labelling

9.1 Labels should be designed to provide the necessary information about the appropriate use of the product, and so as not to discourage breast-feeding.

9.2 Manufacturers and distributors of infant formula should ensure that each container has a clear, conspicuous, and easily readable and understandable message printed on it, or on a label which cannot readily become separated from it, in an appropriate language, which includes all the following points: (a) the words "Important Notice" or their equivalent; (b) a statement of the superiority of breast-feeding; (c) a statement that the product should be used only on the advice of a health worker as to the need for its use and the proper method of use; (d) instructions for appropriate preparation, and a warning against the health hazards of inappropriate preparation. Neither the container nor the label should have pictures of infants, nor should they have other pictures or texts which may idealize the use of infant formula. They may, however, have graphics for easy identification of the product as a breast-milk substitute and for illustrating methods of preparation. The terms "humanized", "maternalized" or similar terms should not be used. Inserts giving additional information about the product and its proper use, subject to the above conditions, may be included in the package or retail unit. When labels give instructions for modifying a product into infant formula, the above should apply.

9.3 Food products within the scope of this Code, marketed for infant feeding, which do not meet all the requirements of an infant formula, but which can be modified to do so, should carry on the label a warning that the unmodified product should not be the sole source of nourishment of an infant. Since sweetened condensed milk is not suitable for infant feeding, nor for use as a main ingredient of infant formula, its label should not contain purported instructions on how to modify it for that purpose.

9.4 The label of food products within the scope of this Code should also state all the following points: (a) the ingredients used; (b) the composition/analysis of the product; (c) the storage conditions required; and (d) the batch number and the date before which the product is to be consumed, taking into account the climatic and storage conditions of the country concerned.

Article 10. Quality

10.1 The quality of products is an essential element for the protection of the health of infants and therefore should be of a high recognized standard.

10.2 Food products within the scope of this Code should, when sold or otherwise distributed, meet applicable standards recommended by the Codex Alimentarius Commission and also the Codex Code of Hygienic Practice for Foods for Infants and Children.

Article 11. Implementation and monitoring

11.1 Governments should take action to give effect to the principles and aim of this Code, as appropriate to their social and legislative framework, including the adoption of national legislation, regulations or other suitable measures. For this purpose, governments should seek, when necessary, the cooperation of WHO, UNICEF and other agencies of the United Nations system. National policies and measures, including laws and regulations, which are adopted to give effect to the principles and aim of this Code 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 this Code.

11.2 Monitoring the application of this Code lies with governments acting individually, and collectively through the World Health Organization as provided in paragraphs 6 and 7 of this Article. The manufacturers and distributors of products within the scope of this Code, and appropriate nongovernmental organizations, professional groups, and consumer organizations should collaborate with governments to this end.

11.3 Independently of any other measures taken for implementation of this Code, manufacturers and distributors of products within the scope of this Code should regard themselves as responsible for monitoring their marketing practices according to the principles and aim of this Code, and for taking steps to ensure that their conduct at every level conforms to them.

11.4 Nongovernmental organizations, professional groups, institutions, and individuals concerned should have the responsibility of drawing the attention of manufacturers or distributors to activities which are incompatible with the principles and aim of this Code, so that appropriate action can be taken. The appropriate governmental authority should also be informed.

11.5 Manufacturers and primary distributors of products within the scope of this Code should apprise each member of their marketing personnel of the Code and of their responsibilities under it.

11.6 In accordance with Article 62 of the Constitution of the World Health Organization, Member States shall communicate annually to the Director-General information on action taken to give effect to the principles and aim of this Code.

11.7 The Director-General shall report in even years to the World Health Assembly on the status of implementation of the Code; and shall, on request, provide technical support to Member States preparing national legislation or regulations, or taking other appropriate measures in implementation and furtherance of the principles and aim of this Code.

ANNEX 2

MEMBER STATES OF THE WORLD HEALTH ORGANIZATION, BY REGION

(at 9 July 1992)

African Region

Algeria	Gabon	Niger
Angola	Gambia	Nigeria
Benin	Ghana	Rwanda
Botswana	Guinea	Sao Tome and Principe
Burkina Faso	Guinea-Bissau	Senegal
Burundi	Kenya	Seychelles
Cameroon	Lesotho	Sierra Leone
Cape Verde	Liberia	South Africa
Central African Republic	Madagascar	Swaziland
Chad	Malawi	Togo
Comoros	Mali	Uganda
Congo	Mauritania	United Republic of Tanzania
Côte d'Ivoire	Mauritius	Zaire
Equatorial Guinea	Mozambique	Zambia
Ethiopia	Namibia	Zimbabwe

Region of the Americas

Antigua and Barbuda	Dominica	Panama
Argentina	Dominican Republic	Paraguay
Bahamas	Ecuador	Peru
Barbados	El Salvador	Puerto Rico*
Belize	Grenada	Saint Kitts and Nevis
Bolivia	Guatemala	Saint Lucia
Brazil	Guyana	Saint Vincent and the Grenadines
Canada	Haiti	Suriname
Chile	Honduras	Trinidad and Tobago
Colombia	Jamaica	United States of America
Costa Rica	Mexico	Uruguay
Cuba	Nicaragua	Venezuela

South-East Asia Region

Bangladesh	India	Myanmar
Bhutan	Indonesia	Nepal
Democratic People's Republic of Korea	Maldives	Sri Lanka
	Mongolia	Thailand

* Associate Member.

European Region

Albania	Israel	Spain
Armenia	Italy	Sweden
Austria	Kyrgyzstan	Switzerland
Belarus	Latvia	Tajikistan
Belgium	Lithuania	Turkey
Bulgaria	Luxembourg	Turkmenistan
Croatia	Malta	Ukraine
Czechoslovakia	Monaco	United Kingdom of Great Britain and Northern Ireland
Denmark	Netherlands	Uzbekistan
Finland	Norway	Yugoslavia
France	Poland	
Georgia	Portugal	Non-Member States
Germany	Republic of Moldova	Holy See
Greece	Romania	Liechtenstein
Hungary	Russian Federation	
Iceland	San Marino	
Ireland	Slovenia	

Eastern Mediterranean Region

Afghanistan	Jordan	Qatar
Bahrain	Kuwait	Saudi Arabia
Cyprus	Lebanon	Somalia
Djibouti	Libyan Arab Jamahiriya	Sudan
Egypt	Morocco	Syrian Arab Republic
Iran (Islamic Republic of)	Oman	Tunisia
Iraq	Pakistan	United Arab Emirates
		Yemen

Western Pacific Region

Australia	Lao People's Democratic Republic	Philippines
Brunei Darussalam	Malaysia	Republic of Korea
Cambodia	Marshall Islands	Samoa
China	Micronesia (Federated States of)	Singapore
Cook Islands	New Zealand	Solomon Islands
Fiji	Papua New Guinea	Tokelau*
Japan		Tonga
Kiribati		Vanuatu
		Viet Nam

* Associate Member.

ANNEX 3

**NATIONAL LEGISLATION AND CODES GIVING EFFECT TO THE
INTERNATIONAL CODE OF MARKETING OF BREAST-MILK SUBSTITUTES**

AFRICAN REGION

Botswana

The Public Health Regulations, 1983. *IDHL*, 35(4): 743 (1984).

Kenya

Kenya Code for Marketing of Breast Milk Substitutes. *IDHL*, 34(4): 779-784 (1983).

Mauritius

The Food and Drugs (Phytopharmaceutical Residues) Regulations 1980. *IDHL*, 33(1): 53 (1982).

The Food and Drugs (Antioxidants in Food) Regulations 1982. *IDHL*, 34(4): 802-803 (1983).

Nigeria

Code of Ethics and Professional Standards for Marketing of Breastmilk Substitutes. *IDHL*, 35(1): 91-93 (1984).

South Africa

Code of Ethics for Infant Food Manufacturers, 1977. *IDHL*, 31(1): 147-148 (1980).

Sudan

The Food Additives (Control of Circulation) Regulations, 1977. *IDHL*, 32(1): 112-113 (1981).

Zambia

The Food and Drug Regulations, 1978. *IDHL*, 32(2): 273-275 (1981).

Zimbabwe

The Public Health Amendment Act, 1985. *IDHL*, 36(4): 1014 (1985).

REGION OF THE AMERICAS

Brazil (São Paulo)

Decree No. 12486 of 20 October 1978 approving special technical standards for foods and beverages. *IDHL*, 32(1): 101-104 (1981).

Order No. 042 of 10 February 1981 of the Office of the Minister of Health. *IDHL*, 33(4): 753 (1982).

Canada

Food and Drug Regulations, amendment. Dated 9 December 1983. *IDHL*, 35(1): 81-87 (1984).

Chile

Decree No. 60 of 5 April 1982 approving the Health Regulations on foods. *IDHL*, 33(4): 757-762 (1982).

Colombia

Resolution No. 5532 of 9 July 1979 of the Minister of Health prescribing rules for the promotion of breast-feeding. *IDHL*, 31(3): 488-489 (1980).

Decree No. 1220 of 23 May 1980 regulating the promotion, labelling, and packaging of breast-milk substitutes and supplements. *IDHL*, 32(3): 468-471 (1981).

Costa Rica

Decree No. 17273-S of 31 October 1986. *IDHL*, 38(4): 805 (1987).

Decree No. 17965-S of 4 February 1988 promulgating Regulations on the functioning of the National Commission on Breast-feeding. *IDHL*, 40(1): 115 (1989).

Decree No. 18078-S of 22 March 1988. *IDHL*, 40(1): 115 (1989).

Ecuador

Decree No. 2215 of 3 November 1983 promulgating Regulations on the marketing of formulas for infants and young children under one year of age. *IDHL*, 35(4): 778-782 (1984).

El Salvador

Order No. 691 of 20 August 1980 of the Ministry of the Interior approving the statutes of the Centre for the Support of Breast-feeding. *IDHL*, 36(1): 51-52 (1985).

Guatemala

Decree-Law No. 66-83 of 6 June 1983 on the marketing of breast-milk substitutes. *IDHL*, 35(3): 630 (1984).

Mexico

Regulations of 4 January 1988 for the implementation of the General Law on health in the field of the health control of activities, establishments, products, and services. *IDHL*, 40(2): 361-362 (1989).

Nicaragua

Decree No. 912 of 15 December 1981 promulgating the Law for the promotion of breast-feeding. *IDHL*, 33(1): 41-42 (1982).

Peru

Ministerial Resolution No. 0041-80-SA/DS of 1 April 1980. *IDHL*, 31(3): 545-546 (1980).

Supreme Decree No. 20-82-SA of 10 September 1982, prescribing regulations on standards for infant feeding. *IDHL*, 34(3): 547-556 (1983).

Ibid. Part II: Standards for the marketing of breast-milk substitutes and complementary infant foods. *IDHL*, 34(3): 556-561 (1983).

Legislative Decree No. 346 of 6 July 1985 promulgating the National Population Policy Law. *IDHL*, 36(4): 980-983 (1985).

Trinidad and Tobago

The International Code of Marketing of Breast-milk Substitutes as applied to Trinidad and Tobago. Dated 1 February 1982. *IDHL*, 33(3): 520-521 (1982).

The Food and Drugs (Amendment) Regulations, 1984. *IDHL*, 37(3): 579-580 (1986).

United States of America

The Child Nutrition Act of 1978. *IDHL*, 31(1): 183-184 (1980).

Part 246 (Special Supplemental Food Program for Women, Infants and Children) of Title 7 (Agriculture) of the United States Code of Federal Regulations. Dated 23 July 1979. *IDHL*, 31(3): 610-613 (1980). Revised versions dated: 3 November 1980: *IDHL*, 32(4): 767-768 (1981); and 7 February 1985. *IDHL*, 36(3): 677 (1985).

Infant formulas: interim guidelines for nutrient composition; notice to manufacturers, packers, and distributors. Notice of the Food and Drug Administration, dated 11 March 1980. *IDHL*, 31(3): 614-615 (1980).

The Infant Feeding Act of 1980. *IDHL*, 32(1): 94-98 (1981).

Enforcement policy: infant formula recalls, Part 7 (Enforcement Policy) of Title 21 (Food and Drugs) of the United States Code of Federal Regulations. Dated 12 April 1982. *IDHL*, 33(3): 521-522 (1982).

(State of New York). An Act to amend the public health law, in relation to the availability of human breast milk for infant consumption. Dated 23 June 1980. *IDHL*, 33(4): 754 (1982).

Infant formula; labeling requirements. Parts 105 and 107 of Title 21 (Food and Drugs) of the United States Code of Federal Regulations. Dated 6 December 1984. *IDHL*, 36(3): 674-677 (1985).

Nutrient requirements for infant formulas, Part 107 (Infant Formula) of Title 21 (Food and Drugs) of the United States Code of Federal Regulations. Dated 7 October 1985. *IDHL*, 37(3): 580-582 (1986).

Infant formula recall requirements, Part 107 of Title 21 (Food and Drugs) of the United States Code of Federal Regulations. Dated 22 December 1988. *IDHL*, 40(3): 613 (1989).

Venezuela

Resolution No. 5 of 16 July 1982 of the Ministry of Health and Social Welfare on the requirements to be fulfilled by infant formulas as regards the relevant legal provisions in force and those to be issued in future by the Ministry. *IDHL*, 34(1): 96-97 (1983).

SOUTH-EAST ASIA REGION

Bangladesh

The Breast-Milk Substitutes (Regulation of Marketing) Ordinance, 1984. *IDHL*, 36(2): 425-427 (1985).

India

Indian National Code for Protection and Promotion of Breast-feeding. Dated 19 December 1983. *IDHL*, 35(2): 359-366 (1984).

Indonesia

Regulations No. 240 Men.Kes./Per/V/85 of 1 May 1985 of the Minister of Health of the Republic of Indonesia on breast-milk substitutes. *IDHL*, 36(4): 1005-1007 (1985).

Sri Lanka

Direction 3 under Section 6(1)(c) of the Consumer Protection Act, No. 1 of 1979. Dated 6 February 1979. *IDHL*, 32(3): 471-472 (1981).

Direction 4 under Section 6(1)(c) of the Consumer Protection Act, No. 1 of 1979. Dated 6 February 1979. *IDHL*, 32(3): 472 (1981).

Direction 28 under Section 6(1)(c) of the Consumer Protection Act, No. 1 of 1979. Dated 2 March 1981. *IDHL*, 32(3): 472 (1981).

Direction No. 44 under Section 6(1)(c) of the Consumer Protection Act, No. 1 of 1979. Dated 3 February 1983. *IDHL*, 34(4): 784-787 (1983).

Thailand

Notification No. 34 of 1979 of the Ministry of Public Health declaring modified milk for infants to be a specially controlled food and prescribing provisions on quality standards and the manufacturing process. Dated 13 September 1979. *IDHL*, 34(4): 791 (1983).

Notification No. 66 of 1982 of the Ministry of Public Health amending Notification No. 55 of 1981 of the Ministry of Public Health. Dated 11 January 1982. *IDHL*, 34(4): 811 (1983).

Notification No. 117 of 1989 of the Ministry of Public Health on feeding bottles. Dated 15 January 1989. *IDHL*, 42(3): 502 (1991).

EUROPEAN REGION**Austria**

Notice of 17 April 1979 (Serial No. 221) of the Federal Government promulgating a consolidated version of the Maternal Protection Law. *IDHL*, 31(1): 20 (1980).

The Colouring Matters in Foods Ordinance. Dated 4 May 1979. *IDHL*, 31(1): 10-11 (1980).

Belgium

Crown Order of 4 August 1983 on foods for special dietary uses. *IDHL*, 37(1): 61 (1986).

Crown Order of 28 February 1986 amending the Crown Order of 4 August 1983 on foods for special dietary uses. *IDHL*, 38(3): 553-559 (1987).

Denmark

Order No. 598 of 28 November 1978 on foods for special dietary uses. *IDHL*, 30(4): 762-763 (1979).

Order No. 75 of 20 February 1981 amending the Order on breast-milk substitutes. *IDHL*, 32(4): 763-766 (1981).

Order No. 51 of 10 February 1986 on dummies and teats for infant-feeding bottles. *IDHL*, 37(4): 808 (1986).

Order No. 447 of 5 September 1985 on the limit values applicable to certain metals in foods. *IDHL*, 37(4): 810-816 (1986).

Finland

Decree No. 630 of 10 July 1979 of the National Board of Trade and Consumer Interests concerning the notices on certain retail packagings. *IDHL*, 31(2): 299 (1980).

The Infant Foods Ordinance (No. 722) of 29 October 1981. *IDHL*, 33(3): 516-520 (1982).

Decree No. 450 of 28 January 1983 of the National Board of Health on the composition of infant foods and breast-milk substitutes and on instructions for their use. *IDHL*, 35(3): 626-629 (1984).

Decree No. 1023 of 18 December 1984 of the Food Directorate on the criteria of microbiological quality for infant foods. *IDHL*, 36(4): 1005 (1985).

Decree No. 84 of 28 January 1986 of the Food Directorate on food additives. *IDHL*, 37(4): 830 (1986).

Decree No. 318 of 27 January 1988 of the National Board of Health amending the Decree of the National Board of Health on the composition of infant foods and breast-milk substitutes and on instructions for their use. *IDHL*, 40(3): 611-612 (1989).

France

Order of 1 July 1976 on foods for special dietary uses. *IDHL*, 27(4): 730-731 (1976).

Decree No. 78-278 of 9 March 1978 for the implementation of the Law of 1 August 1905 on fraudulent practices and misbranding with regard to products or services, in respect of partly or wholly dehydrated preserved milk for human consumption. *IDHL*, 30(1): 37 (1979).

Order of 5 January 1981 amending the Order of 1 July 1976 in respect of dietary foods for infants or young children. *IDHL*, 32(4): 767 (1981).

Decree No. 81-574 of 15 May 1981 for the implementation of the Law of 1 August 1905 on fraudulent practices and misbranding with regard to products or services, in respect of foods and beverages for special dietary uses. *IDHL*, 32(4): 778 (1981).

Order of 18 August 1983 laying down the conditions for the establishment and operation of breast-milk banks. *IDHL*, 35(3): 629-630 (1984).

Orders of 4 August 1986 and 14 December 1988 on the use of additives in the production of foods for special dietary uses. *IDHL*, 38(2): 273-274 (1987) and 41(4): 657 (1990).

Orders of 28 April 1988 and 9 June 1988 fixing the characteristics of dietetic milk foods for infants and dietary foods for infants (under 4 months old) that may be sold by retail and supplied in any way to the public only by pharmacists in pursuance of Article L. 512 of the Public Health Code. *IDHL*, 40(1): 115-116 (1989) and 40(1): 116 (1989).

Circular DH/8D/87 of 7 October 1987 on maternity or adoption leave for and authorized absences by career and non-career employees of the establishments referred to in Section 2 of Law No. 86-33 of 9 January 1986 laying down regulations applicable to the staff in public service in the hospital sector. *IDHL*, 40(1): 76-77 (1989).

Germany

The Nitrosamines in Consumer Goods Ordinance. Dated 15 December 1981. *IDHL*, 33(4): 796-797 (1982).

Greece

Decision No. 3507/79 of 23 November 1982 on the use of nitrates and nitrites in foods. *IDHL*, 35(3): 633 (1984).

Hungary

Ordinance No. 8 of 21 October 1985 of the Minister of Health amending Ordinance No. 4 of 25 June 1978 on the control of hazardous chemical contamination of foods (Annex 2). *IDHL*, 37(2): 292-294 (1986).

Ordinance No. 9 of 17 September 1986 of the Minister of Health amending Ordinance No. 6 of 14 July 1978 on the control of the microbiological contamination of food (Annex II, and Annex III, Part C). *IDHL*, 39(1): 112-113 (1988).

Joint Ordinance No. 10 of 30 June 1988 of the Minister of Agriculture and Food and the Minister of Social Affairs and Health for the implementation of Law No. IV of 1976 on foods. *IDHL*, 40(3): 632 (1989).

Luxembourg

Ministerial Regulations of 27 November 1987 determining the permissible levels of radioactivity in food products. *IDHL*, 39(2): 480 (1988).

Netherlands

The Infant Foods (Agricultural Quality) Regulations. Dated 2 October 1984. *IDHL*, 36(4): 1007-1013 (1985).

Norway

Regulations No. 1251 of 8 July 1983 on the production and offer for sale, etc. of foods for infants and young children. *IDHL*, 35(2): 366-367 (1984).

Portugal

Code of Ethics for the Marketing of Breast-milk Substitutes, Feeding-bottles and Teats [voluntary code]. *IDHL*, 35(1): 94-96 (1984).

Spain

Crown Decree No. 2685 of 16 October 1976 approving Technical Health Regulations on the preparation and marketing of, and trade in, food preparations for special dietary uses. *IDHL*, 28(4): 1047-1050 (1977).

Crown Decree No. 385 of 18 January 1980 amending certain Sections of the Technical Health Regulations on the preparation and the marketing of, and trade in, food preparations for special dietary uses, approved by Crown Decree No. 2685 of 16 October 1976. *IDHL*, 32(4): 781-782 (1981).

Crown Decree No. 1424 of 18 June 1982 amending item 15 of Section 20 of Crown Decree No. 2685/1976 of 16 October 1976 approving Technical Health Regulations on the preparation and marketing of, and trade in, food preparations for special dietary uses. *IDHL*, 36(2): 435-437 (1985).

Sweden

Instructions No. 30 of 18 May 1978 of the National Board of Health and Welfare on the desirability of avoiding the use of human milk substitutes during the first week of life. *IDHL*, 30(2): 322 (1979).

Order No. 17 of 25 May 1978 of the National Food Administration on infant foods. *IDHL*, 30(2): 322-323 (1979).

Regulations No. 21 of 2 May 1983 of the National Board of Health and Welfare for health care and nursing personnel, etc. on the implementation of the International Code of Marketing of Breast-milk Substitutes. *IDHL*, 34(4): 787-791 (1983).

Regulations No. 8 of 15 April 1987 of the National Board of Health and Welfare on the use of breast milk, etc. *IDHL*, 39(1): 56-57 (1988).

Order No. 36 of 10 November 1989 of the National Food Administration amending Order No. 17 of 1978 on infant foods. *IDHL*, 41(2): 285 (1990).

Switzerland

Ordinance on foods. Amendment of 4 November 1987. *IDHL*, 41(2): 291-293 (1990).

United Kingdom

The Miscellaneous Additives in Food (Amendment) Regulations 1982. *IDHL*, 33(1): 59-60 (1982).

The Skimmed Milk with Non-Milk Fat (Amendment) Regulations 1981. *IDHL*, 33(2): 298 (1982).

The Sweeteners in Food Regulations 1983. *IDHL*, 35(1): 103-104 (1984).

The Colouring Matter in Food (Amendment) Regulations 1987. *IDHL*, 39(3): 682 (1988).

Yugoslavia

Regulations No. 3463 of 29 October 1979 on conditions governing the wholesomeness of marketed foods for special dietary uses. *IDHL*, 33(4): 787-793 (1982).

European Communities

Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses. *IDHL*, 41(1): 104-108 (1990).

Commission Directive 91/321/EEC of 14 May 1991 on infant formulae and follow-on formulae. *IDHL*, 42(4): 675-688 (1991).

EASTERN MEDITERRANEAN REGION

Djibouti

Instructions No. 707/I/MSP/DSP of 19 August 1981 for the promotion of breast-feeding. *IDHL*, 34(1): 94-96 (1983).

Egypt

Decision No. 514 of 1980 of the Minister of Health. *IDHL*, 33(2): 298 (1982).

Lebanon

Decree-Law No. 110 of 16 September 1983 on the marketing of breast-milk substitutes. *IDHL*, 35(4): 782 (1984).

Tunisia

Law No. 83-24 of 4 March 1983 on the quality control, marketing, and information concerning the use of breast-milk substitutes and related products. *IDHL*, 35(1): 96-98 (1984).

Decree No. 84-1314 of 3 November 1984 determining the functions, composition, and working procedures of the National Commission for the Promotion of Infant and Child Feeding. *IDHL*, 36(3): 672-674 (1985).

WESTERN PACIFIC REGION**Australia (South Australia)**

The Food and Drugs Regulations, 1978. *IDHL*, 32(2): 276-283 (1981).

Malaysia

The Food Regulations 1985. *IDHL*, 39(1): 113-118 (1988).

The Food (Amendment) Regulations 1988. *IDHL*, 39(4): 883-884 (1988).

New Zealand

The Food Regulations 1984. *IDHL*, 36(1): 75-88 (1985).

Philippines

Executive Order No. 51 adopting a National Code of Marketing of Breastmilk Substitutes, Breastmilk Supplements and Related Products, penalizing violations thereof, and for other purposes. Dated 20 October 1986. *IDHL*, 38(4): 805-809 (1987).

Additional texts not covered in this paper**REGION OF THE AMERICAS****Guatemala**

Governmental Order No. 841-87 of 30 September 1987 on the marketing of breast-milk substitutes. *IDHL*, 43(1): 96-97 (1992).

United States of America

The 1986 Infant Formula Amendments to the Infant Formula Act, introduced in Subtitle A of Title IV of the Drug Enforcement, Education and Control Act of 1986 (Public Law 99-570). *IDHL*, 43(3) (1992) (in press).

Infant formula record and record retention requirements. Part 106 of Title 21 (Food and Drugs) of the United States Code of Federal Regulations. Dated 17 December 1991. *IDHL*, 43(3) (1992) (in press).

WESTERN PACIFIC REGION

Philippines

Rules and Regulations covering the advertising, promotion and marketing of breastmilk substitutes, breastmilk supplements and related products. Dated 26 May 1987. *IDHL*, 43(3) (1992) (in press).

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