THE INTERNATIONAL CODE OF
MARKETING OF BREAST-MILK SUBSTITUTES

by

SAMi SHUBBER

Dr S. Shubber is Senior Legal Officer, Office of the Legal Counsel, WHO. The views expressed in this article are those of the author and not necessarily those of WHO.

An Arabic version of this article appeared in the Journal of Law, 1985, Vol. 9, No. 1, pp. 67-117, published by the Faculty of Law, Kuwait University, Kuwait.
CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. INTRODUCTION</td>
<td>879</td>
</tr>
<tr>
<td>2. THE LEGAL MEANS AVAILABLE TO WHO</td>
<td>880</td>
</tr>
<tr>
<td>Treaties</td>
<td>880</td>
</tr>
<tr>
<td>Regulations</td>
<td>881</td>
</tr>
<tr>
<td>Recommendations</td>
<td>884</td>
</tr>
<tr>
<td>3. THE PRINCIPLES OF THE CODE</td>
<td>885</td>
</tr>
<tr>
<td>Prohibition of advertising and promotion</td>
<td>885</td>
</tr>
<tr>
<td>Prohibition of the giving of samples</td>
<td>886</td>
</tr>
<tr>
<td>Prohibition of gifts and other inducements</td>
<td>886</td>
</tr>
<tr>
<td>Information and education</td>
<td>888</td>
</tr>
<tr>
<td>Encouragement and promotion of breast-feeding</td>
<td>890</td>
</tr>
<tr>
<td>Consumer protection</td>
<td>891</td>
</tr>
<tr>
<td>Implementation of the Code</td>
<td>893</td>
</tr>
<tr>
<td>Legal effect of WHO resolutions</td>
<td>894</td>
</tr>
<tr>
<td>Monitoring of the Code</td>
<td>896</td>
</tr>
<tr>
<td>4. CONCLUSIONS</td>
<td>898</td>
</tr>
</tbody>
</table>

REFERENCES AND NOTES | 899
1. INTRODUCTION

The feeding of an infant in the early months of its life affects its healthy growth and development and accordingly is of importance for the social and economic development of society as a whole. The Director-General of WHO has said that children are a priceless resource, and that any nation which neglects them does so at its peril. The choice between breast-feeding and the use of breast-milk substitutes thus is of considerable importance. WHO has as its objective the attainment by all peoples of the highest possible level of health, a function of which is the promotion of maternal and child health; it is therefore concerned with breast-feeding and with harmful effects on the health of the infant which may result from the use of breast-milk substitutes.

Breast-feeding provides the ideal food for the healthy growth and development of infants; it forms a unique biological and emotional basis for the health of both mother and child; moreover, breast milk has anti-infective properties which help to protect infants against disease. On the other hand, the improper use of breast-milk substitutes may lead to sickness and mortality in infants. A leading expert on paediatric nutrition, Derrick Jelliffe, estimates that there occur some 10 million cases per year of infectious disease and infant malnutrition directly attributable to improper bottle feeding. During the discussions on the draft text of the International Code of Marketing of Breast-milk Substitutes (hereinafter referred to as “the Code”) in Committee A of the World Health Assembly in 1980, the Turkish delegate pointed out that where the infant mortality rate was still 100-150 per 1000, about half the infants died because of malnutrition and in most cases artificial feeding was responsible.

Advertising and other forms of promotion of breast-milk substitutes play a significant role in inducing mothers to use such products, leading to deterioration and decline in breast-feeding. Moreover, the cost of such products may very often constitute a heavy financial burden on the mother. Breast-milk substitutes are used all over the world, particularly in the developing countries, both in urban and rural areas. The delegate of Democratic Yemen summed up the situation when he stated that practising paediatricians and other health workers involved in the care of children in developing countries had noted with concern the spread of infant milk formulas in urban and semi-urban communities on a wide scale; what was more alarming was that the replacement of breast-feeding by artificial feeding with infant milk formulas was spreading in epidemic form to rural communities in almost all developing countries; the epidemic was being promoted by the indiscriminate propaganda of manufacturers’ advertisements, by the mass media, and at times even by misinformed health personnel.

In 1974, the World Health Assembly noted the general decline in breast-feeding in many parts of the world, and urged the Organization’s Member States to review the sales promotion of baby foods and to introduce appropriate remedial measures, including codes of practice on...
advertising, and legislation where necessary.\textsuperscript{10} In 1978, the Assembly again considered the question and recommended Member States to give priority to the prevention of malnutrition in infants and young children, \textit{inter alia}, by supporting and promoting breast-feeding, taking legislative and social action to facilitate breast-feeding by working mothers, and regulating inappropriate sales promotion of infant foods that can be used to replace breast milk.\textsuperscript{11}

A recent study published by the WHO Regional Office for the Eastern Mediterranean Region has shown an important decline in breast-feeding in the Gulf States and a significant increase in bottle-feeding.\textsuperscript{12}

In the latter part of 1978, WHO and the United Nations Children's Fund (UNICEF)\textsuperscript{13} declared their intention of jointly organizing a meeting on infant and young child feeding. The meeting, which was held in Geneva from 9 to 12 October 1979, was attended by 150 representatives of WHO Member States, organizations of the United Nations system, other international organizations, nongovernmental organizations, professional associations, scientists, and the infant food industry. One of the recommendations of the meeting was to request WHO and UNICEF to prepare, in consultation with all the parties concerned, an international code of marketing of breast-milk substitutes.\textsuperscript{14} In 1980, the Thirty-third World Health Assembly endorsed that recommendation and requested the Director-General to prepare such a code in close consultation with Member States and all other parties concerned, either as a regulation or a recommendation.\textsuperscript{15} The Director-General prepared a draft code, after consultation with Member States and all other parties concerned, and submitted it to the Executive Board, at its sixty-seventh session in January 1981, as requested by the Assembly.\textsuperscript{16} The Board unanimously recommended that the Thirty-fourth World Health Assembly adopt the draft code as a recommendation,\textsuperscript{17} which it did on 21 May 1981,\textsuperscript{18} with 118 votes in favour, one against, and three abstentions.\textsuperscript{19}

This article falls into three main parts: the means available to WHO under its Constitution to deal with the question of breast-feeding and its promotion; the principles contained in the Code; and conclusions.

2. THE LEGAL MEANS AVAILABLE TO WHO

The promotion of breast-feeding, the protection of the healthy growth and development of infants and young children, and the adoption of the Code in furtherance of these purposes\textsuperscript{20} are matters falling within the competence of the Organization, which can deal with them by means of three categories of measures: treaties, regulations, and recommendations.

\textit{Treaties.} According to Article 19 of the WHO Constitution, "the Health Assembly shall have authority to adopt conventions or agreements with respect to any matter within the competence of the Organization". Lord McNair defines a treaty as "a written agreement
by which two or more States or international organizations create or intend to create a relation between themselves operating within the sphere of international law". 21

Since the Code deals with matters which fall within the competence of WHO, there was a legal basis for its adoption by the World Health Assembly as a treaty. 22 Nevertheless, in requesting the Director-General to prepare the Code either as a regulation or as a recommendation, the Assembly ruled out the use of a treaty. In doing so, it followed its own practice of dealing with public health matters by measures other than treaties; indeed, since WHO was established in 1948, it has never exercised the authority it possesses under Article 19 of the Constitution.

**Regulations.** According to Article 21 of the WHO Constitution,

The World Health Assembly shall have authority to adopt regulations concerning:

- (d) standards with respect to the safety, purity and potency of biological, pharmaceutical and similar products moving in international commerce;
- (e) advertising and labelling of biological, pharmaceutical and similar products moving in international commerce. 23

Furthermore, according to Article 22 of the Constitution, "regulations adopted pursuant to Article 21 shall come into force for all Members after due notice has been given of their adoption by the Health Assembly except for such Members as may notify the Director-General of rejection or reservations within the period stated in the notice". These regulations may be considered "quasi-legislative" in that they do not bind Member States without their consent. 24

The question then arises whether WHO has authority to adopt regulations concerning breast-milk substitutes on the basis of Article 21. The question might be answered in the affirmative on the following grounds, namely (1) because breast-milk substitutes are considered to be products "similar" to "biological" products; and (2) reliance on the theory of implied powers. 25

So far as (1) is concerned, while breast-milk substitutes cannot be included in the category of biological or pharmaceutical products as such, it could be argued that they are similar to biological products. 26 Breast-milk substitutes are a source of food and assist the growth of a child who, for one reason or another, is not breastfed. They are intended as an adequate replacement for breast milk, which is undoubtedly a biological product. On that view, breast-milk substitutes are embraced by the regulatory power of the Health Assembly under Article 21. The argument in favour of the applicability of Article 21 to breast-milk substitutes is further buttressed by the fact that such products move in international commerce; producers of these products in Europe and the United States export them in large quantities to countries in Africa, Asia, and Latin America. 27

The contents of the Code may throw some light on the relationship between the Code and paragraphs (d) and (e) of Article 21. Thus, Arti-
Article 5 deals with advertising and other forms of promotion of breast-milk substitutes, laying down some principles applicable to the restriction of such practices. In addition, Article 10 deals with the purity and quality of breast-milk substitutes and requires them, when sold or otherwise distributed, to meet applicable standards recommended by the Codex Alimentarius Commission and the Codex Code of Hygienic Practice for Foods for Infants and Children. These standards contain requirements for food aimed at ensuring for the consumer a "sound, wholesome food product free from adulteration, correctly labelled and presented". It will be seen, then, that the conditions laid down in paragraphs (d) and (e) of Article 21 have been fulfilled and accordingly that the Health Assembly is entitled to adopt the Code as a regulation. Finally, in view of the Health Assembly's power to interpret the WHO Constitution, the fact that the Assembly requested the Director-General to prepare the Code either as a regulation or a recommendation recognizes by implication that the requirements of Article 21 are satisfied.

It may be of interest to note that a member of the Executive Board questioned whether the Organization could adopt the Code under Article 21 and asked for the opinion of the Organization's Legal Counsel. The former's remarks are presented in the Summary Records:

Article 2 (u) of WHO's Constitution stated that one of the Organization's functions should be "to develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products" whereas Article 21 (e) stated that the Health Assembly had authority to adopt regulations concerning "advertising and labelling of biological, pharmaceutical and similar products moving in international commerce" without specifically mentioning food. He would therefore like to have a legal opinion as to whether the Code could be adopted.

The Legal Counsel replied that breast-milk substitutes "might be included under a regulation in the sense of Article 21 (d) and (e)". So far as (2) is concerned, the International Court of Justice (I.C.J.) made the following statement with respect to the implied powers of the United Nations: "Under international law, the Organization must be deemed to have those powers which, though not expressly provided in the Charter, are conferred upon it by necessary implication as being essential to the performance of its duties". On the strength of the relevant provisions of the Charter of the United Nations and its purposes and functions, the I.C.J. found that the capacity of the United Nations to exercise functional protection of its agents arose "by necessary intendment out of the Charter". Turning to WHO, it will be seen that the objective of the Organization is the attainment by all peoples of the highest possible level of health; in order to achieve this objective, the Organization has functions including those of promoting maternal and child health and welfare, developing, establishing, and promoting international standards with respect to food, biological, pharmaceutical, and similar products, and generally taking all necessary action to attain the objective of the Organization.
The use of breast-milk substitutes and the protection and promotion of breast-feeding clearly fall within the scope of maternal and child health. In addition, breast-milk substitutes are a source of food for an infant, which is not breast-fed or only partially breast-fed. Applying the findings of the I.C.J. to the objective and the functions of the Organization, in the light of Article 21 of its Constitution, it may well be argued that the Organization has implied powers to adopt the Code as a regulation under Article 21. While there is no express reference to breast-milk substitutes in the provision, it may be maintained that WHO has authority to adopt the Code, by necessary implication, as being essential to the performance of the functions referred to above.

The implied powers argument has been raised as an academic point since Article 21 of the WHO Constitution is a sufficient basis for the action of the Organization. However, the question of the competence of WHO to adopt the Code as a regulation is not an academic question. The Health Assembly could still review the Code and adopt it as a regulation under Article 21. This can be seen from the discussions of the Executive Board in 1981, when it was considering the draft text of the Code. During these discussions, some members of the Executive Board suggested the adoption of the draft Code in the form of a regulation while others proposed its adoption as a recommendation.

In order to avoid any division of opinion within the Executive Board on this question, the Board unanimously adopted a resolution recommending to the Thirty-fourth World Health Assembly the adoption of a resolution, a paragraph of which called on the Assembly to adopt the Code as a recommendation.

The latter resolution also requests the Director-General to report to the Thirty-sixth World Health Assembly in May 1983 on the status of compliance with and implementation of the Code, and “based on the conclusions of the status report, to make proposals, if necessary, for revision of the text of the Code and for the measures needed for its effective application”. This request is ambiguous, as the intention of the Executive Board does not emerge clearly from its wording; for example, it is not clear what is meant by the expression “to make proposals... for the measures needed for its effective application”. It may be helpful, therefore, to refer to the discussions of the Executive Board.

During these discussions, a member of the Board stated that the Health Assembly could opt for a recommendation with a specified time-limit (e.g. three years) and define criteria against which the Director-General could assess the recommendation’s effectiveness over that period; if the recommendation did not prove sufficiently effective, the Organization would have to move to a regulation. The WHO Legal Counsel, on being asked for his views by the Chairman of the Board, stated that it was quite possible to insert a clause in the recommendation providing that, after a certain amount of experience and time, the Health Assembly could adopt a regulation on the same subject; indeed he had understood the draft resolution proposed by Dr Mork in that sense.

*International Digest of Health Legislation, 1985, 36 (4)*
The foregoing shows what the members of the Executive Board had in mind when they proposed that the Health Assembly adopt what became resolution WHA34.22; they envisaged the adoption of the Code in the form of a regulation if the Assembly later considered that the recommendation had not worked effectively. The resolution specified May 1983 (the date of the Thirty-sixth World Health Assembly) as the relevant date for this purpose. However, in his report to the Thirty-sixth World Health Assembly, the Director-General considered that it was premature to propose any revision of the Code, either in form or content, and that he would draw the Assembly's attention, in future biennial reports on infant and young child nutrition, to any development which might have a bearing on the Code. The Health Assembly accepted this position.

**Recommendations.** According to Article 23 of the WHO Constitution, "the Health Assembly shall have authority to make recommendations to Members with respect to any matter within the competence of the Organization". Breast-feeding and its effect on the healthy growth and development of infants, as well as the use of breast-milk substitutes for feeding infants, as matters related to health, fall within the scope of the Organization's authority to adopt recommendations; and indeed the Health Assembly adopted the Code as a recommendation under Article 23 of the WHO Constitution, as has been mentioned earlier.

What is a recommendation and what is the legal nature of recommendations adopted by the Health Assembly? So far as the former is concerned, Castaneda considers that, in normal usage, the term "recommendation" covers "only the acts that the great majority of their authors have characterized as such. From this point of view, there is no doubt that the prevailing meaning is that of 'invitation'; hence recommendations are only the resolutions adopted with no intention of binding their addressees. It would be necessary to exclude from the concept of recommendation, consequently, decisions that carry the legal obligation to execute their content...

It would seem from this description that a recommendation adopted by an international body, be it the United Nations General Assembly or the World Health Assembly, is not intended to bind those to whom it is addressed. In this sense, a recommendation does not have binding effect. It follows that recommendations of the Health Assembly, generally, are not binding on Member States and that the Code does not bind members without their consent. However, some recommendations may create direct legal obligations, or could, under certain circumstances, be binding to some degree on members of the Organization. On the other hand, recommendations of the Health Assembly carry moral or political weight, as they constitute the judgement of the highest international body in the field of health. When this judgement is embodied in a legal instrument, such as the Code, it will not be lightly disregarded, even though it has no binding effect. Furthermore, the adoption of the

*International Digest of Health Legislation, 1985, 36 (4)*
CODE OF MARKETING OF BREAST-MILK SUBSTITUTES

Code may help to make the Member States and their populations aware of the health benefits of breast-feeding and the health problems which may arise from the use of breast-milk substitutes.

3. THE PRINCIPLES OF THE CODE

The aim of the 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". In order to achieve this aim, the Code enunciates the following principles.

Prohibition of advertising and promotion. Article 5.1 reads as follows: "There should be no advertising or other form of promotion to the general public of products within the scope of this Code". According to this provision, any advertisement or promotion of any kind relating to these products addressed to the general public, through television, radio, newspapers, magazines, posters, or in any other form, is prohibited. This prohibition is general and without any qualification. It includes brand and non-brand, direct and indirect advertising and promotion.

It is to be noted that Article 5 deliberately refrains from defining the terms "advertising" and "promotion" so that these terms should be given their ordinary meaning, in accordance with Article 31 of the Vienna Convention on the Law of Treaties, 1969.

The purpose of the prohibition is to ensure so far as possible that mothers and pregnant women are not prompted by such advertisements and promotion to use breast-milk substitutes for feeding their infants. Indeed, it is common to find in advertising and promotional materials or on containers of breast-milk substitutes pictures of healthy-looking infants or statements designed to give the impression that such products produce the same results and have the same benefits as breast milk.

Members of the Executive Board referred in discussion to the relationship between the advertising of breast-milk substitutes and their extensive and undesirable use. Another adverse effect which advertising and promotion of breast-milk substitutes have in relation to breast-feeding is that they seem to cause anxiety and doubt in mothers.

The Code was applied, on a trial basis, in a health care facility in the Philippines, where advertisements for breast-milk substitutes and the distribution of samples to mothers were banned. This led to a 60% increase in breast-feeding.

Article 5.3 of the Code also bans the advertising and promotion of products within the scope of the Code directly to the consumer at the retail level. The provision reads as follows: "... there should be no point-of-sale advertising,... or any other promotion device to induce sales directly to the consumer at the retail level, such as special displays, dis-
count coupons, premiums, special sales, loss-leaders and tie-in sales, for products within the scope of this Code'. This provision deals with one specific aspect of advertising and promotion, namely, retail distribution, and gives examples of the devices that are used. While such advertisements and promotional devices are covered in general by Article 5.1, it would seem that the drafters of the Code considered it necessary to deal with them specifically, since they are employed by some distributors and manufacturers to induce mothers to buy breast-milk substitutes. Nevertheless, it must be stressed that the International Code does not, nor is it intended to, ban or interfere with sales of breast-milk substitutes; it is intended, inter alia, to deal with certain marketing practices relating to these products. The Code expressly recognizes the need for breast-milk substitutes when the mother is unable to breast-feed her infant, for one reason or another, and emphasizes the constructive role played by the manufacturers and distributors of these products.

**Prohibition of the giving of samples.** In accordance with the policy of the Code to encourage and protect breast-feeding and to control inducements to use breast-milk substitutes, Article 5.2 bans the giving of samples of products within the scope of the Code. This provision reads as follows: "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". The provision is directed against the practice, prevalent in many parts of the world at the time of the adoption of the Code, of giving samples of breast-milk substitutes to pregnant women or mothers as an inducement to use such products, with the probable result that their ability to breast-feed was impaired. Article 5.2 is wide enough to cover giving samples not only to a mother or pregnant woman, but also to any member of their families. It also covers the direct and indirect giving of such samples. In addition, Article 5.3 bans the giving of samples of products within the scope of the Code directly to the consumer, at the retail level. In this case, the provision clearly recognizes this practice as a promotional device.

It should be pointed out that the Code is not directed against the giving of samples in appropriate circumstances, for example, for scientific evaluation; thus Article 7.4 of the Code permits the giving of samples of products within its scope to health workers "when necessary for the purpose of professional evaluation or research at the institutional level". However, the giving of samples is not permitted if its purpose is promotional. Accordingly, the health worker is not allowed to give samples of such products "to pregnant women, mothers of infants and young children, or members of their families".

**Prohibition of gifts and other inducements.** One of the measures envisaged under the Code to protect and promote breast-feeding is to ban certain practices which are designed to promote and publicize the

International Digest of Health Legislation, 1985, 36 (4)
use of breast-milk substitutes, such as a direct gift of breast-milk substitutes to the mother, the health worker, or some national institutions. The prohibition extends to certain inducements to the marketing personnel of manufacturers and distributors, such as bonuses based on the volume of sales. The Code, in Article 5.4, expressly enjoins manufacturers and distributors not to distribute to mothers of infants and young children any gifts of articles or utensils which may promote the use of breast-milk substitutes. It has often been the practice to give calendars, booklets, and product samples in health centres and outpatient facilities. Furthermore, Article 7.3 of the Code prohibits manufacturers and distributors from offering "financial or material inducements" to promote products within the scope of the Code to health workers or members of their families. It also prohibits health workers and members of their families from accepting such gifts and inducements. "Inducements" is not defined in the Code, intentionally as it would appear, but the term may cover attendance at conferences, travel funds and funds for research, and so on.

Another aspect of this principle is the restriction imposed in Article 8.1 of the Code on the use of bonuses and quotas as sales incentives for marketing personnel of manufacturers and distributors. The provision reads as follows: "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". The aim of the provision is to temper aggressive marketing which is liable to spread or promote the use of substitutes at the expense of breast-feeding.

The provision is not intended to prevent the giving of bonuses, as such; it states clearly that "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". Furthermore, one feature of the practice under consideration is the donation or low-price sales of such products to institutions or organizations. These could promote the use of the products, and constitute an indirect inducement to mothers to resort to them and so discourage breast-feeding. However, the Code allows such donations and sales, but prescribes restrictive conditions under which they may be made. Article 6.6 of the Code states that "donations or low-price sales to institutions or organizations of supplies of infant formula or other products within the scope of this Code... 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... concerned. Such donations or low-price sales should not be used by manufacturers or distributors as a sales inducement".

Article 6.7, which requires that where donations of such supplies are distributed outside an institution, the institution "should take steps to ensure that supplies can be continued as long as the infants concerned need them", in fact entails a further condition restricting such donations.

*International Digest of Health Legislation, 1985, 36 (4)*
Donors are also required by the provision to bear this responsibility in mind. All these conditions are intended to discourage the practice of using such methods to promote the use of breast-milk substitutes.

These gifts and other inducements might arguably fall within the ambit of promotion of breast-milk substitutes, and as such would be covered by the ban on advertising and promotion discussed elsewhere in this article. Nevertheless, since in the Code this matter is dealt with separately and in some detail in view of this entrenched marketing practice and its various facets, it may be regarded as an independent principle under the Code.

**Information and education.** Article 4.1 of the Code places responsibility for education and information on the governments of Member States. This provision reads as follows: "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."

Accordingly, any information relating to infant and young child feeding is subject to a special regime, which is intended to ensure that it is both objective and consistent. Therefore, the production, planning, provision, design, and dissemination of such information should be carried out by the governments of the Member States, though this task may be delegated by them to individuals, companies, or publishers.

An individual, a company, or a publisher may not publish pamphlets, brochures, or books on infant and young child feeding for use by mothers or pregnant women without permission from the competent authorities of the Member State.

It would seem that Article 4.1 was intended to put an end to the random publication of information on the subject of infant and young child feeding which might not be objective and consistent and might have been issued without any involvement of the competent authorities of Member States in its preparation or dissemination. The purpose of the provision is not to interfere in the freedom of publication and information but to protect the health of infants. The involvement of the health authorities of a Member State should serve to ensure that the information is objective and factual. Health authorities have no financial interests other than those relating to public health, whereas if such information emanates from producers or distributors of products covered by the Code, financial or material benefit is probably involved.

In addition, Article 4.2 provides that "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 clear information on all the following points: (a) the benefits and superiority of breast-feeding; (b) maternal nutrition, and the preparation for and maintenance of
breast-feeding; (c) the negative effect on breast-feeding of introducing partial bottle-feeding; (d) the difficulty of reversing the decision not to breast-feed”.

The provision also requires that, when the materials contain information about the use of breast-milk substitutes, they should provide additional details covering matters such as the social and financial implications of the use of substitutes, and the health hazards of their unnecessary or improper use.

The purpose of the provision appears to be that of furnishing the mother or pregnant woman with all the relevant objective information on breast-feeding and the use of breast-milk substitutes, so that she may take a considered decision on how to feed her infant; this is confirmed by the remark of the Turkish delegate in 1981 in Committee A, related thus in the Summary Records: “it was argued that mothers had a right to choose whether or not they wanted to breast-feed; no one would deny that... provided that [the mother] was properly informed about the facts”. In addition, Article 6.1 of the Code requires the health authorities of Member States to provide health workers with the information referred to in Article 4.2.

While Article 4.2 permits the details and information mentioned therein to be given, it does not permit the use of informational and educational materials for the purpose of promoting breast-milk substitutes. It states clearly that “such materials should not use any pictures or text which may idealize the use of breast-milk substitutes”. The drafters of the Code felt that the use of such pictures or text might prompt mothers or pregnant women to resort unnecessarily to breast-milk substitutes.

Article 4.2 does not expressly state who is responsible for the preparation of the informational and educational materials. The question then arises whether the governments concerned, private individuals, or commercial companies are to be responsible. It would seem that the governments are implicitly referred to; Article 4.1 expressly mentions the responsibility of governments for the planning, provision, design, and dissemination of information on infant and young child feeding. Paragraph 2 could be considered as an example of the kind of information to be presented in an objective and consistent manner about infant feeding. Furthermore, Article 4.3 provides that donations of informational or educational 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”, so that even in this respect the government is involved, either directly or indirectly, or through measures taken by it. It may be concluded that no informational or educational materials can be produced and/or disseminated under Article 4.2 of the Code without the involvement of the government concerned. The government may itself produce and/or disseminate such materials or authorize others to do so, in accordance with certain terms and conditions stipulated by it.

*International Digest of Health Legislation, 1985, 36 (4)*
Encouragement and promotion of breast-feeding. In order to achieve the objective of the Code, the health authorities in Member States are enjoined to take certain measures. Thus, Article 6.1 provides that "the health authorities in Member States should take appropriate measures to encourage and protect breast-feeding..., and should give appropriate information and advice to health workers in regard to their responsibilities, including the information specified in Article 4.2".

The provision leaves to Member States the determination of "appropriate measures", because they are difficult to define in an international instrument. Furthermore, circumstances vary between Member States, according to their social, economic, and legal systems. Some measures which may be considered appropriate are: the introduction of the subject of breast-feeding and its benefits on the health of infants into the teaching and training programmes of health workers; the imposition of an obligation on proprietors of factories to provide special places for mothers to breast-feed their infants during working hours; and the adoption of health regulations which give the mother the right to adequate maternity leave in order to breast-feed her infant. There have been encouraging results from action by the competent authorities. The situation in Canada was evoked by the Canadian delegate during the discussions in Committee A in 1981; her remarks, in the Summary Records, were as follows: "Federal and provincial health authorities had for some time been working, in conjunction with professional and other nongovernmental organizations, in the development and implementation of breast-feeding promotion programmes. The results indicated that the percentage of infants being breast-fed had, during the past 10 years, increased nationally from a low of about 40% to nearly 60%".

Article 7.1 of the Code states that "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...". Here again, the Code leaves the health worker to determine what action could encourage breast-feeding, in the light of his responsibility under the Code. Some examples may be given: the attending physician advising the mother to breast-feed her infant, explaining the benefits for both the mother and infant, and warning her about the health risks to her infant if it is deprived of her milk; and pointing out the financial burden entailed by the use of breast-milk substitutes.

Certain measures in the Code are specifically intended to encourage and promote breast-feeding; these measures include the ban on the use of health care systems for the purpose of promoting breast-milk substitutes, and the ban on the display of these products, or placards or posters concerning them, in such places. Furthermore, Article 6.4 of the Code precludes the use by health care systems of "professional service representatives", "mothercraft nurses", or similar personnel provided or paid for by manufacturers or distributors of products within the scope of the Code. These practices were prevalent in a large number of Member States and were designed to promote the products in
question among mothers visiting a facility of a health care system. A
mother visiting a clinic, child-care institution, or the like was bound to
encounter these promotional devices which could influence her in favour
of breast-milk substitutes. The ban on the use of health care systems
for promoting breast-milk substitutes, and on the use of posters and
placards for that end, is in fact intended as a measure to encourage
breast-feeding. This shows the relationship between the encourage­
ment of breast-feeding and the ban on the promotion of breast-milk
substitutes. Finally, it should be noted that activities falling under the
ban on the use of health care systems to promote breast-milk substitutes
under Article 6 may also come within the ban on advertising and pro­
motion of substitutes under Article 5.1.90

Consumer protection. The Code recognizes the need for breast­
milk substitutes when mothers do not breast-feed, or only do so par­
tially.91 It is therefore necessary to provide a degree of protection for
the consumer (the infant). This protection is expressed in the re­
quirements as to the quality and labelling of products covered by the
Code.

Labelling92 is regulated by Article 9.2 of the Code, which reads as
follows:

Manufacturers and distributors of infant formula should ensure that each con­
tainer 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 ap­
propriate language, which includes all the following points: (a) the words “Impor­
tant 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 text which may idealize the use of infant
formula....

The purpose of the provision is to provide the mother or pregnant
woman with the relevant information on the use of breast-milk
substitutes, without unduly encouraging resort to these products. Fur­
thermore, the involvement of the health worker should ensure
reasonable protection of the infant. The advice on the need for breast­
milk substitutes which may be given by a health worker would,
presumably, be based on the health of the mother and her ability to
breast-feed the infant. The health worker would also advise on the
proper method of using the products. In addition, the instructions for
the appropriate preparation of the products and the warning that health
hazards may arise from inappropriate preparation should alert the
mother to the dangers to the health of her infant. Once on her guard,
the mother is more likely to be careful about hygienic conditions, which
would probably lessen the chances of infection occurring through this
method of infant feeding. Article 9.2 has, therefore, altered the condi­
tions under which breast-milk substitutes should be used.

*International Digest of Health Legislation, 1985, 36 (4)*
Another aspect of consumer protection under the Code is to be found in Article 9.3, which provides that “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”.

The drafters of the Code, concerned that infants should receive adequate food, required that mothers be warned of this risk of health to infants as, if no warning is given, a mother may imagine that the food in question is adequate for infant feeding and the child may suffer malnutrition in consequence. Inadequate food may lead to health problems for the infant and affect its normal growth and development. Article 9.3 singles out one product, “sweetened condensed milk”, as not suitable for infant feeding for this reason.

Another aspect of consumer protection is the requirement laid down in Article 9.4 that the label of food products within the scope of the Code should 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”. These details are intended to show the buyer of the products what he is buying, whether or not they are suitable for consumption, and when he must not buy or use them. These are important elements of consumer protection; since breast-milk substitutes are imported by many developing countries, their quality and soundness may suffer during transport and, if the products deteriorate, their consumption is liable to affect the health of the infant. The delegate of Burundi pointed out in Committee A, during the discussion of the question of infant feeding in 1980, that since powdered milk was imported it was extremely costly; moreover, it frequently deterioriated in transit so that its quality was poor and it was even dangerous, and that, as a consequence, the number of cases of gastroenteritis had increased.

Requirements as to the quality of products covered by the Code are laid down in Article 10. This requires, in paragraph 1, the quality of such products to be of a high recognized standard. Article 10.2 stipulates that at the time when products are sold or otherwise distributed, they should “meet applicable standards recommended by the Codex Alimentarius Commission and also the Codex Code of Hygienic Practice for Foods for Infants and Children”.

Standards recommended by the Codex Alimentarius Commission contain requirements for food aimed at ensuring for the consumer a sound, wholesome food product free from adulteration, correctly labelled and presented. The standards, which are, *inter alia*, intended to protect the health of the consumer, are the subject of detailed discussions and exchanges of views between members of the Commission before adoption, and indeed the whole process may last some years. On the other hand, the Codex Code of Hygienic Practice con-
CODE OF MARKETING OF BREAST-MILK SUBSTITUTES

contains the minimum hygienic requirements for the handling (including production, preparation, processing, packaging, storage, etc.) of infant foods to ensure a safe, sound, and wholesome product.98 By making Codex standards and the Code of Hygienic Practice applicable to breast-milk substitutes, the drafters of the Code have ensured a high standard of quality for such products, thus providing a reasonable measure of protection for the consumer. In the absence of such standards it would be possible to export breast-milk substitutes, even though their quality does not meet the applicable criteria in the exporting country. In 1981 a member of the Executive Board pointed to the apparent assumption that the products referred to in the Code would be manufactured to the same standards for use in the (developed) producing country as for use abroad; in fact, certain categories of product were exported by manufacturers but not marketed in their own countries.99

Implementation of the Code. According to Article 11.1 of the Code, “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”.

This seems reasonable, as some Member States may find it appropriate to enact national legislation to give effect to the Code, because of the absence of any national legislation concerning products covered by the Code. Other Member States, on the other hand, may prefer to adopt regulations to implement the Code, because of the existence of national enabling legislation in this field. Furthermore, leaving the choice of means to implement the Code to Member States assists them in their task since they may find it easier to implement the Code in a ministerial decree or regulations, rather than in national legislation which may take a long time to adopt. Had the drafters of the Code insisted on a specific means of implementation, they would have foregone this flexibility.

Since some Member States may lack the necessary expertise to implement the Code, the drafters inserted the following provision in Article 11.1: “...governments should seek, when necessary, the cooperation of WHO, UNICEF and other agencies of the United Nations system”; indeed, some members have already availed themselves of WHO’s cooperation.100 Another point which should be mentioned here is that Article 11.1 appears to rule out discrimination, in the implementation of the Code, between local manufacturers of products covered by the Code and those marketing them, and foreigners involved in these activities. The article provides that “national policies and measures, including laws and regulations, which are adopted to give effect to the principles and aim of this Code should... apply on the same basis to all those involved in the manufacture and marketing of products within the scope of this Code”. This is a clear indication of the evenhandedness of the Code and that it is not intended as a barrier against the entry into the territory of the implementing State of products covered by it. It also
shows that the Code does not make any distinction between marketing practices inside and outside the territory of the implementing Member.

**Legal effect of WHO resolutions.** It may now be asked how far WHO Member States are under an obligation to implement the Code. As we have seen, the Code was adopted by the World Health Assembly as a recommendation, in a resolution to which the text of the Code was annexed. The Assembly, in the same resolution, urged all Member States "to give full and unanimous support to the implementation... of the provisions of the International Code in its entirety as an expression of the collective will of the membership of the World Health Organization; [and] to translate the International Code into national legislation, regulations or other suitable measures". In 1982, the Assembly again urged Member States "to give renewed attention to the need to adopt national legislation, regulations or other suitable measures to give effect to the International Code".

The question to be considered next is the legal effect of resolutions of the World Health Assembly and whether they are binding on Member States. The same question has been discussed in great detail with respect to resolutions of the United Nations General Assembly. Some writers believe that resolutions of the General Assembly have binding effect only in the internal matters and working of the United Nations, e.g. admission of new members and approval of the budget. Others maintain that, besides resolutions which concern the internal matters and working of the United Nations, certain resolutions of the General Assembly have binding effect. Yet another view is that resolutions of the General Assembly constitute evidence of accepted practice of international customary rules, or form elements creating rules of international customary law, in certain circumstances.

So far as resolutions of the World Health Assembly are concerned, some relate to the internal matters and working of the Organization, such as the admission of new Members, the establishment of certain organs, and the approval of the budget estimates, which seem to be binding on Member States. This category of resolutions resembles those adopted by the General Assembly for similar questions. As regards Health Assembly resolutions on relations between the Organization and Member States, e.g. the adoption of the Code, the position may be expressed as follows: the Health Assembly resolution adopting the Code, and its related resolution on infant and young child feeding, contain certain declarations and findings with respect to the importance of breast-feeding and its effect on the healthy growth and development of infants, and to the role the governments of Member States can play in the protection of breast-feeding; the Assembly, in these resolutions, expressed its conviction that the protection and promotion of infant feeding, including the regulation of the marketing of breast-milk substitutes, affect infant and young child health directly and profoundly; it went on to urge all Member States to give full and unanimous
support to the implementation of the Code, which contains a number of principles as an expression of the collective will of the Organization's membership; the Assembly also urged the translation of the Code into national legislation, regulations, or other suitable measures. These resolutions of the Health Assembly may be considered declaratory of the health principles contained in the Code and of the role of Member States in this connection, including the implementation of the Code in appropriate national measures.

The various views advanced concerning General Assembly resolutions probably apply in like measure to Health Assembly resolutions. Those who consider General Assembly resolutions non-binding would likely take the same view of Health Assembly resolutions. According to this position, Member States are under no obligation to implement the Code. Those who consider some General Assembly resolutions to be evidence of international customary rules or elements creating such rules, would probably take the same stand on the Health Assembly resolutions in question. This also holds good for the view that certain General Assembly resolutions have some binding effect on the argument that these resolutions concern legal or factual findings adopted by a competent organ of an international organization which have legal effect for Members. Castaneda states: "United Nations organs, in the performance of their functions, also make pronouncements as to the existence or non-existence of certain facts of legal situations... On occasion, these pronouncements or estimations have a special characteristic: they are 'determinations' from which may derive under certain circumstances — difficult to formulate in a general manner... — legal consequences that cannot be opposed in a juridically significant way by the members". On the other hand, Higgins is of the opinion that "it is now fairly widely accepted that United Nations resolutions, under certain conditions, can be treated as sources of international law. (These conditions would be that the resolutions are clear, and represent a repeated practice over a sufficient length of time by the great majority of nations)". By contrast, Cheng argues that "not only is it unnecessary that the usage should be prolonged, but there need also be no usage at all in the sense of repeated practice, provided that the opinio juris of the States concerned can be clearly established".

On Castaneda's view, while the Code was adopted in a resolution of the Health Assembly as a recommendation, this resolution and the resolution on infant and young child feeding have created a legal situation which Member States cannot ignore, in view of the principle of good faith. These resolutions could be regarded as "determinations from which may derive legal consequences". Alternatively, these resolutions might be held to constitute the "opinio juris" of Member States, and thus, in Cheng's view, create rules of international customary law. Thus, Member States might be considered bound to give effect to the Code, in taking national measures, as appropriate to their social and legislative framework, be they national legislation,
regulations, or other suitable measures. As the I.C.J. held in the 1971 case of Legal Consequences for States of the Continued Presence of South Africa in Namibia (South West Africa) notwithstanding resolution 276 (1970) of the Security Council, "... it would not be correct to assume that, because the General Assembly is in principle vested with recommendatory powers, it is debarred from adopting, in specific cases within the framework of its competence, resolutions which make determinations or have operative design". 126

The conduct of Member States tends to confirm the view that the Health Assembly resolutions in question have legal effect; some 120 Member States have notified the Director-General of WHO of the adoption of national measures to implement the Code. 127 These have taken various forms: administrative measures, 128 the establishment of committees to study the implementation of the Code, 129 the drafting of implementing legislation, 130 or the enactment of such legislation. 131 This may well indicate that these Members feel under an obligation to implement the Code, otherwise they need not have done so.

Monitoring of the Code. According to Article 11.2 of the Code, "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" (see infra).

Individual monitoring is left to each Member to determine, in the light of its legal system, social framework, and health conditions. For example, if a Member has implemented the Code in national legislation, it may establish an office or department to carry out the monitoring. It may also entrust this task to an existing department of the ministry most concerned, for example the ministry of health or commerce. Individual monitoring is carried out within the territory of the Member State and presupposes that the Code has been implemented by it in national legislation or other suitable legal measures. Collective monitoring is described in paragraphs 6 and 7 of Article 11, which read as follows:

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...

The provisions point to the Health Assembly as the forum for collective monitoring. According to Article 62 of the WHO Constitution, Members are required to send annual reports on the action taken with respect to, inter alia, recommendations made to them by the Organization, which includes the Code. The Director-General examines these reports to see what measures have been taken by the reporting Member with respect to the implementation of the Code. He then submits a biennial report to the Health Assembly on the measures taken by Member States which shows the status and extent of implementation of the Code. When the Health Assembly discusses the Director-General's
report, any Member can raise questions on the measures taken to implement the Code. Equally, any Member may criticize, or comment on, the attitude of those Members who are dilatory. In this way, Member States may be incited to implement, or expedite the implementation of, the Code.

This collective monitoring naturally lacks legal force, but it could be considered a kind of political or moral pressure on Members to take action to implement and apply the Code. The situation can be compared with that prevailing in the International Labour Organisation (ILO), where Members of that organization are required to submit to it reports on the legal position and practices in their territories with respect to conventions and recommendations adopted by the ILO. Member States which are parties to certain ILO conventions are also required to submit reports on measures taken to implement these conventions. The Director-General of the ILO submits to the General Conference a summary of the reports and information submitted by Members.132

Mention should be made of the role of private individuals, nongovernmental organizations, and professional groups and institutions in monitoring the Code. Article 11.4 places on them “the responsibility of drawing the attention of manufacturers or distributors to activities which are incompatible with the principles and the aim of this Code, so that appropriate action can be taken. The appropriate governmental authority should also be informed”. While this role may not seem significant in theory, it can be quite effective in practice. Individuals, consumer groups, and all those mentioned in the provision constitute a large section of any society and are likely to observe any practices of manufacturers or distributors which are incompatible with the Code. If such practices occur, for example, the display of a poster promoting breast-milk substitutes in a facility of a health care system, they would be reported to those responsible so that action can be taken to remedy the situation. If no such action is forthcoming, a complaint could be made to the competent national authority or other bodies.133 This role also helps to achieve the aim of the Code in that it provides the means for cooperation between private individuals and bodies and the manufacturers and distributors of products covered by the Code in the settlement of disputes which may arise from some of the practices of the latter.

An interesting aspect of the process of monitoring of the Code is self-monitoring on the part of the manufacturers and distributors of products within the scope of the Code. Article 11.3 provides that, independently of any other measure of implementation, manufacturers and distributors “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”. This means that a manufacturer or distributor would, for example, be required to monitor the activities of its branches and the practices of its component companies with respect to the observance of the provisions of the Code, whether or not the State in whose

*International Digest of Health Legislation, 1985, 36 (4)*
CURRENT PROBLEMS IN HEALTH LEGISLATION

territory such activities have taken place has implemented the Code.\textsuperscript{134} However, it is probable that this provision applies only where no legal measures have been taken to implement the Code. If measures have been taken, e.g. legislation or an administrative decision having legal force, the manufacturer or distributor in question will be obliged to respect them and abide by the provisions of the Code as implemented in the State concerned.

4. CONCLUSIONS

The Code constitutes a significant advance in the protection of the health of infants. It has for the first time created an international instrument which contains clear principles intended to regulate certain practices of manufacturers and distributors of breast-milk substitutes and other products covered by the Code. In adopting the Code, WHO intended to remedy a public health problem which continues to affect many infants in various parts of the world, particularly in developing countries. It is the first instrument of its kind ever adopted by WHO.

No one can pretend that the Code is a perfect instrument or free from ambiguities, but its defects are those to be expected from an international instrument adopted as the result of compromise, under the circumstances then prevailing. However, the Code is envisaged as only one of several important actions for the protection of the healthy growth and development of infants and, as such, it provides Member States with a means of regulating practices in the marketing of breast-milk substitutes, for the benefit of the health of infants of present and future generations. In the words of the representative of the Executive Board at the Health Assembly in 1981, "we are dealing with a health issue of essential importance to all Member States, and particularly to developing countries, and of importance to the children of the world and thus to all future generations."\textsuperscript{135} A delegate described the adoption of the Code by the Health Assembly as a "historic event for all the children of the world, and especially those of the developing world".\textsuperscript{136}

The usefulness of the Code and its contribution to the protection of the health of infants depend upon its implementation by Member States. Although the implementation of the Code is by no means complete, the action of the Members so far, as reflected in the report of the Director-General to the Health Assembly in May 1983,\textsuperscript{137} provides grounds for optimism.
REFERENCES AND NOTES


4. Ibid., Article 2, item (i).


8. The Tunisian delegate stated during the discussions of Committee A in 1981 that quite apart from the immunological and emotional advantages of mother’s milk, the economic aspect was becoming progressively more important in view of the adverse effect of the increasing costs of breast-milk substitutes on the family budget of poorer families. See supra ref. 1, at p. 196. It is estimated that in 1980 developing countries spent more than US$ 1,000 million on the import of breast-milk substitutes. See NASHAT, M. Le Code International de Commercialisation des Substituts du Lait Maternel. Annuaire français de droit international, 27: 490 (1981). The total value of nominal sales for 1980 in the baby-food market in Denmark, France, the Federal Republic of Germany, Ireland, and the United Kingdom has been estimated at over US$ 746 million. See The economist, 31 January 1981, p. 66.

9. See his statement during the discussions in Committee A of the World Health Assembly of the question of adopting an international code on breast-feeding and the promotion of breast-feeding, supra ref. 7, at p. 73.


12. See WORLD HEALTH ORGANIZATION. Breast-feeding patterns: a review of studies in the Eastern Mediterranean Region. Alexandria, Regional Office for the Eastern Mediterranean, 1982 (Technical Publication No. 4), pp. 78, 136, 172, 217, and 260. The studies show that many mothers in Bahrain, Iraq, Kuwait, Qatar, and the United Arab Emirates have abandoned breast-feeding in favour of bottle-feeding. According to Jack Ashley, a Member of the United Kingdom Parliament,
"96% of babies in Brazil were breast-fed in 1940: by 1974 the proportion had fallen to 39%". The Lancet, 1: 566 (1981).


16. Ibid., paragraph 6(5).

17. See resolution EB67.R12, ibid., p. 91.

18. See resolution WHA34.22, ibid., p. 91.


20. The Organization's functions cover a wide range of subjects and are specified in Article 2 of its Constitution.


CODE OF MARKETING OF BREAST-MILK SUBSTITUTES

regulations adopted under Article 21 of the WHO Constitution as international treaties ("accords internationaux"), for example, the International Health Regulations; see Vignes, C.-H. Le réglement sanitaire international — aspects juridiques. Annuaire français de droit international, 11: 654 (1965). Others do not consider them international treaties; see Skubiszowski, K. Enactments of international organizations. British yearbook of international law, 41: 223-224 (1968). It is worth mentioning that the International Civil Aviation Organization possesses a similar power under the Chicago Convention of 1944, with respect to international standards. See Articles 37, 38, 54(1), and 90(a) of the Chicago Convention.

25. This view was taken by the International Court of Justice in its advisory opinion on Reparation for injuries suffered in the service of the United Nations. [1949] I.C.J. Reports, 182.


27. For an estimate of the import of these products by developing countries in 1980 alone, see supra ref. 8.

28. On this point, see p. 885.

29. On the Codex Alimentarius Commission, see p. 892.

30. Ibid.


32. See Article 75 of the WHO Constitution: "Any question or dispute concerning the interpretation or application of this Constitution which is not settled by negotiation or by the Health Assembly shall be referred to the International Court of Justice...".

33. See supra, ref. 15.

34. See Dr R. J. H. Kruisinga's statement, World Health Organization. Executive Board, sixty-seventh session, Geneva, 14-30 January 1981. Summary records. Geneva, 1981 (document EB67/1981/REC/2), p. 312. In explaining the vote cast by the United States against the Code, the United States delegate said, in Committee A, that "the United States was seriously concerned about WHO's involvement in commercial codes...". See supra ref. 1, at p. 200. There are those who even deny that WHO has the authority to adopt the Code. See A. Keller, who, commenting on the Code, wrote "even though its purported goal of the promotion of infant breast-feeding is universally accepted, this is clearly a matter over which each member state has exclusive jurisdiction — and which thus falls outside the legal competence of WHO". International herald tribune, 17 April 1981.

35. See supra ref. 34, at p. 319. Dr Kruisinga's argument involves deciding whether breast-milk substitutes are a "food" or a product "similar" to biological products. If breast-milk substitutes are a mere "food", they are only doubtfully covered by Article 21; however, the fact of marketing them as an adequate substitute for breast milk (which is a biological product) brings them clearly within the scope of the Article in that breast milk contains antibodies, thereby inhibiting disease; if breast-milk substitutes do not contain biological products, the marketing of substitutes purporting to be such products may be prohibited under Article 21.


37. Ibid., p. 184.
38. Article 1 of the WHO Constitution.
43. See the statements made by Drs A. Al-Saif and A. Al-Ghassany in favour of a regulation, and those of Professors E. J. Aujaleu and I. Doğramaci in favour of a recommendation, see *supra* ref. 7, at pp. 314, 315, 306, and 309. The majority of delegates at the Thirty-fourth World Health Assembly supported the latter standpoint of the Executive Board. See the statements made by the Swedish delegate on behalf of the Nordic countries and by the Turkish delegate, *supra* ref. 1, at pp. 190 and 194.
45. *Ibid.*, resolution WHA34.22, paragraph 5(4). The original draft resolution proposed by Dr T. Mork contained, instead of the wording "and the measures needed for its effective application", the following: "and, according to Articles 21 and 22 of the WHO Constitution, recommend the adoption of the Code as a regulation". See *supra* ref. 7, at p. 309.
47. See Dr H. J. H. Hiddlestone's statement, *supra* ref. 34, at p. 310.
48. *Ibid.*, p. 317. Another member of the Executive Board, Dr A. W. Patterson, supported Dr Hiddlestone's suggestion; see *ibid.*, p. 313.
50. Resolution WHA34.22, paragraph 5(3), see *supra* ref. 18.
52. See p. 880.
54. Bowett makes the following comment with respect to a recommendation of the UN General Assembly: "Although as a general rule it can have no legally binding effect on the members, there are some circumstances in which a recommendation may create direct legal obligations for members, for example by the Assembly's approval of the budget... or by decisions on elections to various organs or admission to membership; such matters normally relate to the internal working of the Organization as distinct from a recommendation addressed to a member". See *supra* ref. 24, at pp. 45-46.
CODE OF MARKETING OF BREAST-MILK SUBSTITUTES 903

55. For details, see pp. 894-896.


57. Article 1 of the Code.

58. Article 2 of the Code describes the products to which the Code applies: (1) breast-milk substitutes; (2) other milk products, foods and beverages, including bottle-fed complementary foods, when marketed or otherwise represented as suitable for use as a partial or total replacement of breast-milk; and (3) feeding bottles and teats.

59. An unsuccessful attempt was made to qualify the ban on advertising and promotion in Article 5.1 by the insertion of the expression "to the detriment of breast-feeding". The qualification was first proposed in the Joint WHO/UNICEF Meeting on Infant and Young Child Feeding, in October 1979, and was adopted by the Meeting. See supra ref. 14, at p. 28, footnote. However, in its comments on the origin of Article 5.1 of the International Code, the International Council of Infant Food Industries (ICIFI) suggested that the wording adopted by the Meeting should be adhered to, but this was not accepted. A controversy arose in this connection in the Netherlands, between a consumer organization and a producer of breast-milk substitutes. The latter put an advertisement in a newspaper relating to its activities, to which the organization objected on the ground that this action was not compatible with the International Code. The matter was referred to the National Committee on Advertising Practice of the Board of Appeal. The company, under a misapprehension, argued that the Code banned advertising "to the detriment of breast-feeding". The Board of Appeal rejected the appeal on the ground that the legal status of the Code was not clear in the Netherlands.


62. Paragraph 1 of Article 31 provides: "A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose."

63. Dr E. Yacoub maintained that "mothers were often persuaded by advertisements to use [breast-milk substitutes] instead of breast-feeding their infants." See supra ref. 7, at p. 306. Another member, Mr K. Al-Sakaaf, stated that "excessive use of breast-milk substitutes was brought about by uncontrolled advertising...". Ibid., p. 311. It was further pointed out by Dr J. J. A. Reid that "there was need both to foster breast-feeding and to protect mothers from influences which might discourage this, and the Code clearly had an important part to play in the latter process". Ibid., p. 309. Moreover, the World Health Assembly recognized in 1982 "... that commercial marketing of breast-milk substitutes for infants had contributed to an increase in artificial feeding". See resolution WHA35.26, fourth preambular paragraph, WHO Handbook, Vol. II, p. 92. Article 3 of the International Code defines "marketing" as "product promotion, distribution, selling, advertising, product public relations, and information services".

64. "Also, and unappreciated, successful breast-feeding literally depends physiologically on confidence. Advertising can have the subtle and unique side-effect of causing anxiety and doubt, and thus undermining the production of the rival product, human milk". See JELLIFFE, D. & JELLIFFE, E. F. Feeding young infants in...


66. See the statement of the Swiss delegate during the discussions of the draft Code in Committee A of the Assembly in 1981: "there should be no misunderstanding on this subject: the Code recognized objectively that breast-milk substitutes fulfilled a need and it did not set out to prevent such products from being sold or used when necessary". See supra ref. 1, at p. 193. The Turkish delegate pointed out that "one misunderstanding was that the Code was directed against the manufacturers of breast-milk substitutes. In fact, the Code in no way discouraged industry from manufacturing substitutes"; ... "the whole purpose of the Code was to avoid encouraging future mothers and especially new mothers to resort unnecessarily to bottle-feeding...". Ibid., p. 194.

67. See the sixth and fifteenth preambular paragraphs of the Code.

68. Commenting on the effect of publicity and promotion on the mother's choice of breast-feeding or using breast-milk substitutes, the Turkish delegate pointed out during the discussions of the Code in Committee A in 1981 that "...If the expectant mother was showered with clever publicity and sometimes even free samples of breast-milk substitutes, she could not always be expected to make a wise decision in the best interests of the health of her baby. The aim of the Code was precisely to protect mothers and future mothers from unethical marketing practices". See supra ref. 1, at p. 194. It has been remarked, in connection with the giving of samples, that "promotional activities have also been directed through the health services, with, for example, free samples to all mothers discharged from maternity units...". See supra ref. 64, at p. 73.

69. See p. 885.

70. A "health worker", according to Article 3 of the Code, means "a person working in a component of... a health care system, whether professional or non-professional, including voluntary, unpaid workers".

71. This seems to apply even if the mother or pregnant woman is the health worker's wife, because the provision is general and can be said to include any woman, irrespective of her relationship to the health worker. See also the experiments carried out at a health care facility in the Philippines, supra ref. 65.

72. According to Article 3 of the Code, "marketing personnel" means "any persons whose functions involve the marketing of a product or products coming within the scope of this Code". For the definition of "marketing", see supra ref. 63.

73. Article 5.4 reads as follows: "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".

74. See supra ref. 64, at p. 73.

75. See supra ref. 64. Article 7.5 of the Code requires manufacturers and distributors of products covered by the Code to "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". The provision also requires the recipient to make similar disclosures.

76. Other provisions of the Code are designed to reduce the possibilities of con-
tact between the marketing personnel of manufacturers and distributors of products within the scope of the Code and pregnant women and mothers of young children. Article 5.5 of the Code provides that "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". Furthermore Article 8.2 of the Code provides that "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 infant and young children".

77. See p. 885.

78. According to the WHO and UNICEF Notes on the International Code of Marketing of Breast-milk Substitutes, "... it is the responsibility of the governments of Member States to ensure that objective and consistent information is given on infant and young child feeding to families and others concerned with infant and young child nutrition". See supra ref. 60, at p. 3, paragraph 12.

79. A member of the Executive Board, Dr T. Mork, made the following point when the Board was considering the draft Code: "regarding the strengthening of education, training and information on infant and young child feeding, there was an urgent need for material on that subject both for training all categories of health workers and as educational material intended for pregnant women, mothers, and the general public. That material should be independent of the food industry...". See supra ref. 7, at p. 303.

80. See supra ref. 1, at p. 194.

81. See p. 885.

82. See p. 889.

83. See supra ref. 1, at p. 195.

84. For example, the health worker is responsible for advising whether breast-milk substitutes should be used (Article 9.2(c)).

85. Breast-feeding "... forms a unique biological and emotional basis for the health of both mother and child...". Fourth preambular paragraph of the Code.

86. See p. 879.

87. According to Article 3 of the Code, "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".

88. Paragraphs 2 and 3 of Article 6.

89. These are women who may or may not be nurses, who sometimes work in health care facilities, e.g. hospitals.

90. See p. 885.

91. See sixth preambular paragraph of the Code. See also the indirect recognition of this need in Article 6.5, which reads as follows: "Feeding with infant formula... 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...".

92. According to Article 3 of the Code, "label" means "any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to, a container... of any products within the scope of this Code".
According to Article 3 of the Code, "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'".

Thirty-third World Health Assembly, supra ref. 7, at p. 75.

See supra ref. 31.


For Dr A. Al-Ghassany's statement, see supra ref. 7, at p. 315. The Algerian delegate stated in Committee A in 1981 that "he had been surprised to see no mention in the draft Code of the responsibility that exporting States should have for ensuring that the products leaving their countries adhered to the standards that would be applicable in the home market". See supra ref. 1, at p. 190.

Two examples will suffice: in November 1982, the Secretariat of the Caribbean Community (CARICOM) requested WHO's cooperation in connection with the development of a uniform code for the implementation of the Code in the Member countries of the Community; and in February 1983, the Secretariat of the Council of Arab Ministers of Health of the Gulf States made a similar request on behalf of its members.

Resolution WHA34.22, paragraph 1, see WHO Handbook, Vol. II, p. 91.

See resolution WHA35.26, paragraph 1, ibid., p. 92.


Article 4 of the UN Charter.

Article 17 of the UN Charter.

See Castaneda, supra ref. 53, at pp. 111, 117, 150, and 171; see also SCHACHTER, O. Towards a theory of international obligations. In: Schwebel, S. M., ed. The effectiveness of international decisions. Leyden, the Netherlands, Sijthoff, 1971, p. 371.

International Digest of Health Legislation, 1985, 36 (4)


110. Article 6 of the WHO Constitution.

111. Article 18(e) of the WHO Constitution.

112. Article 56 of the WHO Constitution.

113. See resolution WHA34.22, first, second, and third preambular paragraphs, supra ref. 18; and resolution WHA35.26, operative paragraph 1, supra ref. 102.

114. See resolution WHA34.22, fifth preambular paragraph, supra ref. 18.

115. See supra ref. 103.

116. See supra ref. 108.

117. See supra ref. 109.

118. See supra ref. 107.

119. See supra ref. 53, at p. 117.

120. On the sources of international law, see Article 38 of the Statutes of the ICJ.


122. See supra ref. 109, at p. 37. Schachter comments on the legal effect of General Assembly resolutions: "... in some cases you may have a single expression of a consensus in a resolution which will be accepted for a long time as a statement of obligatory requirements. If we place our sole emphasis on UN practice as customary law, it does not quite cover those situations which did not involve repetition and continued usage but nonetheless involved an understanding that a specific obligation resulted from a resolution...". See supra ref. 107, at p. 371.

123. Professor Virally maintains: "... A State which has not declared its acceptance of a recommendation is not bound by it, though it may be fairly asked whether the principle of good faith will permit a State to disregard a recommendation which it has formally approved by its affirmative vote". See Virally, M. The sources of international law. In: Sørensen, M., ed. Manual of public international law. London, Macmillan, 1968, p. 161. Higgins comments on voting: "... There are really three options available to a state: it can vote against, it can abstain, or vote for, making a collateral statement indicating that it does not believe the statement to be a correct enunciation of the law or one that requires action from it. So that if it declines to exercise any of these three options and votes for, with adequate time for consultation at home, having gone through the ad referendum process, it is then arguable that it is bound". She goes on: "my point went to the acceptance really by vote of states of a recommendation, an acceptance that arguably changed the nature of the recommendation. It is not the recommendation that binds, but the acceptance of the states through the vote". In: Schwebel, supra ref. 107, at pp. 398 and 399. For a contrary view, see MacGibbon, supra ref. 103, at p. 13. This author finds it difficult to subscribe to the view that voting in favour of a resolution, as such, can have the effect described by Higgins.

124. See supra ref. 53, at p. 117.

125. See supra ref. 109, at p. 37.


127. See supra ref. 51.

International Digest of Health Legislation, 1985, 36 (4)
128. See for example the Circular issued by the Moroccan Ministry of Public Health on 6 April 1982, the Decision of the Secretary of the People’s General Committee for Health of the Libyan Arab Jamahiriya, and the action taken by the Director-General for Preventive Medicine in Saudi Arabia, ibid., p. 29, paragraph 73, and p. 34, paragraphs 107 and 108 (many of the measures taken in this field have been covered in this journal).

129. See, for example, the measures taken by Gabon, Jordan, and Yemen, ibid., p. 20, paragraph 8, p. 34, paragraph 105, and p. 35, paragraph 111.

130. See the measures taken by the Governments of India and Mozambique, ibid., p. 20, paragraph 13, and p. 25, paragraph 40. In December 1983 the Indian Government adopted a national code for the implementation of the International Code.

131. See action taken by New Zealand and Trinidad and Tobago, ibid., p. 24, paragraph 35, and p. 36, paragraph 119. Tunisia adopted a national code in March 1983. In some Member States, voluntary agreements with infant-food industries have been employed to implement the Code, e.g. in Austria, Denmark, and the Federal Republic of Germany. Ibid., p. 26, paragraphs 48 and 54, and p. 28, paragraph 63. The Council of Arab Ministers of Health of the Gulf States approved, at its sixteenth meeting in January 1984, a uniform draft law for the marketing of breast-milk substitutes based on the Code. The member countries of the Council are: Bahrain, Iraq, Kuwait, Oman, Qatar, Saudi Arabia, and the United Arab Emirates.

132. See Articles 19, 22, and 23 of the ILO Constitution.

133. See, for example, the proceedings involving a consumer group and a producer of breast-milk substitutes in the Netherlands, supra ref. 59.

134. In February 1982, Nestlé, the Swiss-based multinational food company, declared its intention of complying with the Code and issued instructions to that effect to all of its companies and to agents and distributors of breast-milk substitutes. Furthermore, it set up the Nestlé Infant Formula Commission, headed by a lawyer and a former United States Senator, Edmund Muskie, to examine complaints of non-compliance by Nestlé with the provisions of the Code. The Commission issues quarterly reports which describe the complaints and its decisions thereon. Some other undertakings have declared, or are in the process of declaring, their intention of complying with the provisions of the Code.

135. See Dr Mork’s statement, supra ref. 5, at p. 36.

136. See the statement of the Kuwaiti delegate at the Thirty-fourth World Health Assembly, supra ref. 19, at p. 264.

137. See supra ref. 51.