THE CODE HANDBOOK

A Guide to Implementing the International Code of Marketing of Breastmilk Substitutes

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2nd Edition

INTERNATIONAL CODE DOCUMENTATION CENTRE

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User-friendly colour coding:

white	:	Chapters 1 to 11
yellow	:	Model Law
green	:	Selected National Measures
blue	:	International Code and resolutions

Foreword

Legislation and breastfeeding are two words that most people would not put together. Yet in this book they are, in every chapter, in every section. The ultimate aim of *The Code Handbook* is to give the right to breastfeed back to the mother. When the Code was adopted by the World Health Assembly in 1981, they knew only a fraction of the multiple advantages of breastfeeding known today. Yet even now, 25 years later, too few governments have enacted legislation in order to protect breastfeeding from commercial competition by manufacturers of breastmilk substitutes, feeding bottles and teats.

Breastfeeding is not like a tap which can be turned on and off. Mothers need to have confidence in their capacity to provide milk. Breastmilk allows babies to thrive without any other food or drink until the child is six months old. As with most things, the start is the most sensitive. The mother's hormones are already active before birth, triggering the various production mechanisms. The delivery of the milk, however, depends on the "let-down reflex" and that is very susceptible to psychological and emotional stress.

A mother's confidence is easily upset by subtle messages. Companies understood this a long time before objective researchers established the link. For instance, suggestions about 'not enough milk' will cause the mother anxiety and most likely result in her not having enough, leaving the baby hungry and crying, the mother upset and uncertain. The doubts and pressures invariably lead to artificial feeding, a vicious circle, cleverly fostered by company booklets, advertisements and even product labels.

Over the past 60 years, inappropriate hospital routines have also undermined breastfeeding. Unwittingly, doctors and nurses have allowed themselves to become endorsers of bottle feeding. It took years of public pressure before concerted action was taken to protect breastfeeding. Recognising the dangers, in all countries, of the downward spiral of breastfeeding, WHO and UNICEF finally embarked upon drafting the Code of Marketing of Breastmilk Substitutes.

As an international recommendation, the Code is to be put into effect at the national level. This process continues to be very slow. By 1988, only six countries had turned all of the Code into law. By 1991, ten years after the adoption of the Code, that number had increased to just nine. Yet it was not a matter of disinterest; it was rather that governments found it complicated to transform global recommendations into national legislation or other measures that could be implemented and monitored.

The International Baby Food Action Network (IBFAN) had set up the International Code Documentation Centre (ICDC) with the task of keeping track of Code compliance both by governments and by companies. ICDC was soon requested to help individual countries draft legislation. Working with one country at a time, however, was quite time-consuming and by 1992, it was decided that regional and annual courses were a more efficient method to assist countries with their national legislation. Over the past 13 years the Training Courses have been instrumental in increasing the number of countries with the entire Code as law: 30 by 2005, several inadequate laws were amended and 23 countries now have comprehensive drafts waiting to be adopted.

Ellen Sokol, ICDC's Legal Advisor from 1991 to 1998, had gradually developed a course manual using a Model Law as the central tool to facilitate the drafting process. Initially, each course had its own photocopied manual and led to new insights and to improvements in the Model Law. Many

organisations and governments asked ICDC to publish it for wider circulation. By 1997 the Code Handbook was adapted, expanded and printed to be used as a resource on its own. It was subsequently translated into Spanish, French, Portuguese and Russian. The Code Handbook became the main tool in 27 Training Courses in different regions and in different languages. Some 600 government officials from 130 countries were trained. In 2003, Ellen Sokol began working on the second edition.

With the assistance of ICDC's current Legal Advisor, Yeong Joo Kean, and David Clark, the legal officer of the Nutrition section in UNICEF New York, Ellen incorporated important global policy changes including the recommendation that mothers breastfeed exclusively for six months, the 2002 WHO/UNICEF Global Strategy, new knowledge about the importance of exclusive breastfeeding and risks of formula feeding, and more than 20 new or revised national laws or other measures.

Ellen writes in a clear and logical fashion, admirably combining her legal expertise with her experience as a breastfeeding mother. Each Article of the Code is carefully analysed and examples are given of how different countries have avoided particular weaknesses and loopholes. The wording of the Model Law is explained in detail and there is a nice mix of concrete examples of marketing techniques and their effects (on mothers, on breastfeeding management, on doctors, etc) with clear suggestions for drafting protective provisions.

ICDC is also proud to present with the main text the most complete collection of related documents under one cover: the full International Code, all subsequent relevant WHA resolutions up to 2005, the Innocenti Declaration, a global roster of laws and regulations, the relevant parts of the Global Strategy, as well as a selection of inspired baby food marketing laws from all over the world.

We have included the complete text of legal measures from six countries, representing different regions of the world and different kinds of measures: *legislation* (India), *regulations* (Brazil and Ghana), a *voluntary code* (Malaysia), a *decree* (Yemen) a *regional measure* (European Union) and… finally, the newest baby on the block: a set of regulations from Botswana, adopted in June 2005, just as this Handbook was being edited and finalised for printing. Therefore, apart from a brief reference in Chapter 10, there are no examples from the Botswana Regulations elsewhere in the text. However, the Regulations are so clear and so complete that we felt compelled to include the full text in the section on National Measures.

Another new and wonderful feature of this version is the Index. It was difficult and painstaking to prepare but we know that thousands of readers will be grateful. There now is also a full bibliography.

I have no doubt that the Handbook will be very useful to lawyers and law-makers, public health administrators, the medical profession, parliamentarians, IBFAN groups, journalists and to the baby food companies. The reference value make this book a must for libraries with a focus on international affairs and public health. The comprehensive coverage of the history of the Code, of the history of baby milk marketing and of the purpose and achievements of the Code, makes this book valuable reading, not only for lawyers but for everyone who wants to study the legal aspects of the breastfeeding campaign.

Annelies Allain
IBFAN/ICDC

Acknowledgements

The Code Handbook was first published by ICDC in 1997. In 2003, we decided to begin writing a supplement to update the 1997 book. Mid-way through the process, we realised that with so much new material, a full revision of the Code Handbook was merited. As with the original Handbook, everyone at ICDC pitched in at every step of the way to realise this project. Annelies Allain's keen eye helped me to see things from a different angle and to bring out the essential elements from events and documents cited in the book. I also thank her for having the foresight to arrange what was necessary for my comfortable and prolonged stay in Penang while completing this project. Yeong Joo Kean, with her ability to "cut the wheat from the chaff" was instrumental in keeping me on track whenever I began to stray too far afield and was always available for discussions. I cannot thank too many times Ajeyya, who painstakingly transformed the endless drafts and corrections into an over 300-page book– an enormous job. And then there is Lye Choy Lean who devoted hours and hours to putting together an index and pouring over the drafts to give the text a beautiful consistency.

Thanks also go to Sita Sinnathamby for proofreading and her general willingness to pitch in to do whatever was needed and for taking care of my personal needs while staying in Penang. And to Komala, who has always helped to keep a smile on my face and who was also willing to help out in any way including proof reading long legal documents. Karyn showed enormous patience in ploughing through the minutia of the footnotes and devising a system to bring to them some consistency. Jean-Pierre Allain also deserves a big thank you for the many translations he provided for source materials (including numerous legal texts), for coordinating the Brazil Case Study and for generally being available whenever a question arose over a foreign-language text. Many thanks also to David Clark of UNICEF for giving his time to read and comment on the entire text.

I also thank the many IBFANers around the world who provided details and answers almost as quickly as questions were posed, including Teresa Toma, Marina Rea and Rosana de Divitiis for putting together the material that formed the basis for the Brazil Case Study. Finally, a warm personal thank you to the many friends in Penang, including Susan, Sarah, Siva, Anwar, Mahmuda, Pierre, Lee, Jean Pierre (the small one), Greg and the gang from Penang HHH who made my stay in Penang as special as always and thank you to my family for all the loving support during these long months.

Abbreviations

AAP	American Association of Pediatrics
AFASS	Acceptable, feasible, affordable, sustainable and safe
ANVISA	Agência Nacional de Vigilância Sanitária (Brazil National Health and Food Control Agency)
APMAIF	Advisory Panel for the Marketing in Australia of Infant Formula
ARA	Arachidonic acid
BFHI	Baby Friendly Hospital Initiative
BMA	Baby Milk Action
CIIR	Catholic Institute for International Relations
Codex	Codex Alimentarius Commission
CRC	Convention on the Rights of the Child
DHA	Docosahexaenoic acid
DHHS	US Department of Health and Human Services
EU	European Union
FAO	Food and Agriculture Organisation
FSMP	Foods for Special Medical Purposes
GATT	General Agreement on Tariffs and Trade
HIV	Human Immunodeficiency Virus
HON	Health on the Network
IAP	Indian Academy of Pediatrics
IBFAN	International Baby Food Action Network
ICDC	International Code Documentation Centre
ICIFI	International Council of Infant Food Industries
IFM	International Association of Infant Food Manufacturers
IGBM	Interagency Group on Breastfeeding Monitoring
INBC	International Nestlé Boycott Committee
INFACT	Infant Formula Action Coalition
IPA	International Paediatric Association
LBW	Low Birth Weight
NGO	Non-Governmental Organisation
PAG	Protein-Calorie Advisory Group of the United Nations
SPS	Agreement on Sanitary and Phytosanitary Measures

TBT	Agreement on Technical Barriers to Trade
UN	United Nations
UNAIDS	United Nations Programme on HIV/AIDS
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
USAID	US Agency for International Development
WABA	World Alliance for Breastfeeding Action
WHA	World Health Assembly
WHO	World Health Organization
WTO	World Trade Organization

Symbols and Terms in Footnotes

¶	=	paragraph
§	=	section
ibid	=	same as preceding reference
supra	=	as above

Laws and documents are identified with a full citation the first time each is mentioned in each chapter. Subsequent references to a law or document in the same chapter are cited with a shortened name followed by *supra* and the number of the footnote that contains the full citation. For example, if a full citation to the Ghana Regulations appears in footnote 5, subsequent citations to the Ghana Regulations in the same chapter would appear as follows: Ghana Regulations, *supra* note 5, Article 3.

Introduction

This Handbook is written to aid governments in developing measures to implement the World Health Organization *International Code of Marketing of Breastmilk*[1] *Substitutes* (International Code), which was adopted by the World Health Assembly (WHA) in May 1981. At that time the World Health Assembly was concerned about the aggressive and often inappropriate marketing of breastmilk substitutes, which was contributing to an alarming decline in breastfeeding and the associated increased malnutrition, morbidity and mortality among infants and young children worldwide.

When the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) convened a *Meeting on Infant and Young Child Feeding* in Geneva in October 1979, the participants recommended that an International Code be developed and stated:

> Poor infant-feeding practices and their consequences are one of the world's major problems and a serious obstacle to social and economic development. Being to a great extent a man-made problem it must be considered a reproach to our science and technology and our social and economic structures, and a blot on our so-called development achievements. It is not only a problem of the developing world: it occurs in many parts of the developed world as well.[2]

Twenty-five years later, the International Code is just as, if not more relevant than it was in 1981. In 2002, the World Health Assembly adopted the *Global Strategy for Infant and Young Child Feeding,* which was the result of a call for "a revitalisation of the global commitment to appropriate infant and young child nutrition".[3] The new strategy, developed jointly by WHO and UNICEF, was a response to the still alarmingly high number of deaths of children due to malnutrition, mainly in the developing world and the realisation that the majority of these deaths are preventable through low-cost interventions such as exclusive breastfeeding.

The *Global Strategy* reaffirms the urgency of implementing the International Code as one of the key steps to improving infant and young child feeding and ultimately, child survival. A

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[1] In the title of the International Code, the term *breast-milk substitute* is spelled with a hyphen. In this Handbook, ICDC like UNICEF and many other organisations and writers, spell *breastmilk* and *breastfeeding* as one word to reflect that breastfeeding, unlike bottle feeding, is an uninterrupted, continuous motion. This spelling is used throughout the book, even when reference is made to other documents or materials that use a hyphen when spelling the words *breastmilk* or *breastfeeding*.

[2] WHO and UNICEF, "WHO/UNICEF Meeting on Infant and Young Child Feeding", *WHO Chronicle,* 1979, 33: 435.

[3] WHO and UNICEF, *Global Strategy for Infant and Young Child Feeding,* Geneva: WHO, 2003 (*hereinafter* WHO and UNICEF Global Strategy), p. 1. The *Global Strategy* was endorsed, by consensus, on 18 May 2002 by the fifty-fifth World Health Assembly, and on 16 September 2002 by the UNICEF Executive Board.

large number of countries have already incorporated the principles and provisions of the International Code into a national law or policy. Many, however, still have not. Moreover, several countries have older measures in need of revision in accordance with new knowledge and practices.[4]

Knowledge about the importance of infant and young child nutrition, particularly breastfeeding, has vastly surpassed what was known in 1981. The *Global Strategy* stresses the following global public health recommendation:

> Infants should be exclusively breastfed for the first six months of life to achieve optimal growth, development and health. Thereafter, to meet their evolving nutritional requirements, infants should receive nutritionally adequate and safe complementary foods while breastfeeding continues for up to two years of age or beyond.[5]

Appropriate feeding practices play a crucial role in achieving optimal health. There is nothing that equals breastfeeding. Breastmilk is a living substance that fulfils all of a baby's nutritional requirements and has the additional advantage of containing antibodies that help protect the baby against many common childhood illnesses. Research continues to reveal benefits to the child from breastmilk and breastfeeding that simply cannot be replaced or replicated. It is safe and clean, always at the right temperature, inexpensive and nearly every mother has more than enough for her baby. There is also an important relationship between breastfeeding and child spacing.

When the International Code was adopted in 1981, concern was most often focused on the problems associated with bottle feeding. Babies who are partially breastfed or not breastfed at all are fed with some type of substitute, usually by bottle. Bottle feeding under poor conditions often leads to illness and death. For bottle feeding to be safe there must be access to clean water, fuel and facilities to boil the water and sterilise the equipment, adequate income to be able to afford the milk powder and a level of literacy that allows for the mixing and sterilising instructions to be carefully followed.

The problems traditionally associated with bottle feeding still exist, but today there is a greater awareness of the important relationship between the absence of breastfeeding, particularly exclusive breastfeeding during a child's first six months, and infant and childhood malnutrition, which leads to illness and death. Continued breastfeeding well beyond the first six months also plays a major role in optimal child nutrition and health.

In the developing world, the risk of death from diarrhoea and pneumonia for infants who do not breastfeed is seven and five times greater respectively, in the first five months of life than that of babies who are fed only breastmilk.[6] In more affluent countries, studies have demon-

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[4] *Figure 2* in Chapter 10 shows the state of implementation of the International Code in 192 countries.

[5] WHO and UNICEF Global Strategy, *supra* note 3, ¶ 10.

[6] Black, R.E., Morris, S.S. and Bryce, J., "Child Survival I: Where and why are 10 million children dying every year?", *Lancet*, 2003, 361: 2226-34.

strated numerous risks that are associated with the feeding of infant formula or the absence of breastfeeding.[7] For example, even in the best conditions, formula-fed babies have been shown to have a much greater chance of gastro-intestinal infections than those who are breastfed.[8] A 2004 study in the US showed that breastfeeding has the potential to save 720 infants from death in the United States each year.[9] Moreover, the American Academy of Pediatrics (AAP) has identified breastfeeding as an important intervention for the prevention of childhood obesity.[10]

Despite the broad base of knowledge on which these recommendations are based, WHO researchers have found that "The size of the gap between breastfeeding practice and recommendations in developing countries is striking".[11] While nearly all babies receive some breastmilk even at one year of age in developing countries, only 39 percent of infants below the age of six months are exclusively breastfeed.[12] Rates vary by region, with the lowest of 25 percent in Africa.[13]

The low global rates of exclusive breastfeeding can be attributed to many factors. Commercial practices that discourage breastfeeding is one of these factors. Although different from what they were in 1981, such practices are still abundant. The Internet has brought product promotion to all corners of the world. New products, unheard of when the International Code was adopted, are marketed as ways to familiarise mothers with company and brand names and logos. Moreover, corporate sponsorship of health professionals or offers to assist governments in research or policy formulation have become more prevalent.[14] The International Code provides one part of a multi-pronged approach to increasing breastfeeding, thereby improving the survival of infants and young children.

This Handbook was written as part of the core materials for the International Code Documentation Centre's (ICDC) Training Courses on Implementing the International Code. It is designed to explain the provisions of the International Code against the backdrop of practices employed to promote and sell breastmilk substitutes. Its other major goal is to aid in the drafting of legislation or other measures that will most effectively stop those practices.

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[7] *See* International Baby Food Action Network, *Fourteen Risks of Formula Feeding: A brief annotated bibliography*, Penang, Malaysia: IBFAN-ICDC, 2004. The risks are listed in Chapter 7, note 12.

[8] Howie, P.W., Forsyth, J.S., Ogston, S.A. et al., "Protective effect of breastfeeding against infection", *British Medical Journal,* 1990, 300: 11-16.

[9] Chen, A. and Rogan, W.J., "Breastfeeding and the Risk of Postneonatal Death in the United States", *Pediatrics,* 2004, 113: e435-39.

[10] American Academy of Pediatrics, "Prevention of Pediatric Overweight and Obesity", *Pediatrics*, 2003, 112: 424-30.

[11] Lauer, J.A., Betrán, A.P., Victora, C.G. et al., "Breastfeeding Patterns and Exposure to Suboptimal Breastfeeding among Children in Developing Countries: Review and analysis of nationally representative surveys", *BMC Medicine*, 2004, 2: 26.

[12] *Ibid.*

[13] *Ibid.*

[14] For a detailed discussion of the impact on health of corporate public relations techniques and the international regulation of large corporations, *see* Richter, J., *Holding Corporations Accountable: Corporate conduct, international codes and citizen action*, London: Zed Books, 2001.

Chapter highlights

Chapters 1 to 3 provide the historical background to the International Code and subsequent WHA resolutions, the marketing practices that led up to them and explore international policy developments that have taken place since the Code was adopted. Chapters 4 through 9 discuss each of the following principles on which national legislation should be based:

1. The measure shall apply to a defined range of products, the promotion of which encourages bottle feeding, discourages breastfeeding or interferes with efforts to protect and promote breastfeeding.
2. Products within the scope of the legislation shall not be advertised or otherwise promoted to the public at the retail level or through health care facilities.
3. Company contact with health workers shall be limited to the sharing of non-promotional information and health workers and health care facilities shall not be used as a means of promoting products to the public.
4. Information about infant and young child feeding must not in any way discourage or undermine breastfeeding or promote products within the scope of the legislation.
5. All products within the scope shall be labelled in a prescribed manner that protects and promotes breastfeeding.

These chapters highlight areas of the International Code that have proved difficult to implement and loopholes that companies have exploited. The clarifications provided by World Health Assembly resolutions that came after the adoption of the International Code are also analysed.

In most countries, legislation is the most effective means for implementing the International Code. Some countries have and will find other approaches to be more appropriate, such as voluntary measures or controlling imports or sales of breastmilk substitutes and feeding implements. Soundly drafted legislation, once part of a country's body of law, must be monitored by knowledgeable and persistent groups and individuals so that it can be implemented and enforced. The various forms of national measures that countries have adopted as well as their application and enforcement are discussed in Chapter 10.

Legislation should be neither the beginning nor the end of each country's response to this problem. Political will and commitment must come first, prompted or accompanied by public support through organised efforts. Chapter 11 focuses on advocacy tools for bringing implementation of the International Code on to the national agenda.

The Handbook also presents the ICDC Model Law, which was developed to assist governments in translating the International Code into national measures. The chapters refer to the Model Law as a way of proposing solutions to problems governments have experienced in implementing the Code. The chapters incorporate a wealth of examples from legislation and other measures adopted in over 50 countries.

CHAPTER 1

The International Code: Historical Background

Milk and Murder

Only 30 years ago, it was still a matter of debate as to whether there was a link between advertising of breastmilk substitutes and the declining rate of breastfeeding and associated "bottle-baby syndrome". The syndrome has often been described as the vicious cycle of diarrhoea, dehydration and malnutrition resulting from bottle feeding under less than ideal conditions.[1]

Dr. Cicely Williams, a paediatrician working in Singapore in the late 1930s made that link ahead of others. She spoke of it in a public address to the Rotary Club in 1939 entitled *Milk and Murder.* Dr. Williams decried the promotion of sweetened condensed milk, stating "misguided propaganda on infant feeding should be punished as the most criminal form of sedition and these deaths should be regarded as murder".[2]

Dr. Williams later became the first Director of Maternal and Child Health for the WHO in 1948 and was one of the first proponents of the importance of breastfeeding. Yet it took half a century before breastfeeding became an acceptable topic for government action.

In the sixties, Dr. Williams' warnings were beginning to be echoed by others in the health care profession, notably, Dr. Derrick Jelliffe of the Food and Nutrition Institute in Jamaica. He coined the term *commerciogenic malnutrition* to describe the impact of industry marketing on infant health.[3] Dr. Jelliffe's research in the Caribbean drew attention to the problems caused by bottle feeding. On another continent, Dr. Catherine Wennen, a Dutch paediatrician working in Nigeria in the 1960s, wrote about advertising and other promotional practices of milk companies there in *Tropical and Geographical Medicine.*[4]

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[1] Much of the information in Chapters 1 and 2, unless otherwise noted, comes from Andrew Chetley's detailed account of the events surrounding the development of the *International Code of Marketing of Breastmilk Substitutes* and the worldwide campaign to resolve the problem of aggressive marketing of baby foods. *See* Chetley, A., *The Politics of Baby Foods: Successful challenges to an international marketing strategy,* London: Frances Pinter, 1986 (*hereinafter* Chetley). Details concerning the development and drafting of the International Code were also drawn from Annelies Allain's "IBFAN on the Cutting Edge", *Development Dialogue,* 1989: 2 (revised and published as offprint, April 1991).

[2] Williams, Cicely D., *Milk and Murder,* Address to the Rotary Club of Singapore, 1939.

[3] Jelliffe, D.B., "Commerciogenic Malnutrition?", *Food Technology,* 1971: 25.

[4] Wennen, C.A., "The Decline of Breastfeeding in Nigeria", *Tropical and Geographical Medicine,* 1969: 93-96.

The United Nations (UN) system first became involved in the infant feeding controversy in November 1970. Upon the urging of Dr. Jelliffe, the UN Protein-Calorie Advisory Group (PAG) held a meeting in Bogota, Colombia. There, for the first time, representatives of the industry, UN agencies including UNICEF and the Food and Agriculture Organisation (FAO), and paediatricians discussed industry marketing practices and their relationship to the decline in breastfeeding. A comprehensive public report of this meeting never appeared, but the discussion continued in a series of meetings around the world.

The discussions led PAG to develop a statement, in June 1972, which it later revised in November 1973. The statement reflected the heavy involvement of the industry in the discussions. Rather than moving towards a solution to the problems of artificial feeding, the statement encouraged the development in and introduction of breastmilk substitutes to countries lacking such products; it advocated government subsidies for infant formulas and free distribution to needy families; and encouraged product promotion as a way to inform consumers about nutritious food for children. The PAG statement included only the following two points about marketing: industry personnel should be instructed not to discourage breastfeeding in any way and it is inappropriate to promote to mothers in hospitals just after giving birth.[5]

The PAG Statement was clearly an inadequate public response to the problem. A different sort of response was contemplated by the International Organization of Consumers Unions, (now called Consumers International), which proposed a draft *Code of Practice for Advertising of Infant Foods* to the Codex Alimentarius Commission (Codex) in early 1972. This Commission, created by the FAO and WHO, deals with international standards for quality and labelling of food products. The Codex Commission felt that such a code was outside its area of competence, but fell rather within the purview of WHO and UNICEF.

Publications and lawsuits

In 1973, the issue was thrust into the public limelight when the *New Internationalist,* a British magazine, ran a cover story based on interviews with Dr. David Morley and Dr. Ralph Hendrickse, two paediatricians with long experience in developing countries. The interviews focused on the role of commercial promotion in the decline of breastfeeding and increased infant malnutrition.[6]

The *New Internationalist* used this interview to begin an action campaign for changes in company marketing practices. This led the London-based development agency, War on Want, to publish *The Baby Killer* in March 1974, a devastating report spotlighting promotional methods of milk companies, mainly in Africa.[7]

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[5] UN Protein-Calorie Advisory Group, *Promotion of Special Foods (infant formula and processed protein foods) for Vulnerable Groups,* PAG Statement N° 23, 18 July 1972, revised 28 November 1973.

[6] Geach, H., "The Baby Food Tragedy", *New Internationalist,* August 1973.

[7] Muller, M., *The Baby Killer,* London: War on Want, March 1974, 2nd ed., May 1975.

Soon after, the World Health Assembly recognized the problem for the first time. In a 1974 resolution, the Assembly noted the general decline in breastfeeding in many parts of the world and urged Member States to "review sales promotion activities on baby foods and to introduce appropriate remedial measures, including advertisement codes and legislation where necessary".[8]

In May 1974, a small Swiss student group called Arbeitsgruppe Dritte Welt (Third World Action Group) translated the War on Want publication into German. The group gave *The Baby Killer* a new title, which translates into *Nestlé Kills Babies.* The translated report received wide press coverage in Switzerland, home to Nestlé's corporate headquarters. Nestlé responded by filing a libel suit against the group in July of 1974. Nestlé later offered to settle the case out of court, but the group preferred to go on with the trial, hoping to present the truth to a wider public.

The trial went through three hearings. By the first hearing in November 1975, eight infant food companies formed a council called the International Council of Infant Food Industries (ICIFI). The initial members were Cow & Gate, Dumex, Meiji, Morinaga, Nestlé, Snow Brand, Wakado and Wyeth. ICIFI drafted a *Code of Ethics* and released it to the public two days after the end of the first hearing.[9] ICIFI publicised its Code far and wide in a public relations move to convince the world that the companies were doing something to solve the problem. The ICIFI Code was sadly lacking in marketing restrictions, not even prohibiting mass media advertising. It allowed most promotional practices to continue, provided that breastfeeding was mentioned as the first choice for infant nutrition.

Two months after the second hearing in the Nestlé suit, a lawsuit was filed on the other side of the Atlantic related to the marketing practices of the American company Bristol-Myers, manufacturer of Mead Johnson infant formula. In February 1976, a Bristol-Myers shareholder, a Catholic order of nuns called the Sisters of the Precious Blood, claimed that Bristol-Myers had made misstatements in its proxy statement. The proxy statement said that Bristol-Myers' formula products were neither marketed directly to the public nor promoted in ways that could lead to misuse or harmful effects. The case eventually ended in an out-of-court settlement, but not before the Sisters had gathered sworn affidavits from people in 18 developing countries, creating a great deal of publicity in the United States.

Similarly, in Switzerland, public interest was ablaze over the Nestlé trial as many health professionals came, often at their own expense, to testify about promotional tactics designed to make mothers switch from breast to bottle. The verdict in the Nestlé case was issued in June 1976. The Third World Action Group was found guilty on one count of libel related to the title of the book because it had not proved that Nestlé killed babies in the criminal sense. Nestlé dropped the other three counts. The 13 members of the group were each fined 300 Swiss francs. The judge's words to Nestlé, however, were harsh. In his closing statement, he declared, "If

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[8] Resolution WHA27.43 (1974).

[9] ICIFI, *Code of Ethics and Professional Standards for Advertising, Product Information, Advisory Services for Breastmilk Substitutes,* Zurich: ICIFI, 1975 (amended 1976).

Nestlé S.A. wants to be spared the accusations of immoral and unethical conduct, it will need to change its advertising practices." [10]

One year later, in July 1977, frustration and anger over the continuation of Nestlé's unchanged marketing practices led a group from Minneapolis in the US, the Infant Formula Action Coalition (INFACT), to launch a boycott against Nestlé products. The group chose to boycott Nestlé primarily because it had the largest market share. Thus, changes in Nestlé's marketing policies would likely lead other companies to make similar changes. Moreover, tactics used to pressure American companies, such as shareholder resolutions and lawsuits could not be used in the United States against Swiss-based Nestlé. The Nestlé Boycott steadily gained supporters in the US and later spread to many other countries.

An international meeting

In 1978, United States Senator Edward Kennedy, who then chaired a subcommittee on Health and Scientific Research, decided to hold a hearing on the advertising and promotion of infant formula in developing countries. The Senate Hearing led to a further wave of publicity, which generated more and more pressure on the infant food companies. Senator Kennedy ultimately asked Dr. Halfdan Mahler, Director-General of the WHO, to convene an international meeting on the topic of marketing of breastmilk substitutes.

The industry, represented through ICIFI, was quick to support the idea of an international meeting. Nestlé in particular was seeking strategies to reduce public pressure. "In Nestlé's words '. . . the industry wished to shift the discussion on infant formula marketing back to the sphere of relevant government authorities, health professionals and industry experts.' "[11]

WHO, together with UNICEF, took up this suggestion and held a *Meeting on Infant and Young Child Feeding* in October 1979. The meeting brought together 23 government delegates, 19 delegates from non-governmental organisations (NGOs), 26 from industry and 22 experts specialising in such fields as nutrition, paediatrics, sociology, public health and marketing. There were also 14 officials from the UN and other specialised agencies. This was the first time that peoples' organisations and industry were invited as equal participants with government delegates in a United Nations meeting.

The participants at the meeting split into five working groups. Each group dealt with a specific issue: the encouragement and support of breastfeeding; the promotion and support of appropriate and timely complementary feeding practices; education, training and information on infant and young child feeding; the improvement of the health and social status of women; and appropriate marketing and distribution of infant formula and weaning foods.

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[10] Nestlé, "History", *Baby Milk Issue Facts*, http://www.babymilk.nestle.com/History/Legal+Battle.htm (accessed 3 May 2005).

[11] Chetley, *supra* note 1, p. 57 *(quoting* McComas, M., Fookes, G. and Taucher, G., *The Dilemma of Third World Nutrition: Nestlé and the role of infant formula,* Vevey: Nestlé, 1983, p. 14).

By the end of the meeting, representatives from six of the NGOs decided to form the International Baby Food Action Network (IBFAN), principally to exchange information. One of its objectives was to monitor the marketing practices of the industry around the world and to share and publicise widely the gathered information.

The participants to the 1979 meeting, including the industry representatives, adopted by consensus a *Statement on Infant and Young Child Feeding* and *Recommendations.*[12] One of the most significant recommendations states, "There should be an international code of marketing of infant formula and other products used as breastmilk substitutes."[13] The significance the participants accorded to the impact of marketing is evident in another of the recommendations, which states:

> There should be no marketing or availability of infant formula or weaning foods in a country unless marketing practices are in accord with the national code or legislation if these exist, or, in their absence, with the spirit of this Meeting and the recommendations contained in this report or with any agreed international code. [14]

Drafting the International Code

UNICEF and WHO staff were responsible for the drafting of the International Code but they consulted with experts, government delegations, NGOs and industry, mostly through ICIFI, the association formed during the Nestlé trial in Switzerland. ICIFI refused to acknowledge that the recommendations that came out of the October 1979 meeting should lead to restrictions of their commercial activities. ICIFI was constantly lobbying WHO and UNICEF staff in an attempt to keep the yet to be drafted International Code as unrestrictive and loose as possible. ICIFI went so far in its efforts to influence the drafting process as to hire Dr. Stanislas Flache, a former Assistant Director-General of WHO, as its Secretary-General. Flache began his new post with ICIFI on 1 August 1980, the day after he retired from WHO.

The NGOs, on the other hand, were pushing WHO and UNICEF to make the Code as strong and protective as possible. The NGOs were angered that WHO and UNICEF had adopted a role as mediators between their organisations and industry. The International Code, they felt, should not be a compromise, but should protect infant health.

The WHO Secretariat and UNICEF staff prepared a first draft of the International Code between the end of the October 1979 meeting and February 1980. In February 1980, the two agencies held a consultation with experts, who felt the draft was good, but needed more precision. A similar consultation was held with NGOs one week later with a similar conclusion. Nearly 50 governments also sent comments on the International Code.

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[12] WHO and UNICEF, "WHO/UNICEF Meeting on Infant and Young Child Feeding", *WHO Chronicle*, 1979, 33: 435-43.
[13] *Ibid.,* p. 442.
[14] *Ibid.,* p. 443.

In its comments, the United States called for a voluntary code that would be, "subject to full intergovernmental negotiations", meaning that it should not be left to the WHO Secretariat and UNICEF staff to draft the International Code. Proponents of the International Code saw this suggestion as one that would surely prolong the process and weaken the resulting document.

A second draft was ready in time for the May 1980 World Health Assembly and had been commented on by governments, industry, NGOs, UN agencies and experts. The majority of governments were in favour of the draft, but some of the major milk-exporting countries, including the United States, rejected it.

At the May 1980 Assembly, the United States made a last minute attempt to incorporate the idea of international negotiations into the resolution, which was being finalised by a drafting group. The attempt was unsuccessful. The resolution was carried, adopting the recommendations that had come out of the October 1979 meeting. WHO and UNICEF were to carry on developing the International Code in close consultation with Member States and with all other concerned parties. The International Code was to be governed, *inter alia,* by the following principles:

(i) the production, storage and distribution, as well as advertising, of infant feeding products should be subject to national legislation or regulations, or other measures as appropriate to the country concerned;

(ii) relevant information on infant feeding should be provided by the health care system of the country in which the product is consumed;

(iii) products should meet international standards of quality and presentation, in particular those developed by the Codex Alimentarius Commission, and their labels should clearly inform the public of the superiority of breastfeeding.[15]

The resolution further stated that the International Code was to be submitted to the WHO Executive Board for consideration at its next session and gave the Director-General the choice of submitting the International Code as either a regulation or a recommendation.[16]

WHO and UNICEF prepared a third draft and held two more consultations in August and September 1980. The first consultation included all of the groups from the 1979 meeting, except governments, who attended the second consultation. The legal form the International Code would take, in other words, what binding force it would have, was one of the pressing issues discussed by the participants.

The WHO Constitution gives WHA the power to adopt conventions, regulations and recommendations.[17] A convention creates a binding relationship between participating nations or international organisations and operates under the principles of international law. It requires a two-thirds majority of the WHA and comes into force for each Member State when ratified in

[15] Resolution WHA33.32 (1980) ¶ 6(4).
[16] *Ibid.*, ¶ 6(5).
[17] *Constitution of the World Health Organization,* Articles 19, 21 & 23 (*hereinafter* WHO Constitution).

accordance with the Member's constitutional process.[18] The 1980 Assembly, however, did not make a convention one of the options. In any case, according to Andrew Chetley, who has chronicled the events surrounding the adoption of the Internatinal Code, a convention "would take too long to come into force and would involve too much political manoeuvering to ensure getting the necessary two-thirds vote at the WHA".[19]

Regulation or recommendation?

In contrast to a convention, WHA regulations require only a majority of the Members present for adoption. Regulations come into force for all Member States after due notice of their adoption by the Assembly, except for those Member States that reject the regulation or express reservations within a specified time-period.[20]

The World Health Assembly may also make recommendations to Member States regarding any matter within its competence.[21] Dr. Sami Shubber, a former Senior Legal Officer at WHO states that although recommendations are generally not binding, they "carry moral or political weight, as they constitute the judgment on a health issue of the collective membership of the highest international body in the field of health".[22]

During the August and September consultations, the question of what legal form the International Code would take, (regulation or recommendation) was never formally raised, although there was much negotiating taking place in the corridors, notably by American government participants and industry lobbyists. According to the American participants of the government consultation, the legal nature of the International Code was the most important issue for almost all of the countries that had participated in an earlier meeting of industrialised countries.[23]

The Americans lobbied not only other country delegations, but WHO staff as well. While the final decisions would rest with governments, WHO officials could be very influential behind the scenes. These officials were keen to achieve a consensus about the International Code and realised that pushing for a regulation might jeopardize that goal. The WHO Secretariat was under pressure from different camps but was eager to please the United States and the other industrialised countries. "With the United States paying for 25 percent of the WHO's regular budget and another dozen industrialised countries boosting that figure to 70 percent, WHO had to listen very carefully to what the industrialised countries were saying."[24]

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[18] *Ibid.*, Article 19.
[19] Chetley, *supra* note 1, p. 80. At the time the International Code was drafted, WHO had never, since its founding in 1946, adopted a convention, and had adopted only two regulations, neither one on a controversial topic. *Ibid.,* p. 87 n. 23. WHO has since adopted the Framework Convention on Tobacco Control in 2003.
[20] WHO Constitution, *supra* note 17, Articles 22 & 60(b).
[21] *Ibid*., Article 23.
[22] Shubber, S., "The International Code of Marketing of Breastmilk Substitutes", *International Digest of Health Legislation,* 1985, 36: 884.
[23] Chetley, *supra* note 1, p. 83.
[24] *Ibid.,* p. 84.

After the September consultation, the WHO Secretariat and UNICEF staff completed the drafting process. The fourth draft went through four revisions. War on Want, which had been a key group in bringing the whole infant feeding issue to light, felt that although the fourth draft had been the best so far, each revision reflected increasing industry influence and the wording had become less and less clear.[25]

By the time the International Code was ready, WHO officials, mainly under US pressure, had decided to press for a recommendation and not a regulation. WHO was relying on the United States to ensure, in exchange, that it would get the support of the other industrialised countries for a unanimous vote and a strong resolution. WHO also wanted to make sure that the content of the International Code would not be watered down. The final decision regarding legal form would, however, take place at the WHO Executive Board meeting and the May 1981 World Health Assembly.

The fourth draft of the International Code was submitted to the WHO Executive Board in January 1981. Only a few of the 33 Board Members expressed a clear preference that the International Code be adopted as a recommendation. Nine were staunchly in favour of a regulation. Six others also favoured a regulation, but accepted that a unanimous recommendation would be stronger than a regulation supported by only a majority of the Assembly. Two Members suggested that a recommendation be tried for two or three years and then strengthened to a regulation if necessary. The United States obtained special permission to address the Executive Board and indirectly stated that it would not support the International Code if it were presented as a regulation.

The Executive Board approved the draft International Code without changes and, in a resolution, asked the WHA to adopt it as a recommendation, with the clear understanding that support would be unanimous at the World Health Assembly.[26]

Between the January Executive Board meeting and the May Assembly, the American companies lobbied the US government against voting in favour of the International Code. They were worried about setting a precedent whereby UN agencies could interfere with 'commercial freedom of expression'. If the UN were to restrict marketing of baby foods, they claimed, the drug companies would be next. The International Code might be good for health but it was bad for business.

Subject to this corporate lobby by the three American infant food companies and others, was a government in the throes of an election year. While the previous administration had lobbied other delegations as well as the WHO Secretariat into believing that the US would agree to the Code if it were adopted as a recommendation, the winds changed as Ronald Reagan took over the US Presidency.

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[25] *Ibid.*

[26] Executive Board of the World Health Organization, Resolution 67.R12, January 1981.

Voting at the World Health Assembly

When the Assembly opened in May 1981, the US delegation did not have firm instructions on how it was to vote. Yet, by the end of the second week, word got out that the United States would definitely oppose the International Code. Among the roughly 2,000 delegates to the Assembly, IBFAN had been able to bring 40 representatives of small groups from all over the world. Half of them came to Geneva early and helped to lobby national delegations, the other half came to witness the historic vote and make sure that governments, once back home, would not be able to forget their commitments made at the Assembly.

Industry also had a strong presence at the Assembly, which it used to lobby government delegates against voting for the Code. ICIFI hosted a hospitality and information suite at Geneva's luxurious Intercontinental Hotel where visiting delegates and journalists were offered food and drink. All government delegates were invited to visit the suite. Industry lobbyists were also wining and dining delegates at expensive restaurants in order to convince them that the International Code was flawed.

On 20 May 1981, the International Code came up for debate at the WHA. More than 50 countries had registered their desire to speak with more to follow and the WHO Secretariat was worried about the time the discussion might take. There was also uncertainty about how they might handle all kinds of amendments and pressures. Hence, a secret arrangement had been made for the delegation from Belgium to move for "closure of debate" towards the end of the afternoon. Belgium made the motion, but much too early, after only nine delegations had spoken.

Once a debate is officially closed, the item under discussion, in this case the International Code, comes immediately to a vote. Two countries, Chad and Bangladesh, angry and confused, found themselves voting against the International Code while they thought they were still opposing the motion to close the debate. Several others were not present because they were convinced the debate would go on until the next day or longer. Fortunately others were quick to react and knew the Assembly's protocol. Dr. Ondaye of the Congo instantly called for a roll-call vote, meaning that each country would have to clearly indicate its position: in favour, against or abstention. WHO tries to avoid roll-call votes because they take much longer than a simple show of hands and more significantly, because it is potentially embarrassing for governments to have their individual positions known to the world. IBFAN wanted exactly that and knew that very few countries would dare to publicly vote against the International Code.

The vote that afternoon was 93 in favour, three against (the USA, Bangladesh and Chad) and nine abstentions. It was clear to IBFAN, observers and lobbyists that some of the votes had been cast in confusion and could be reversed. The following day at the plenary, Committee reports came for final approval, normally a quick formality. This time, however, another roll-call vote was demanded and the final results were different: 118 in favour, one against (the US) and three abstentions (Argentina, Japan and Korea). Spontaneous applause welcomed the International Code and up in the public gallery a baby started crying. The Assembly chairperson heard it and said the baby was reminding everybody of what was really at stake.

The International Code was adopted as an annex to the 1981 World Health Assembly Resolution 34.22. Resolution 34.22 urges 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".

Public opinion in the United States was aroused over the lone negative vote against the International Code. A flurry of editorials appeared in newspapers across the United States expressing dismay and disappointment over the US government's decision. Two officials from the US Agency for International Development (USAID), Dr. Stephen Joseph, the organisation's chief health professional and Eugene Babb, Deputy Assistant Administrator for Food and Nutrition, resigned from their positions in reaction to the US vote. Congressional hearings were called to examine the vote and public demonstrations were held in five American cities.

Giving effect to the International Code

WHA's adoption of the International Code was the end of one process and the beginning of another: that of implementation. Article 11 of the International Code directs Member States to report each year to WHO regarding action taken at the national level to give effect to the Code. It also requires the WHO Director-General to report to the Assembly in even years regarding the status of implementation. No similar mechanism was built into the International Code for monitoring and enforcing compliance by the companies.

Prior to the adoption of the International Code, the new President of ICIFI, who was also a Nestlé vice-president, had called it highly restrictive, irrelevant and unworkable.[27] Shortly after the International Code was adopted, however, in a sudden switch, Nestlé went all out to improve its public image. One of its first efforts was to hold a large press conference in March 1982 where it presented policy guidelines that it would apply in countries that had not yet implemented the International Code. Nestlé also made public a set of its instructions to Nestlé staff reflecting its interpretation of the various articles of the International Code.[28]

In another reaction to public criticism, the company announced the formation of the Nestlé Infant Formula Audit Commission on opening day of the 1982 World Health Assembly. The Commission, which was selected and financed by Nestlé, was to independently audit the company's implementation of its instructions on the International Code. During the 1982 World Health Assembly several delegates criticised the Nestlé instructions, UNICEF and a group of independent legal experts attending a WHO meeting on Code implementation in June 1982 also criticised the Nestlé instructions. In reaction to the strong criticism, Nestlé issued a revised set of instructions in October 1982.[29]

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[27] Saunders, E.W., President of ICIFI, Letter to WHO Executive Board, January 1981.

[28] Nestlé, *WHO International Code of Marketing of Breastmilk Substitutes: Instructions to all companies of the Nestlé Group and to agents and distributors who market infant formula under trade marks owned by Nestlé,* Vevey: Nestlé, February 1982.

[29] Nestlé, *WHO International Code of Marketing of Breastmilk Substitutes: Revised instructions to companies of the Nestlé Group and to agents and distributors who market infant formula under trade marks owned by the Nestlé Group,* Vevey: Nestlé, October 1982.

The first status report on compliance with and implementation of the International Code was to come at the 1983 World Health Assembly, as requested in the 1981 resolution adopting the Code. The 1981 resolution had also requested the Director-General to make proposals, if necessary, for revision of the text and for measures needed for effective application. This reflected the earlier suggestion made to the 1981 Executive Board that the legal status of the International Code be changed to a regulation if deemed necessary after several years.

Such a change, however, did not take place. Informally, delegates were warned by the WHO Secretariat that opening up the International Code would be like opening Pandora's box; everyone would seek to change and weaken it. As it turned out, the 1983 WHA did not recommend any change to the text of the International Code nor to its form. The Director-General's report to the 1983 WHA noted that no Member State had proposed any revision in form or in content and suggested, "it would be premature at this time to propose any revision".[30] Thus, the International Code as adopted in 1981 was likely to be final at the international level. Only at the national level might it be strengthened and modified to fit national situations.

[30] WHO Director-General, *Infant and Young Child Nutrition: Including the nutritional value and safety of products specifically intended for infant and young child feeding and the status of compliance with and implementation of the International Code of Marketing of Breastmilk Substitutes,* Report A36/7 to WHA, Geneva, 15 March 1983.

CHAPTER 2

The International Code: Post-Adoption Developments

The International Code was adopted by a resolution of the World Health Assembly. As explained in Chapter 1, WHA resolutions are recommendations that carry moral or political weight as judgments on health issues of the collective membership of the world's highest international body in the field of health.[1] Since the WHA adopted the International Code, it has adopted other resolutions concerning infant and young child nutrition.

Some of the subsequent WHA resolutions clarify questions that have arisen over the years concerning the interpretation of certain articles of the International Code. The later resolutions also serve to keep the International Code up to date with scientific developments and changes in marketing practices. The subsequent resolutions have the same status as the 1981 WHA resolution adopting the International Code. This Chapter examines international events after the adoption of the International Code, subsequent WHA resolutions and other international developments related to infant and young child feeding.

Ending the first Nestlé Boycott

At the time of the 1983 World Health Assembly, representatives from the IBFAN groups that had been boycotting Nestlé in the United States, Canada, the United Kingdom, Sweden and Germany met to plan and coordinate their activities. The groups decided to continue the Boycott despite Nestlé's stated policy changes, because the changes reflected an inadequate interpretation of the Code and because Nestlé was still marketing in ways that violated the International Code. As long as Nestlé controlled half the world's market in baby food, the groups reasoned, it could clearly expect to have to bear the brunt of public criticism. Moreover, it was clear that if the market leader were to decide on changes, smaller companies would have to follow suit.

In early 1983, the Boycott groups circulated a petition calling on Nestlé to abide by the International Code in full. Signatures were collected from 38 countries and totalled 112,000. The groups delivered these, nicely labelled, in a baby carriage to the annual Nestlé shareholders' meeting and also sent a joint letter to the company to inform it of the groups' commitment to intensify and expand the Boycott internationally and to act as a united front. The letter called

[1] *See* Chapter 1, p. 11.

on Nestlé to negotiate with the International Nestlé Boycott Committee (INBC), which had been formed in 1979 to represent the various Boycotting organisations.

As a basis for such negotiations, INBC drew up a position paper outlining the four substantive points of difference it saw between the Nestlé instructions and the International Code. At a press conference on 15 December 1983, INBC announced that it would recommend suspension of the Boycott if Nestlé were to make significant improvements in these four areas.

In the early part of January 1984, Nestlé did finally sit down for a series of meetings with INBC, but insisted they were not negotiations. Nestlé made concessions and promises on each of the four points. On 25 January 1984, an INBC representative and the Vice-President of Nestlé announced in a joint statement that INBC would recommend a suspension of the Boycott at the international level and that it was suspending it immediately in the United States.

INBC had decided to invite all the groups involved in IBFAN to a conference in Mexico in order to put more pressure on the company and explain the negotiations with Nestlé. At the Mexico conference, in February 1984, the Boycott leaders, notably the US INFACT, had a difficult time justifying the reasons for recommending the suspension of the Nestlé Boycott. After long and trying discussions, the hundred or so participants finally agreed to suspend the Boycott for six months while the network performed extensive monitoring to see whether Nestlé was indeed complying with the International Code.

The main difference of opinion was over the principle of "universality": was it a Third World issue or should breastfeeding be protected all over the world? The difficulty arose because INFACT, who was negotiating with Nestlé on behalf of INBC, neglected to take into account certain views of INBC as a whole when it announced an end to the Boycott. Most of the other Boycott groups, particularly the Europeans, felt that the Boycott should not be ended until Nestlé complied with the International Code in all countries, not only in developing countries.

In September 1984, INBC and Nestlé held a joint press conference announcing the end of the first international boycott against Nestlé. The monitoring results had not been conclusive and 'goodwill' prevailed.

Free supplies

Among the four points that had been raised by the INBC position paper as an area for improvement by Nestlé was what came to be known as *free supplies*. Research by IBFAN and other consumer groups into industry marketing practices had for a long time shown that in most industrialised countries and in many developing countries, companies gave large quantities of free infant formula and sometimes feeding bottles to hospitals on a regular basis.

Many hospitals received unsolicited cartons of formula every month from a number of companies. As a result, nearly all mothers in those hospitals received free formula during their stay in the hospital and samples upon discharge. This practice was extremely harmful to efforts to encourage breastfeeding and hospitals had become dependent on the free supplies of formula. Bottle feeding had become the normal way to feed newborns in the hospital. Mothers saw

hospital use of formula as an endorsement of the practice by the medical profession. Moreover, much evidence was collected in later years to show that even a bottle or two in the first few days reduces significantly the likelihood of a mother successfully breastfeeding.

During the consultations to draft the International Code, *free supplies* had been discussed extensively and seemingly solved by Article 6, paragraphs 6 and 7. Article 6 allows donations of supplies of products (defined as quantities provided for an extended time, free or at low price, for social purposes) to institutions or organisations to be used only for "infants who have to be fed on breastmilk substitutes".

According to Dr. Halfdan Mahler, who was Director-General of the WHO when the International Code was drafted, the term *institutions and organisations* was intended "to mean orphanages and similar social welfare agencies. They were not intended to refer to direct health care providers, that is to say health care facilities such as hospitals and maternities, where in most cases infants remain for only a limited period before rejoining their families at home".[2]

Several of the government officials consulted when the International Code was being drafted had considerable experience in hospitals and had trouble believing that hospitals could afford to purchase the required amounts of formula. These were health professionals who had been trained in the heyday of bottle feeding and could not conceive of a hospital with 98 percent breastfeeding rates. They wanted to allow for a restrained but continued flow of free formula for those in need.

Monitoring after adoption of the International Code showed that most companies continued to give unlimited free supplies. Nestlé, the only company claiming at the time to abide by the International Code, stated that the Code did not preclude it from giving free formula to hospitals. In its February 1982 instructions to marketing personnel, Nestlé had initiated a supply/request procedure whereby health authorities could request free formula on a special form. There were no limits to the amount that could be requested.

Nestlé argued, for one, that Articles 6.6 and 6.7 were addressed to governments, not to industry. It further noted that it gave supplies only upon request and that it was up to the hospital to determine how to distribute them. It was out of Nestlé's control if the hospital chose to give samples on discharge. Companies also contended that they could give supplies to hospitals and maternities because in their view, any child whose mother does not breastfeed for whatever reason, "has to be fed on breastmilk substitutes". Its economic argument was that unilateral action would make no useful contribution to changing the situation, as other companies would be more than willing to provide the supplies that Nestlé refused to give.

In 1982, WHO and UNICEF had issued *Notes on the International Code of Marketing of Breastmilk Substitutes* in which the two agencies attempted to provide some guidance on the meaning of Article 6. The *Notes* stated that breastmilk substitutes should be used only when necessary, for example on "medical, economic, or social grounds".[3]

[2] Dr. H. Mahler, Director-General of WHO, Letter to the Finnish Minister of Health, 29 August 1985.
[3] WHO and UNICEF, *Infant and Young Child Feeding: Notes on the International Code of Marketing of Breastmilk Substitutes,* Geneva, 1982.

That commentary did not solve the problem because industry did not consider itself bound to stop giving free supplies. During the negotiations between INBC and Nestlé, which led to the end of the first Nestlé Boycott, Nestlé agreed that supplies should only be made available to mothers of infants who *need* to be artificially fed. Nestlé had agreed to accept whatever definition of *need* that UNICEF developed.

Defining the word 'need'

WHO and UNICEF eventually agreed that a definition of which "infants have to be fed on breastmilk substitutes" was necessary. The WHO Secretariat, however, felt that it could only develop general guidelines and the task of creating definitions was within the role of the WHA. A plan was eventually developed whereby a few governments would be encouraged to request technical assistance from WHO on the meaning of the terms in Article 6.6, thus forcing the organisation to provide clarification.

Meanwhile, IBFAN decided to put more of its own pressure on WHO and UNICEF and initiated an international campaign towards developing a consensus definition of *need*. A definition was developed and circulated to hundreds of health professionals around the world who signed petitions in support.

At the 1985 World Health Assembly, delegates from a number of countries requested WHO to provide clarification about the meaning of the phrase "infants who have to be fed on breastmilk substitutes". The Assembly called for a joint consultation to produce a definition of the phrase.

The Technical Consultation was held in Geneva, December 17-18, 1985. The participants included ten experts in the fields of paediatrics, nutrition, obstetrics and gynaecology, public health and social welfare as well as WHO and UNICEF staff. The report of the Technical Consultation reflected the views of the group of experts. The experts concluded:

> The number of infants who need to be fed on breastmilk substitutes for absolute physiopathological or socioeconomic reasons is very small. In maternity wards and hospitals this number is smaller still since some of the conditions on which this need is based only manifest themselves after a mother and her infant have been discharged. Thus, the routine availability of breastmilk substitutes, which are not only unnecessary but potentially dangerous because they could increase the likelihood of their being used to the detriment of breastfeeding, should not be permitted in maternity wards and hospitals. Since only very small quantities of breastmilk substitutes are ordinarily required to meet the needs of a minority of infants in these facilities, they should be acquired through normal purchasing channels. Maternity wards and hospitals should not be recipients of free or subsidised supplies of breastmilk substitutes.[4]

[4] WHO, *Report of a Joint WHO/UNICEF Consultation Concerning "Infants who have to be fed on Breastmilk Substitutes",* Geneva, 17-18 December 1985, WHO/MCH/NUT/86.1, April 1986.

Following the Technicial Consultation with its concise report, WHO in consultation with UNICEF, published *Guidelines concerning the Main Health and Socioeconomic Circumstances in which Infants have to be fed on Breastmilk Substitutes* and submitted the Guidelines to the 1986 World Health Assembly.[5] While the Guidelines outlined in detail the needs of infants in different circumstances, they did not address the question of marketing and the practice of free supplies to hospitals as the report of the Technical Consultation had done. The Assembly, however, was not dissuaded and, led by Dr. O. Ransome-Kuti, the Nigerian Minister of Health, adopted Resolution 39.28, which incorporates the conclusion that had come out of the Technical Consultation. Resolution 39.28 urges Member States to

> ensure that the small amounts of breastmilk substitutes needed for the minority of infants who require them in maternity wards and hospitals are made available through the normal procurement channels and not through free or subsidized supplies.

Resolution 39.28 touches on two other important issues, that of marketing of follow-up milks and complementary foods. The resolution draws the attention of Member States to the following:

(a) any food or drink given before complementary feeding is nutritionally required may interfere with the initiation or maintenance of breastfeeding and therefore should neither be promoted nor encouraged for use by infants during this period;
(b) the practice being introduced in some countries of providing infants with specially formulated milks (so-called "follow-up" milks) is not necessary.

Even this strong resolution discouraging free supplies, however, failed to convince the companies to change their practices. Not considering themselves bound by the 1986 resolution, the companies continued to give free supplies. For example, in 1987, American Home Products, manufacturers of Wyeth infant foods, stated that it complied with the International Code, but that the 1986 resolution was addressed to Member States and not to manufacturers.[6] It would comply only if required by national law or policy. The Ross Laboratories division of Abbott-Ross, manufacturer of *Similac* and other infant foods, made a similar disclaimer of responsibility and stated that the resolution did not alter the International Code in any way. The company also stated that donated formula was the "normal procurement channel" in many hospitals.[7]

Despite Nestlé's 1984 agreement to abide by whatever definition would be adopted of *need*, it also used every angle to avoid compliance. Nestlé claimed that Resolution 39.28 did not modify the International Code, which it intended to follow. Further, as the resolution was directed at governments, it would wait for government action.

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[5] WHO, *Guidelines Concerning the Main Health and Socioeconomic Circumstances in which Infants have to be fed on Breastmilk Substitutes,* A39/8 Add. 1, Geneva, April 1986.
[6] Emerling, C.G., American Home Products Corp., Letter to Ms Dorothy L. Smith, 13 February 1987.
[7] McCollough, T.D., Ross Laboratories, Letter to Dorothy Smith, 18 February 1987.

After two years of such arguments and no action, an American NGO, Action for Corporate Accountability, whose predecessor INFACT had been among the boycotting groups, announced in 1988 the beginning of a new boycott against Nestlé. Its main challenge to the company was to halt free supplies. Nestlé declined to respond formally until the middle of 1989 when it announced a *10-point plan*, which would include a phased withdrawal of supplies in certain countries. Moreover, the company would study the problem further by ending free supplies in Cote d'Ivoire, Thailand and Mexico to determine whether the practice was indeed harmful.[8]

Up to this time, the International Code and subsequent World Health Assembly resolutions were the only international documents that addressed the need to promote and protect breastfeeding. The end of the 1980s, however, saw the beginning of a series of historic United Nations meetings and conferences that put breastfeeding firmly on the international agenda for policy formation.

Baby-friendly hospitals

In 1989, WHO and UNICEF published the Joint Statement *Protecting, Promoting and Supporting Breastfeeding: The special role of maternity services.* The statement succinctly lists *Ten Steps to Successful Breastfeeding* and urges each facility providing maternity services to carry out these steps. Among the ten steps is one that requires training of health care staff in breastfeeding skills and another that changes the practice of separating mother and baby to that of 'rooming-in'. Breastfeeding is to be initiated within one-half hour of birth and breastfeeding on demand is to be encouraged. Newborns in a baby-friendly hospital are given no food or drink other than breastmilk unless medically indicated. This step helped to reduce the use of free supplies. The Joint Statement had been developed as UNICEF became more and more aware that low breastfeeding rates in maternity wards was not only due to the availability of free formula, but also because of the lack of knowledge among health workers about breastfeeding.

In August 1990 a group of high-level policy makers from 32 countries and 10 United Nations agencies gathered in Florence, Italy, for a meeting sponsored jointly by UNICEF, WHO, USAID and the Swedish International Development Authority. The participants to the meeting adopted the *Innocenti Declaration,* which called for concrete actions for governments to take by 1995, including taking action to implement the International Code and the relevant subsequent resolutions of the World Health Assembly.[9] The strongly-worded declaration was endorsed by world leaders attending the World Summit for Children in September 1990. The World Health Assembly officially endorsed the *Innocenti Declaration* in May 1992.

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[8] Nestlé, *Nestlé and the Infant Feeding Controversy,* Vevey: Nestlé 1993, p. 4.

[9] WHO and UNICEF, *Innocenti Declaration on the Protection, Promotion and Support of Breastfeeding*, adopted July 1990 at policy-makers meeting on "Breastfeeding in the 1990s: A Global Initiative", Florence Italy, 30 July to 1 August 1990. The Declaration's four operational goals for all governments include appointing a national breastfeeding coordinator and national committee; ensuring that all maternity facilities practice the "Ten Steps to Successful Breastfeeding"; taking action to implement the International Code of Marketing of Breastmilk Substitutes and enacting legislation protecting the breastfeeding rights of working women.

With policy makers committed in writing to certain goals in support of breastfeeding, a consortium of major international non-governmental organisations joined together in February 1991 to form the World Alliance for Breastfeeding Action (WABA). The main focus of WABA is the achievement of the operational targets of the *Innocenti Declaration.* WABA organises World Breastfeeding Week each year during the first week of August. In 1994, the theme was "Making the Code work!"

In May 1991, the UNICEF Executive Board endorsed the *Innocenti Declaration*.[10] The Executive Board resolution was followed by the historic launch in June 1991 of the *Baby Friendly Hospital Initiative* (BFHI) at a meeting of the International Paediatric Association (IPA) in Ankara, Turkey. The joint UNICEF/WHO initiative is aimed at promoting adoption of the *Ten Steps to Successful Breastfeeding* in hospitals worldwide. The BFHI is designed to remove hospital barriers to breastfeeding by creating a supportive environment with trained and knowledgeable health workers.

The programme began with 12 starter countries before being expanded to countries around the world. By the end of 2001, the Initiative was being implemented in about 16,000 hospitals in 171 countries.[11] The Initiative has had a major impact on changing hospital practices and raising awareness about the importance of breastfeeding all over the world. A 2004 study conducted in Scotland showed that babies born in *baby-friendly* hospitals were 28 percent more likely to be exclusively breastfeeding seven days after birth than those born in other hospitals.[12]

Like any programme, however, if momentum is not maintained, it will begin to falter. Despite studies indicating that the Initiative can significantly increase duration and exclusivity of breastfeeding, some countries reported to WHO that commitment to the programme was weakening. Hospitals interpret diminishing input of resources from WHO and UNICEF as a sign of reduced international interest.[13] In June 2001, WHO and UNICEF convened a meeting of coordinators of BFHI programmes from 18 industrialised countries to assess obstacles and strategies for the success of the programme. In 2005, on the occasion of the 15-year anniversary of the *Innocenti Declaration*, a meeting will be convened to assess progress towards the four targets set in 1990.

No ads in the US

In the United States, where free trade often reigns above other concerns, the Department of Health and Human Services felt it was necessary to adapt the *Ten Steps* in order to make the BFHI feasible for the country. By 1995, 143 American hospitals had received certificates of intent to become *Baby Friendly*, but most hospitals, being privately owned, can choose to

[10] UNICEF Executive Board, Resolution 1991/22, New York, 1991.
[11] WHO, *Childhood Nutrition and Progress in Implementing the International Code of Marketing of Breastmilk Substitutes*, Report by the Secretariat, EB109/11, 11 December 2001 (*hereinafter* WHO Progress Report), p. 4.
[12] Broadfoot, M. et al., "The Baby Friendly Hospital Initiative and Breastfeeding Rates in Scotland", *Archives of Disease in Childhood, Fetal and Neonatal Edition,* 2005, 90: 114-16.
[13] WHO Progress Report, *supra* note 11, p. 4.

ignore initiatives of the Health Department.[14] Even without *Baby Friendly* hospitals, however, Americans had been spared media advertising of infant formula for many years.

This ironic development in the only country to vote against the International Code was not accidental. A voluntary ban on advertising had been practised for years between the three American producers of infant formula. Each of the three companies also sells pharmaceuticals and had built up an extensive network of selling through the doctors and hospitals and had no need to advertise directly to the public.

In the mid-1980s, Nestlé entered the American market by buying the Carnation company and launching two new brands of infant formula. Unlike the other American companies, Nestlé ignored the anti-advertising agreement and marketed these two brands directly to the consumer. In 1993, Nestlé filed a lawsuit against two of the American manufacturers as well as the AAP alleging that the agreement not to advertise created an artificial barrier to trade in violation of American anti-trust law. The lawsuit was ultimately settled out of court, but did little for the campaign in the United States to implement the principles of the International Code.

Free supplies revisited

Despite the positive developments at the international level to protect, promote and support breastfeeding, companies continued to donate free supplies to hospitals. In 1991, international efforts were renewed to end free and low-cost supplies beause they had been universally recognised as harmful. Even a Nestlé-funded study conducted in Mexico indicated that "hospital procedures often result in the use of free and low-cost supplies in ways that do not encourage breastfeeding".[15] On July 15, 1991, the General Synod of the Church of England voted to back the Boycott of Nestlé *Nescafé* and demanded that Nestlé stop giving free supplies of breastmilk substitutes in hospitals and maternity wards.

The cessation of free supplies had been built in as a goal of the BFHI. UNICEF and WHO were working with two complementary strategies: one to encourage health facilities to implement the *Ten Steps to Successful Breastfeeding*, and the other to encourage industry and governments to take action to end free supplies. The 1991 UNICEF Executive Board resolution had called on manufacturers and distributors to stop supplying free breastmilk substitutes to maternities and hospitals by the end of 1992.[16] The World Health Assembly, at its annual meeting in 1992 also adopted a strong resolution calling on companies to end the practice of donating free supplies in health care facilities providing maternity services.[17]

The infant food companies, through the International Association of Infant Food Manufacturers (IFM), the trade association that succeeded ICIFI, responded by agreeing to work with

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[14] Baumslag, N., *Milk, Money and Madness: The culture and politics of breastfeeding,* Westport, Connecticut: Bergin & Garvey, 1995, p. 176.
[15] Nestlé Corporate Affairs Department, *Policy Update*, Vevey, Switzerland: December 1990.
[16] UNICEF Executive Board Resolution 1991/22, New York, 1991.
[17] Resolution WHA45.34 (1992).

governments one-by-one to develop regulatory or other official measures to end free supplies by the end of 1992.[18] WHO and UNICEF wrote a joint letter to the heads of all countries asking for their personal support for the BFHI, including the elimination of donations of breastmilk substitutes as an important element in promoting breastfeeding.[19]

Yet the IFM had agreed only to work in *developing* countries. When pushed for a definition of *developing*, IFM proposed to focus on those countries with an infant mortality rate of more than 12 per thousand. UNICEF and WHO encouraged the companies to also refrain from initiating free supplies in countries where they had never engaged in this practice in the past including central and eastern Europe and the independent states of the former Soviet Union. The International Code and other WHA resolutions clearly apply to all countries and although these were efforts to facilitate a step-by-step implementation, ultimately, the companies have to halt free supplies everywhere.

Throughout the next few years, many countries issued directives or circulars forbidding health care facilities to accept free or low-cost supplies. Other governments entered into agreements with the infant food companies to end such practices. Yet by 1994 the practice of giving free supplies was still occurring. For the most part, industry's commitment to end supplies applied only to infant formula, not to other products like feeding bottles and teats. In addition, even where they had stopped donating formulas to maternities, companies started using the backdoor by supplying formula to paediatric wards and other health services. Giving free or low cost supplies was obviously too profitable for companies to easily abandon. They were using all possible loopholes to continue the process. In 1994, the World Health Assembly felt compelled to restrict the marketing practices more clearly and resolved that Member States should

> ensure that there are no donations of free or subsidized supplies of breastmilk substitutes and other products covered by the International Code of Marketing of Breastmilk Substitutes in any part of the health care system.[20]

This resolution is important because it clarified the International Code and WHA resolutions, and made the entire health care system off-limits for supplies. Also, for the first time, the United States did not oppose a resolution concerning the International Code. After lengthy debate, the resolution was adopted by full consensus of the Assembly.

Recommended length of exclusive breastfeeding

In 1991, WHO developed breastfeeding indicators and defined an exclusively breastfed infant as one who receives only breastmilk and no other liquids or solids.[21] Research showing that exclusive breastfeeding is much safer than breastfeeding mixed with water, infant formula,

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[18] IFM, Letter to James P. Grant, 18 June 1991.

[19] Nakajima, H., Director-General of WHO and Grant, J.P., Executive Director of UNICEF, Letter to Heads of States, 30 August 1991.

[20] Resolution WHA47.5 (1994).

[21] WHO, Division of Child Health and Development, "Indicators for Assessing Breastfeeding Practices", reprinted report of an informal meeting, 11 -12 June 1991, Geneva. The definition includes infants who receive vitamins, mineral supplements or medicines in drops or syrup.

cow's milk, cereal mixes or other foods or drinks is relatively recent.[22] Research also indicates that mothers all over the world supplement breastmilk with liquids or foods very soon after birth. The evidence showing the value of exclusive breastfeeding continues to grow and includes decrease in disease, better growth, longer duration of breastfeeding and fewer pregnancies.[23]

In response to the growing evidence of its importance, international policy-makers began to promote exclusive breastfeeding as the optimal way to feed a child. It was only recently, however, that a consensus was reached over how long a baby should be breastfed exclusively. Previously, there had been debate over what was known as the 'weanling's dilemma' or the choice, mainly in developing countries, between the known protective effect of exclusive breastfeeding against infection and the possibility that breastmilk alone may not be sufficient to satisfy the infant's energy and micronutrient requirements after four months of age.

For many years, international infant feeding recommendations suggested that complementary foods be added to an infant's diet between four and six months.[24] Yet the Committee on Nutrition of the American Academy of Pediatrics had already stated back in 1980, "breastmilk meets all known nutritional requirements of the average infant for the first six months of life and for breast-fed infants there are no apparent advantages and (some) disadvantages to early complementary feeding".[25] Since the adoption of the *Innocenti Declaration* many health care organisations and individual health professionals had been urging WHO to adopt a recommendation of exclusive breastfeeding for a full six months as the optimal way to feed an infant.

In 1994, the World Health Assembly moved closer to this position when it urged Member States to foster "appropriate complementary feeding practices from the age of about six months."[26] The same resolution emphasised continued breastfeeding as well as feeding with foods grown or made locally rather than expensive, imported processed foods or follow-up milk. In 1996, the Assembly urged Member States to "ensure that complementary foods are not marketed for or used in ways that undermine exclusive and sustained breastfeeding".[27]

Despite the 1994 WHA resolution recommending exclusive breastfeeding for about six months, WHO continued to refer to exclusive breastfeeding for four to six months.[28] Companies lobbied heavily over the years to maintain the four to six month recommendation. A change in the

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[22] *See, e.g.*, Victora, C., Smith, P., Vaughan, J. et al., "Infant Feeding and Deaths due to Diarrhea: A case-controlled study", *American Journal of Epidemiology*, 1989, 129: 1032-41 (infants who received powdered milk or cow's milk had four-fold increased risk of death from diarrhoea as compared with exclusively breastfed infants; risk of death from diarrhoea for babies who received no breastfeeding was 14 times higher than those exclusively breastfed).

[23] The value of exclusive breastfeeding is further discussed in Chapter 4, p. 45.

[24] In 1990, the authors of the *Innocenti Declaration* recommended that women be enabled to breastfeed exclusively for four to six months. *See Innocenti Declaration, supra* note 9.

[25] American Academy of Pediatrics, Committee on Nutrition, *Pediatrics* 1980. The AAP's policy, current as of 2005, states "exclusive breastfeeding is sufficient to support optimal growth and development for approximately the first six months of life". American Academy of Pediatrics, Section on Breastfeeding, "Breastfeeding and the Use of Human Milk", *Pediatrics*, 2005, 115: 496-506.

[26] Resolution WHA47.5 (1994).

[27] Resolution WHA49.15 (1996).

[28] Kramer, M.S. and Kakuma, R., *The Optimal Duration of Exclusive Breastfeeding: A systematic review*, Geneva: WHO, 2002, p. 4 (WHO continued to recommend exclusive breastfeeding for four to six months whereas UNICEF preferred the wording "for about six months").

policy would have obvious commercial implications, as mothers who buy processed complementary foods would be encouraged to introduce them up to two months later (resulting in a loss of sales of the quantity that would have been consumed by each baby during those two months). Companies also pointed to the effect of the recommendation for babies who are not breastfed, as it was less clear as to when complementary feeding should begin for formula-fed babies.

After much urging from health professionals and other breastfeeding advocates, WHO finally, in 2000, commissioned a review of scientific literature on optimal duration of exclusive breastfeeding with a view to shaping a new infant feeding recommendation. The Cochrane review encompassed more than 3000 articles.[29] The reviewers of the literature concluded that no benefits to introducing complementary foods between four and six months had been demonstrated. They found that infants breastfed exclusively for six months had reduced morbidity from gastrointestinal infection and that no observable deficits in growth had been shown.[30]

WHO then convened an expert consultation to evaluate the systematic review. The experts concluded that the recommendation for optimal infant feeding should be revised to recommend a full six months of exclusive breastfeeding.[31] Based on this conclusion, the 2001 World Health Assembly adopted a landmark resolution urging Member States to "strengthen activities and develop new approaches to protect, promote and support exclusive breastfeeding for six months as a global public health recommendation".[32]

Agreement over the optimal length of exclusive breastfeeding has been important for the implementation of the International Code. The International Code does not specify any particular age for which certain products within its scope are recommended. Instead, it defines a *breastmilk substitute* as a food represented as a replacement for breastmilk and a *complementary food* as a complement to breastmilk or infant formula when either is no longer sufficient to meet the infant's nutritional requirements. Because the International Code relates to the marketing of breastmilk substitutes, it is important for both governments and infant food companies to know which products fall within that definition. The 2001 WHA resolution clarifies that anything fed to an infant up to the age of six months is a breastmilk substitute within the meaning of the definition of *breastmilk substitutes* in the International Code.[33]

HIV and infant feeding

In the late 1980's the first reports appeared showing that the human immunodeficiency virus (HIV) could be transmitted from mother to child through breastfeeding.[34] The reports were heavily publicised, leading to fear of breastfeeding for HIV-positive women, as well as for

[29] *Ibid.*

[30] *Ibid., pp. 19-20.*

[31] WHO, *Report of an Expert Consultation: The optimal duration of exclusive breastfeeding* (Geneva, 28-30 March 2001), WHO, 2002.

[32] Resolution WHA54.2 (2001).

[33] Chapter 4 on the scope of the International Code discusses in detail all the products that come within the meaning of the term *breastmilk substitutes* and hence fall within the scope of the Code.

[34] A study in Rwanda showed that 8 out of 212 babies born to mothers who were HIV-negative at the time of birth, seroconverted. The mother and baby became HIV-positive at the same time. *See* Van de Perre, P. et al., "Postnatal Transmission of Human Immunodeficiency Virus Type 1 from Mother to Infant: A prospective cohort study in Kigali, Rwanda", *New England Journal of Medicine*, 1991, 325: 593–98.

women who did not know their HIV status. The majority of women in HIV-prevalent areas are unaware of their HIV status. Testing is not readily available and many of those who have access are unwilling, out of fear, to submit to testing.

Breastfeeding advocates were concerned that there would be a massive turn away from breastfeeding, which would jeopardise the lives of millions of babies. There was also fear that infant food companies would capitalise on the HIV pandemic. For example, the head of public relations for Nestlé UK told British school children in 1989 that up to 50 percent of African mothers should not breastfeed because they are HIV-positive.[35]

Many countries developed programmes to reduce mother to child transmission of HIV. Infant food companies have tried to participate in these programmes by offering free infant formula. In 1998, for example, Honduras developed a package of interventions to reduce transmission of HIV from mothers to their babies. The package included voluntary HIV testing and counselling; anti-retroviral drugs as well as infant formula. Nestlé offered to provide, free of cost, enough formula to feed the infants born to HIV-positive mothers for 12 months.[36]

When Wyeth learned that UNICEF was planning similar pilot programmes in Africa in 1998, it offered UNICEF enough free formula to feed up to 100,000 infants for six months.[37] Around the same time, Nestlé contacted the United Nations Programme on HIV/AIDS (UNAIDS), and reportedly was pushing for donations that would be channelled through the industry's trade association.[38] UNICEF rejected Wyeth's offer and, instead, decided to purchase the formula that would be needed for the pilot programmes.[39]

An article published in the New York Times in 1998, put the risk of transmitting HIV through breastmilk in perspective. The author recounted the realities of formula feeding in a remote African village. Even if formula were donated and delivered to her home, states a village mother, it would be difficult to fetch the water, boil it, prepare the meals while also working in the garden and cooking for the rest of the family. The chief of obstetrics and gynaecology at a medical school in Uganda is quoted as stating that while 27 percent of babies born to infected mothers will become HIV-positive from breastfeeding, in rural areas, 85 percent would die from dirty water in the bottles.[40]

The percentage of women infected with HIV varies in each community, but can be as high as 25 or even 40 percent.[41] Between 14 and 42 percent of babies born to HIV-positive women will

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[35] Erlichman, J., "Nestlé Accused of AIDS 'Scare'", *The Guardian*, 21 November 1989.

[36] *See* Lutter, C. and Freire, W., "Maternal HIV Infection and Breastfeeding in Honduras: Analysis of need for infant formula, Honduras, June 8-12, 1998", Pan American Health Organization.

[37] Freedman, A. and Stecklow, S., "As UNICEF Battles Baby-formula Makers, African Infants Sicken", *Wall Street Journal,* 5 December 2000.

[38] *Ibid.*

[39] UNICEF decided in 2002, based on its experiences with the pilot programmes, that it would no longer procure and provide infant formula.

[40] Specter, M., "Breastfeeding and HIV: Weighing the health risks", *New York Times*, 19 August 1998.

[41] Linkages, *Breastfeeding and HIV/AIDS Frequently Asked Questions*, Washington D.C.: Academy for Educational Development, updated April 2004.

contract the virus through pregnancy, during childbirth or from breastfeeding.[42] It is estimated that 5 to 20 percent of infected babies contract the virus as a result of breastfeeding.[43] Examined in another light, in a community with an HIV prevalence rate among women at the time of delivery of 25 percent, about 4 percent (15 percent of the 25 percent of infected women) of the infants will be infected via breastfeeding.[44]

As the *New York Times* article indicates, these figures cannot be evaluated properly without also looking at the risks of illness for babies who are not breastfed. Infants who are not breastfed have a higher risk of mortality and morbidity than those who are. Absence of breastfeeding exposes children to an increased risk of malnutrition, diarrhoea and pneumonia, especially in the first year of life.[45] Even in developed countries an infant who is not breastfed is at increased risk of diarrhoea. Studies done in developing countries show that babies who are not breastfed are six times more likely to die from infectious diseases during the first two months of life than breastfed infants. The risk then drops, but is still nearly three times higher for four-to-five month old babies.[46] The protective effect of breastfeeding, when it is exclusive is even higher.[47]

A report from South Africa where HIV prevalence rates are among the highest in the world states:

> The overwhelming majority of babies born to HIV-infected women and all babies born to uninfected women will benefit from exclusive breastfeeding for about six months. Therefore, even in areas of high HIV prevalence, we believe it is more appropriate to promote exclusive breastfeeding as public health policy, and counsel individual women on infant feeding choices, rather than implement and support superficially attractive measures that offer free replacement feeds, but with potentially disastrous consequences for maternal and child health.[48]

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[42] UNICEF, UNAIDS, WHO et al., *HIV Transmission through Breastfeeding: A review of the available evidence*, Geneva: WHO, 2004, p. 8.

[43] De Cock K.M., Fowler, M.G., Mercier, E. et al. "Prevention of mother-to-child HIV transmission in resource poor countries: Translating research into policy and practice", *Journal of the American Medical Association,* 2000, 283: 1175-82.

[44] One can perform the same calculation using global statistics. In 1999, an estimated 620,000 children became infected with HIV and about one-third to one-half, or 200,000 to 300,000 are estimated to have occurred during breastfeeding. See Humphrey, J. and Iliff, P., "Is Breast not Best? Feeding Babies Born to HIV-Positive Mothers: Bringing balance to a complex issue", *Nutrition Review*, 2001, 59: 119-27.

[45] UNICEF, UNAIDS, WHO et al., *HIV and Infant Feeding: Guidelines for decision-makers,* Geneva: WHO, 2003, (*hereinafter* HIV Guidelines for Decision-makers), p. 8.

[46] WHO Collaborative Study Team on the Role of Breastfeeding on the Prevention of Infant Mortality, "Effect of Breast-feeding on Infant and Child Mortality due to Infectious Disease in Less Developed Countries: A pooled analysis", *Lancet*, 2000, 355: 451–55.

[47] Black, R.E., Morris, S.S. and Bryce, J., "Child Survival I: Where and why are 10 million children dying every year?", *Lancet*, 2003, 361: 2226-34.

[48] Dobson, R., "Breast is Still Best even when HIV Prevalence is High, Experts Say", *British Medical Journal,* 2002, 324: 1474.

There is also evidence that exclusive breastfeeding may result in a lower likelihood of transmission of HIV from mother to infant than breastfeeding combined with other foods or drinks.[49] The studies suggest that feeding with anything but breastmilk may risk damaging the mouth and gut of the infant, thus increasing the ease with which the virus can pass into the child's blood.

Based on these facts and figures, WHO, UNICEF and UNAIDS developed global policy guidelines about HIV and infant feeding. The Guidelines have evolved since the first WHO policy statement that was issued in 1992. The 2003 *HIV and Infant Feeding: Guidelines for decision-makers* recommend that mothers who are HIV-negative as well as those who do not know their HIV status should breastfeed exclusively for six months followed by continued breastfeeding with appropriate complementary feeding for two years and beyond.[50]

For mothers who know they are infected with HIV, the Guidelines state:

> When replacement feeding[51] is acceptable, feasible, affordable, sustainable and safe (AFASS), avoidance of all breastfeeding by HIV infected mothers is recommended. Otherwise, exclusive breastfeeding is recommended during the first months of life and should then be discontinued as soon as feasible.[52]

The five conditions (AFASS) have been defined as follows: replacement feeding would be considered *acceptable* as long as the mother is not under any social or cultural pressure not to use replacement feeding or can cope with such pressure and can deal with any stigma that might be attached to replacement feeding. It would be *feasible* if the family has time, knowledge, skills and other resources to properly prepare and feed the baby 10-12 times per 24 hours.

Replacement feeding is considered *affordable* if the family can "pay the cost of purchasing/producing, preparing and using replacement feeding, including all ingredients, fuel, clean water, soap and equipment, without compromising the health and nutrition of the family" as well as health care costs in case of need. The term *sustainable* means that a family will be assured

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[49] *See* Iliff, P.J., Piwoz, E., Tavengwa, N. et al., "Early Exclusive Breastfeeding Reduces the Risk of Postnatal HIV-1 Transmission and Increases HIV-free Survival", *AIDS*, 2005, 19: 699-708. Coutsoudis, A., Pillay, K., Kuhn, L. et al., "Method of Feeding and Transmission of HIV-1 from Mothers to Children by 15 Months of Age: Prospective cohort study from Durban, South Africa", *AIDS,* 2001, 15: 379-87; Coutsoudis, A., "Promotion of Exclusive Breastfeeding in the Face of the HIV Pandemic", *Lancet,* 2000, 356: 1620-21 and Coutsoudis, A., Pillay, K., Spooner, E. et al., "Influence of Infant Feeding Patterns on Early Mother-to-Child Transmission of HIV-1 in Durban, South Africa: A prospective cohort study", *Lancet,* 1999, 354: 471-76.

[50] HIV Guidelines for Decision-makers, *supra* note 45, p. 9.

[51] The Guidelines define *replacement feeding* as

> feeding infants who are receiving no breastmilk with a diet that provides the nutrients infants need until the age at which they can be fully fed on family foods. During the first six months of life, replacement feeding should be with a suitable breast-milk substitute. After six months the suitable breastmilk substitute should be complemented with other foods. *Ibid.,* p. vi.

[52] *Ibid*. Resolution WHA54.2 (2001) also urges Member States to recognise that when replacement feeding is acceptable, affordable, sustainable and safe, avoidance of all breastfeeding by HIV-positive women is recommended; otherwise, exclusive breastfeeding is recommended during the first months of life; and that those who choose other options should be encouraged to use them free from commercial influences.

of a reliable supply for as long as products are needed; for as long as one year or more. Finally, replacement feeding is considered *safe* if the feeds can be prepared, stored and fed hygienically and fed in nutritionally adequate quantities.[53]

In 2004, UNICEF called for stronger support for exclusive breastfeeding stating that studies had confirmed "that exclusive breastfeeding is currently the most feasible way to keep the majority of babies born in HIV endemic countries alive and healthy through infancy." The press statement noted that it is rare that the conditions for replacement feeding can be met in the communities where the majority of HIV-positive women live. UNICEF also said that "women who are not helped to exclusively breastfeed are likely to resort to mixed feeding, which sky rockets the odds of HIV infection and infant mortality".[54]

Global Strategy for Infant and Young Child Feeding

As the 20th century drew to a close, WHO and UNICEF decided to renew commitments to improved infant and young child nutrition. The goals set by the World Summit for Children in 1990 to eliminate major forms of malnutrition by the year 2000 had not been met in most countries.[55] In 2000, malnutrition was cited as a direct or indirect cause of an annual 6.6 million deaths in children under five years old.[56] WHO noted that poor feeding practices are often associated with such deaths.[57] In a series of papers published in the *Lancet* on child survival, it was estimated that there are 10.8 million annual child deaths. The absence of breastfeeding was cited as an important risk factor for child mortality.[58]

WHO and UNICEF set out to develop a new global strategy to improve infant and young child feeding. They began the process by organising a technical consultation in the year 2000, bringing together experts concerned with all aspects of infant and young child feeding.[59] The consultation resulted in a draft strategy for the coming decade.

In 2000 and 2001, a series of national and regional consultations were conducted to review and revise the draft *Global Strategy for Infant and Young Child Feeding*. In May 2002, the World Health Assembly, "convinced that it is time for governments to renew their commitment to protecting and promoting the optimal feeding of infants and young children", endorsed the *Global Strategy* and urged Member States to implement it.[60]

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[53] HIV Guidelines for Decision-makers, *supra* note 45, p. 10.
[54] UNICEF, "World Missing Opportunity to Reduce Mother-to-child HIV Transmission Through Exclusive Breastfeeding", Press release, New York, November 2004.
[55] WHO, *Childhood Nutrition and Progress in Implementing the International Code of Marketing of Breastmilk Substitutes,* Report A55/14, Geneva, 19 March 2002, ¶ 11.
[56] WHO and UNICEF, *Global Strategy for Infant and Young Child Feeding*, Geneva: WHO, 2003, (*hereinafter* WHO and UNICEF Global Strategy) ¶ 1.
[57] *Ibid.*
[58] Black, Morris and Bryce, *supra* note 47, p. 2227.
[59] WHO and UNICEF, *Technical Consultation on Infant and Young Child Feeding*, Geneva, 13-17 March 2000.
[60] Resolution WHA55.25 (2002).

The strategy reaffirms the urgency of achieving the four operational targets of the *Innocenti Declaration* and adds several new operational targets.[61] All governments are urged to ensure that exclusive breastfeeding is protected, promoted and supported for six months, with continued breastfeeding up to two years and beyond; to promote timely, adequate, safe and appropriate complementary feeding; and to provide guidance on feeding infants and young children in exceptionally difficult circumstances such as those of HIV-infected women, those living in emergency situations and low birth-weight babies.[62]

The risks of formula feeding

The mounting evidence of the risks of formula feeding led the US Department of Health and Human Services (DHHS) to develop a breastfeeding awareness campaign, which was to be launched at the end of 2003. The highly anticipated $40 million media campaign was designed to emphasise the risks associated with not breastfeeding: a departure from usual public education campaigns that focus on the benefits of breastfeeding.

When Mead Johnson and Abbott-Ross, the two largest US infant formula manufacturers, got wind of the content of the campaign, they used their influence to persuade top officials of the American Academy of Pediatrics (which receives large donations from the formula companies) to lobby the DHHS to modify the public messages. When finally aired in June 2004, the public service announcements, while focusing as planned on the risks of not breastfeeding, downplayed those risks somewhat by not including, as originally conceived, specific statistics on the level of the risk to formula-fed babies of developing diarrhoea, ear infections or obesity. The risks of developing diabetes and leukaemia were left out completely.

In 2002, another risk of feeding infants with infant formula came to light. Health departments in the US, Canada and Belgium issued warnings of a high mortality rate associated with the heat-resistant pathogen *Enterobacter sakazakii* found in tins of powdered baby milk.[63] In 2004, outbreaks in New Zealand and France led to several deaths and cases of serious illness in infants.[64] In addition, in early 2005, infant formulas produced in France and exported to 11 different countries had to be recalled due to *Salmonella* contamination.[65]

The Codex Committee on Food Hygiene has been revising the *Code of Hygienic Practice for Foods for Infants and Young Children*, which will address this risk to infants.[66] The Codex Committee, however, will need several more years to finalise the revision. The 2005 WHA, realising that a

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[61] WHO and UNICEF Global Strategy, *supra* note 56, ¶ ¶ 30 & 31. The four operational targets of the *Innocenti Declaration* are listed *supra,* note 9.

[62] *Ibid.,* ¶ 33.

[63] *See* U.S. Food and Drug Administration, Health Professionals Letter on Enterobacter sakazakii Infections Associated with use of Powdered (dry) Infant Formulas in Neonatal Intensive Care Units, 11 April 2002 (revised 10 October 2002); Health Canada, Health Professional Advisory, *Enterobacter sakazakii* Infection and Powdered Infant Formulas, 23 September 2002.

[64] International Food Safety Authorities Network (IFOSAN), *Enterobacter sakazakii in Powdered Infant Formula*, Information Note N° 1/2005, 13 January 2005.

[65] WHO, *Report by the Secretariat on Infant and Young Child Feeding,* 58th World Health Assembly, A58/15, 4 May 2005, ¶ 5.

[66] Codex Alimentarius Commission, Report of the 37th Session of the Codex Committee on Food Hygiene, ALINORM 05/29/13, ¶ ¶ 35-57 (2005).

more immediate response was necessary, urged Member States to inform health-care personnel and families about the risk of pathogenic microorganisms in infant formula and to ensure that this information be conveyed (where applicable) by an explicit warning on the package.[67]

With the risks associated with not breastfeeding becoming better known, it is even more imperative that infant food and bottle and teat companies comply with the International Code, relevant WHA resolutions and national measures. Yet the latest IBFAN monitoring report shows that companies continue to violate the International Code. The *State of the Code by Company 2004* showed that none of the 16 infant food companies and 14 feeding bottle and teat companies examined was in compliance with the International Code. Nearly all companies were found to substantially violate different articles of the Code.[68]

[67] Resolution WHA58.32 (2005). The risk of contamination of infant formula with *Enterobacter sakazakii* and other pathogens and related warnings on package labels is discussed in Chapter 9, pp. 128-29.

[68] International Baby Food Action Network, *State of the Code by Company 2004*, Penang, Malaysia: IBFAN-ICDC, 2004.

CHAPTER 3

Marketing in Perspective

Up until the 19th century, nearly all babies were breastfed, whether they were born in Europe or Asia, Africa or North America, in a rich family or a poor one, in an urban community or a farming village. Yet, beginning with the more affluent countries and communities and gradually spreading to poorer ones, breastfeeding has declined at alarming rates. Even with new research being published all the time about the near miraculous qualities of breastmilk, breastfeeding rates remain sub-optimal in all parts of the world. The reasons are numerous, but the two most significant are the marketing practices of the industry that manufactures and sells baby food and the medical practices that undermine breastfeeding.[1] As we will see, the two are intertwined.

Historical context

The decline in breastfeeding rates in Europe and North America in the 19th and early 20th centuries is closely linked to the influence of the medical profession. There was a real misunderstanding of the process of lactation, particularly the importance of unrestricted demand feeding and proper positioning. The medical profession introduced separation of mother and baby; curtailing the frequency and duration of breastfeeds; washing nipples; and giving prelacteal and supplementary artificial feeds. These are all practices that, as we now know, will lead to a reduction of breastmilk supply, sore nipples and ultimately abandonment of breastfeeding.

Mothers who now found themselves with breastfeeding problems turned to replacements and feeding bottles. New processing techniques for milk were just being discovered. With the invention of tinned condensed milk, mothers could artificially feed their infants at home without having direct access to a cow.[2]

Nestlé has its own favourite story of how in 1867 it started in the infant food business by mixing toasted flour and condensed milk of Swiss cows, which saved the life of a premature infant. Henri Nestlé, who had until then sold mustard, grains and oil lamps, knew he had a sure market: "My discovery will have a tremendous future because there is no food that might be compared to my flour mixture."[3]

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[1] Palmer, G., *The Politics of Breastfeeding,* London: Pandora Press, 1988.
[2] *Ibid.*, p. 203.
[3] Buffle, J.C., *Dossier, N. . . comme Nestlé,* Paris: Alain Moreau, 1986, p. 15.

From flour mixture to infant formula was a small step. By 1890, a Harvard University team had started experimenting with diluted cow's milk. Doctors began developing recipes for imitating human milk. They would add chemical compounds, and vary the 'formula' according to the perceived need of each baby at various ages. There was close medical supervision and only rich babies could afford to go back every few weeks to get a new recipe, often an incredibly complicated newly formulated mixture, a new 'formula'.

Eventually more generic formulas were found to suit a variety of children and the individually made-up mixtures ceased altogether. At this time, many commercial infant foods had been developed and were being widely advertised. Doctors were not happy to lose the function of developing infant foods and industry recognised that it was not in their best interests to alienate this influential profession. Thus, manufacturers began to work with the doctors. Manufacturers agreed not to place instructions on the package, but would instead instruct mothers to consult their doctor before using the product.

Doctors then became associated with certain brands. Mead Johnson developed its first formula in 1911 and advertised it widely. Yet the company always included the doctor by stating in its advertising copy that it was the doctor who could control the 'feeding problem'.[4] Wyeth launched *Simulated Milk Adaptation*, the formula now known as *SMA,* in 1915. The formula was widely advertised to both the lay public and to doctors. In France, the same letters, *SMA*, were used to promote the food with the phrase "*Son Meilleur Aliment*", literally "his best food".

As artificial feeding spread in Britain and the US along with increased industrialisation and urbanisation, infant mortality rates also increased. This experience did not inhibit the invasion of markets abroad. By 1873, Nestlé was selling 500,000 boxes a year of its *Nestlé's Milk Food* all over Europe, America, Australia, Argentina, the Dutch East Indies and Mexico.[5] Other companies followed. In Malaysia, then under British rule, several brands of canned milk were advertised for babies from the 1880s onward. By 1915, there was regular competitive advertising for six brands of infant milk food as well as for feeding bottles. Health workers were impressed with 'modern' technology. On 5 August 1931, the Times of Malaya wrote, "Medical authorities are agreed today that canned foods are not only more nutritious (than fresh food), but that they are more pure due to the great advance that has taken place in the canning industry".

Expanding the market

By the end of the Second World War, opportunities abounded for international trade. Nestlé and other companies such as the British Cow and Gate, already had a market in the countries under colonial rule. As birth rates in the industrialised countries began to drop, infant milk companies sought new markets for their products. High birth rates in developing countries were attractive for sellers of baby foods. By this time, most homes in Britain had piped water.

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[4] Palmer, *supra* note 1, p. 206.

[5] Two years after, in 1875, it all became too much for Henri Nestlé and he sold the Nestlé milk food factory for a million Swiss francs and a splendid horse-drawn carriage. Buffle, *supra* note 3, p. 15.

Industrialised countries had amassed the wealth necessary to construct the infrastructures of public health, medical services and communication vital to withstand some of the risks of bottle feeding.[6] This was not the case in most of the colonies where safe drinking water was not readily available.

Baby milk companies intensified marketing in these countries, often through the health care system. Most health workers have always believed that cow's milk is essential for health, even in countries where drinking cow's milk is unusual or even unheard of. The health care agencies unwittingly helped the milk industry by giving away milk for free, often as a way to lure mothers into clinics. In Chile, the government introduced a free milk scheme in the 1940s. That country saw a near total abandonment of breastfeeding over the course of a 20-year period.[7]

The trend towards bottle feeding in non-Western countries began with the well-to-do families who were usually in positions of power. The men were often educated in Europe or North America. Bottle feeding became associated with authority and affluence. The trend spread quickly, however, to the rest of the populations "with an infinitely shorter time-lag than in the Western world during the preceding 50 years".[8] Breastfeeding was in rapid decline in many parts of the world by the 1960s. In Mexico, almost 100 percent of six-month-old babies were breastfed in 1960. By 1970, the figure had dropped to nine percent.[9] In Singapore, over 80 percent of three-month-old babies were breastfed in 1951, yet by 1971 the rate had dropped to five percent.[10]

Substitutes for human milk?

Between the end of World War II and the 1970s, companies were continuously changing the composition of infant formulas in an attempt to modify it to more closely resemble human milk, to correct inadequacies, to have a technological advantage over competitors or to economise on a more costly ingredient.[11] If the 1950s and 1960s was the 'naive period' in attempts to mimic the composition of human milk,[12] what then was the period at the turn of the 19th century when companies claimed to have invented the 'perfect infant food' by mixing malt flour and cow's milk? It has been stated that the "introduction of infant formulae as breastmilk substitutes represents by far the largest in vivo experiment without a control series".[13] These modifications, of course, continue to this day in the never-ending search for the perfect imitation of breastmilk. By 1979, 50 brands and 200 varieties of infant formulas were being distributed across 100 countries.[14]

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6 Catholic Institute for International Relations (CIIR), *Baby Milk: Destruction of a world resource,* London: CIIR, 1993, (*hereinafter* CIIR), p. 9.
7 Muller, M., *The Baby Killer,* London: War on Want, 1974, 2nd ed., May 1975 (*hereinafter* Muller), p. 4.
8 Jelliffe, D.B. and Jelliffe, P., *Human Milk in the Modern World,* Oxford: Oxford University Press, 1978 (*hereinafter* Jelliffe and Jelliffe), p. 213.
9 *Ibid.*
10 CIIR, *supra* note 6, p. 19.
11 Jelliffe and Jelliffe, *supra* note 8, p. 205.
12 Rolles, C., "Can We Really Mimic Human Milk?", *Nursing Mothers' Association of Australia Newsletter,* 1976, 12: 1.
13 Jelliffe and Jelliffe, *supra* note 8, p. 209.
14 CIIR, *supra* note 6, p. 20.

Radio jingles and milk nurses

In the sixties and seventies, companies used radio, television, loudspeaker vans, the press and billboards to advertise their products. In a 1974 survey in one Nigerian city, 38 percent of 400 mothers recalled at least one advertisement for baby milk. This was a large number, given that only 14 percent of the community could read and 52 percent ever listened to the radio.[15] A survey in Sierra Leone in 1970 noted 14 radio advertisements in one day for Nestlé's *Lactogen*, and in one month, 135 for *Lactogen*, 45 for *Cow and Gate* and 66 for Abbott-Ross's *Similac*.[16]

The prominent message was about the strength, health, energy and power-giving properties of the products. If radio jingles were catchy enough, people would be humming them all day long. An Indian paediatrician can still sing the tune: "A Glaxo baby is a sunshine baby" which he heard on the radio when he was a boy. Dr. Catherine Wennen was shocked by a radio advertisement in Nigeria: "Mother, believe in *Lactogen* . . . All things in mother's milk are also present in *Lactogen*. Mother, watch the health of your baby, and give him the best, give *Lactogen*."[17] She also recalled a roadside billboard in 1969, showing a large smiling baby holding a tin of *SMA* formula alongside the phrase, "Welcome to Nigeria, where *SMA* babies are healthy and happy".[18] A mother in Nigeria recalled an advertising phrase in pidgin English that went "Hi, go make your pikin big pokopoko and make am strong poi" ("It will make your baby fat and robust, and also make her very strong.").[19]

Another favourite theme stressed in advertisements was "use this product when breastmilk is not enough". This theme persists in company materials even to this day. While studies have shown that lactation failure is extremely rare, particularly in traditional societies, many women are quick to believe that their milk is not enough.[20] Insufficient milk is one of the most common reasons women cite for supplementing or replacing their breastmilk with artificial milk. The belief is no less real in its consequences and companies exploited it to the fullest.

The companies also employed 'milk nurses' or 'mothercraft nurses'. These women were usually trained nurses whose task was to talk to mothers and teach them about infant care as well as give out samples and sell products. Often the nurses were paid a commission based on sales, and they were given sales quotas that they had to meet in order to keep their jobs.[21] Although the 'nurses' were company employees, they worked in hospitals and were generally welcome because they took some of the workload off the staff, gave them presents and made the patients happy with samples.

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[15] Muller, *supra* note 7, p. 10.
[16] Chetley, A., *The Baby Killer Scandal,* London: War on Want, 1979 (*hereinafter* The Baby Killer Scandal), p. 58.
[17] Chetley, A., *The Politics of Baby Foods: Successful challenge to an international marketing strategy,* London: Frances Pinter, 1986, p. 40.
[18] Wennen, C.A., "The Decline of Breastfeeding in Nigeria", *Tropical and Geographical Medicine,* 1969, p. 93.
[19] Muller, *supra* note 7, p. 10.
[20] Akre, J., ed., "Infant Feeding: The physiological basis", *The Bulletin of the World Health Organization,* 1989, Supplement to vol. 67, pp. 43, 50-51.
[21] Muller, *supra* note 7, p. 11.

A study in Nigeria found that 87 percent of mothers used artificial milk because they had been advised to do so by hospital staff. In most cases, the 'hospital staff' were company-paid milk nurses.[22] It was a splendid marketing technique; everybody was happy and sales increased. It took a major campaign in the seventies to stop this direct promotion, first by convincing employers that it was unethical for milk nurses to wear the same uniform as hospital nurses, then by convincing hospitals and clinics to stop giving the milk nurses direct access to patients.

Free samples and bonny baby labels

One of the other major promotional practices frequently cited by women as the reason for discontinuing breastfeeding was the distribution of free milk samples. Samples, given out by the medical profession helped to give bottle feeding a high social status. Companies hoped that free samples would 'hook' the mother, who would later buy the product. Wyeth's 1975 *Infant Formula Sales Manual* states, "maternity services should be given primary allocation of free samples, geared to producing potential sales".[23] Nestlé did research in the Philippines to test this proposition and determine if the technique was worth the cost. Surprisingly, they found it to be a "particularly bad case of sampling" because only 50 percent of the mothers continued to use the milk.[24]

Literature intended to educate the mother was often a disguised form of advertising. Nestlé's *Mother Book* for East Africa, for example, illustrated only bottle feeding.[25] Many mothers who gave birth in a hospital left with a baby book published by a commercial firm. The photos depicted large, healthy babies; smiling mothers; modern kitchens and feeding utensils that rarely matched the reader's circumstances.

Product labelling was another way through which companies discouraged breastfeeding. Labels were nearly always adorned with a photo of a chubby smiling baby. Which mother didn't yearn for a baby who resembled the one on the tin? All she had to do was choose this or that particular brand. The text and slogans rarely mentioned the superiority of breastfeeding. Instead phrases such as the following, found in 1978 on a tin of Abbott-Ross's *Similac*, abounded: "There is no food equivalent that more closely resembles the milk of healthy well-fed mothers—*SIMILAC* with IRON—similar to mother's milk." Wyeth's *S-26* label stated, "Nourishes the baby like mother's breast - *S-26* - a superior food for the infant".[26]

Using the doctors

Selling through the medical profession also grew quickly as a promotional method in the developing world. Doctors usually come from the more affluent parts of society that have adopted so-called 'progressive practices' such as bottle feeding. Most doctors from Africa,

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[22] Baumslag, N., *Milk, Money and Madness: The culture and politics of breastfeeding,* Westport, Connecticut: Bergin & Garvey, 1995, p. 150.
[23] The Baby Killer Scandal, *supra* note 16, p. 96.
[24] Muller, *supra* note 7, p. 12.
[25] *Ibid.*
[26] The Baby Killer Scandal, *supra* note 16, p. 77.

Asia and Latin America had studied medicine in the West, where instruction on breastfeeding was next to nil. A Chilean doctor stated in the early seventies that medical-school teaching about infant feeding was like ". . . chemistry class. We used to spend all our time mixing up different kinds of artificial formulations in the laboratory. Our teachers were far more interested in this than in breastfeeding."[27]

Companies were quick to blame illness and death on product misuse rather than on the conditions under which it was sold. By selling through the doctors, they hoped to shield themselves from blame. They went so far as to introduce new products that could mitigate the problems of misuse. For example, Nestlé, noting that mothers dilute the formula to economise or replace it with inadequate weaning foods too early, stated that doctors should recommend *Lactogen Full Protein*, touted to cover the full daily protein requirements of six-to-twelve month old infants in only two feeds.[28]

Companies like Bristol-Myers and Abbott-Ross employed a cadre of representatives to visit doctors and explain the benefits of their products. These companies sold pharmaceuticals and simply added infant formula to their line of products that was to be presented to the doctor. The medical representatives advocated formula the way they sold drugs: praising their qualities and effectiveness, pointing to relevant studies and leaving samples to pass on to patients.

Visits from the representatives were backed by advertisements in the medical journals, lectures by company-sponsored speakers and grants to attend conferences. Dr. Derrick Jelliffe termed such help to the health professionals "manipulation by assistance". A seemingly endless range of more or less useful paraphernalia was generously distributed: diaries, prescription pads, all kinds of pens, pencils and markers, umbrellas, sunhats and T-shirts, key chains, desk sets, clocks, mirrors, and more. A group in Thailand once showed how one could fully equip a doctor's office with company gifts, inclusive of the white coat and gloves. All these items sport either a brand or a company name or logo, just to make sure the brand easily comes to the doctor's mind.

Nurses in the clinics gladly accepted company posters for decorating their otherwise drab waiting rooms. These often consisted of instructions written by an infant food company about infant care or feeding; about how to properly bottle feed or introduce the baby's first solid food. The posters always displayed the brand name of an infant food and the company's name or logo. "The illiterate mother will find them interesting. And though the bright modern household, the clean white baby clothes, the crib and the recommended foods are almost certainly out of her monetary reach, the feeding bottle is not. She might be given it free by a nurse. And if there are posters in the clinic about bottle feeding, there cannot be much wrong with it."[29]

Companies denied that these practices were harmful. They often claimed that the products were needed because breastfeeding inevitably declines with urbanisation. Yet, as Dr. Jelliffe noted,

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[27] Muller, *supra* note 7, p. 8.
[28] *Ibid.,* p. 13.
[29] *Ibid.*, p. 9.

> the needs for the feeding of young infants in such urban societies are usually quite different - [they] include crèches and other measures to permit working women to nurse their babies, and the unadvertised availability of low-cost formula for those really unable to breastfeed. This is a quite different situation from the aggressively advertised expensive milk formulas promoted with modern sales techniques in areas where there is no chance of them being afforded in sufficient amounts...[30]

Effects of marketing run deep

It was the increasing awareness of these trends and practices that led to the passage in 1981 of the *International Code of Marketing of Breastmilk Substitutes*. The International Code, as we will see in the following chapters, forbids advertising, free samples, mothercraft nurses, promotion through health care facilities, inducements to health workers, words or pictures on labels or in materials that idealise bottle feeding, and requires that information to health professionals be limited to matters that are factual and scientific.

But while the International Code seeks to end commercial promotion of products that discourage breastfeeding, it can do little to erase the effects of the advertising and promotional campaigns of the last 100 years, which have already influenced millions of people in so many societies. Advertising campaigns, if successful, sow seeds of product recognition that later bloom into acceptance and perceived need. In countries where advertising for infant formula has ceased, the jingles and product names are still recalled a decade later. Women ask their breastfeeding daughters to give the baby supplemental feeds of infant formula because the benefit and 'need' has been ingrained from the promotional campaigns of the past.

Doctors continue to recommend baby milks to mothers all too quickly because of their prior experience. "Decades of misinformation have led health workers to witness more breastfeeding failure (including their own) and many believe that the problems caused by the damaging medical practices are actually faults of nature."[31]

Even if the effects of the past could be erased, breastfeeding continues to be threatened by commercial promotion for substitutes. There are several reasons that explain why the International Code has not yet spelled an end to such practices. For one, the companies had a major influence in drafting the International Code, an influence that is reflected in the many promotional practices that are arguably permissible. Second, some companies simply ignore the International Code in some or all countries.

In Malaysia, for example, Dumex was still advertising the position of "Mothercraft Nurse" in the newspapers, three years after the International Code was adopted. In countries such as Hong Kong, Singapore and the United Arab Emirates where purchasing power is high, violations are commonplace. In China, where nearly 19 million annual births make for a lucrative market, competition among infant food companies is fierce. Despite the adoption of the *Rules*

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[30] Jelliffe and Jelliffe, *supra* note 8, p. 231.
[31] CIIR, *supra* note 6, p. 11.

Governing the Administration of Marketing of Breastmilk Substitutes in 1995, advertising of infant foods on television, radio, in magazines as well as leaflets is widespread.

Finally, companies are constantly adapting their marketing practices to exploit the loopholes and ambiguities in the International Code. The later chapters examine in detail how companies continue to leave an imprint in the minds of mothers and health workers.

What does the future hold?

Until countries enact strong legislation prohibiting all marketing outside of placing these products on grocery store shelves, infant food companies will continue to find new ways to promote their products. As the old Gerber slogan said: "Babies are our business." With over 100 million babies born in the world each year, selling infant food is indeed a lucrative business. It was estimated that the retail value of sales of baby foods, which include baby milk and prepared and dried baby foods would be about US$20 billion in 2005.[32]

The introduction of DHA-ARA fortified infant formulas illustrates just how lucrative is the market is for baby foods. Docosahexaenoic acid (DHA) and arachidonic acid (ARA) are long-chain fatty acids that occur naturally in breastmilk and are associated with human brain and eye development. The discovery of how to add these fatty acids to foods has led to a marketing and sales boom for infant formulas. In 2005, Martek Biosciences, the company that developed a blend of the two fatty acids, which it derives from algae and fungi, was selling the blend to 16 different manufacturers of infant formula worldwide, representing more than 70 percent of the market.[33] Companies push the formulas "for smarter babies" and have added DHA and ARA to the whole range of products including pre-term formulas, standard infant formulas, follow-up formulas, growing-up milks (GUMs) as well as milks and other drinks promoted especially for pregnant and lactating women.[34]

Whether or not the addition of these algae/fungi-derived oils to formulas for infants, young children and mothers results in better brain and eye function for infants seems to be a secondary question.[35] A quote appearing in Martek's 1996 Investment Thesis shows that profits come first:

> Infant formula is currently a commodity market, with all products being almost identical and marketers competing intensely to differentiate their product. Even if Formulaid [the name of Martek's DHA/ARA fatty acid combination] has no benefit, we think it would be widely incorporated into formulas as a marketing tool and to allow companies to promote their formula as 'closest to human milk'.

The fat blend has been profitable for Martek and for the licensee formula companies. In 2003, a Martek executive expected global sales of its formula supplement to reach US$100

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[32] "World Market for Baby Food", *Euromonitor International,* 2001, Forecast data to 2005.

[33] Martek Bioscience Corporation, "Introduction to DHA & ARA", *Nutritional Products,* http://www.martekbio.com/Nutritional_Products/Infant_Formula_Manufacturers.asp (accessed 11 May 2005).

[34] The various products marketed for infant and young child feeding are discussed in detail in Chapter 4.

[35] For a more detailed discussion of the studies showing effects of DHA and ARA in formulas, *see* Chapter 7, p. 95.

million. All companies that added the blend to their formulas also had increased overall sales.[36] In 2004, Martek's revenues grew by almost $70 million from $114.7 to $184.5 million.[37]

In contrast to the companies' focus on marketing, James Post and Edward Baer, in 1979, put forth the concept of demarketing, which deserves mention today as a strategy that countries may wish to adopt. "It involves setting sales targets that are not profit-related, but are related to the nutritional needs and social and economic conditions prevalent in the community. It puts a limit on the quantity of the product that is on the market, while at the same time requires positive action to repair the damages that 25 [now 50] years or so of unrestricted marketing has imposed on developing countries."[38]

Thanks to the *Baby Friendly Hospital Initiative* and the efforts of groups like La Leche League and others associated with WABA who inform mothers in all countries about the enormous differences between breastfeeding and artificial feeding, perhaps marketing techniques will begin to have less of an impact. But the road is still long and the two tracks of breastfeeding promotion and breastfeeding protection must continue to run together. The International Code is still relevant even after nearly 25 years of existence. To be effective, however, it must be strengthened at the national level and integrated into the education of all health professionals and the community in general.

[36] *See* Retsinas, G., "The Marketing of a Superbaby Formula", *The New York Times*, 1 June 2003.
[37] Martek, *Annual Report,* 2004.
[38] Post, J.E. and Baer, E., "Demarketing Infant Formula: Consumer products in the developing world", *Journal of Contemporary Business,* 1979, 7: 17.

CHAPTER 4

Defining the Scope

Relevant provisions of the International Code

Article 2. Scope of the Code

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

Article 3. Definitions

"Breastmilk substitute" *means any food being marketed or otherwise represented as a partial or total replacement for breastmilk, whether or not suitable for that purpose.*

"Infant formula" *means a breastmilk 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".*

"Complementary food" *means any food, whether manufactured or locally prepared, suitable as a complement to breastmilk 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 "breastmilk supplement."*

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[*] In 2001, the World Health Assembly adopted Resolution WHA54.2 recommending exclusive breastfeeding for a full six months. The WHA reaffirmed this recommendation in Resolution WHA58.32 (2005). The Codex, which sets worldwide food standards, is revising the Codex Standard for Infant Formula. *See* Codex Alimentarius Commission, *Draft Revised Standard for Infant Formula and Formula for Special Medical Purposes* (at step 6), *in* Report of 26th Session of the Codex Committee on Nutrition and Foods for Special Medical Purposes, ALINORM 05/28/26, Appendix IV (2004).

Relevant parts of World Health Assembly Resolutions

WHA39.28 (1986)

Any food or drink given before complementary feeding is nutritionally required may interfere with the initiation or maintenance of breastfeeding and therefore should neither be promoted nor encouraged for use by infants during this period.

The practice being introduced in some countries of providing infants with specially formulated milks (so-called "follow-up milks") is not necessary.

WHA47.5 (1994)

Member States are *urged to "foster appropriate complementary feeding practices from the age of about six months."*

WHA49.15 (1996)

Member States are urged to "ensure that complementary foods are not marketed for or used in ways that undermine exclusive and sustained breastfeeding."

WHA54.2 (2001)

Member States are "urged to strengthen activities and develop new approaches to protect, promote and support exclusive breastfeeding for six months as a global public health recommendation, taking into account the findings of the WHO expert consultation on optimal duration of exclusive breastfeeding, (note 1) and to provide safe and appropriate complementary foods, with continued breastfeeding for up to two years of age or beyond, emphasizing channels of social dissemination of these concepts in order to lead communities to adhere to these practices"

Note 1: As formulated in the conclusions and recommendations of the expert consultation (Geneva, 28 to 30 March 2001) that completed the systematic review of the optimal duration of exclusive breastfeeding (see document A54/INF.DOC./4).

WHA58.32 (2005)

Member States are encouraged "to continue to protect, promote and support exclusive breastfeeding for six months as a global public health recommendation, taking into account the findings of the WHO Expert Consultation on optimal duration of exclusive breastfeeding, and to provide for continued breastfeeding up to two years of age or beyond".

The first consideration in developing legislation to control marketing is to define the scope, or more simply, what types of products the legislation will cover. Once the overall scope is defined, it can be determined whether some sections of the law should apply only to certain classes of products.

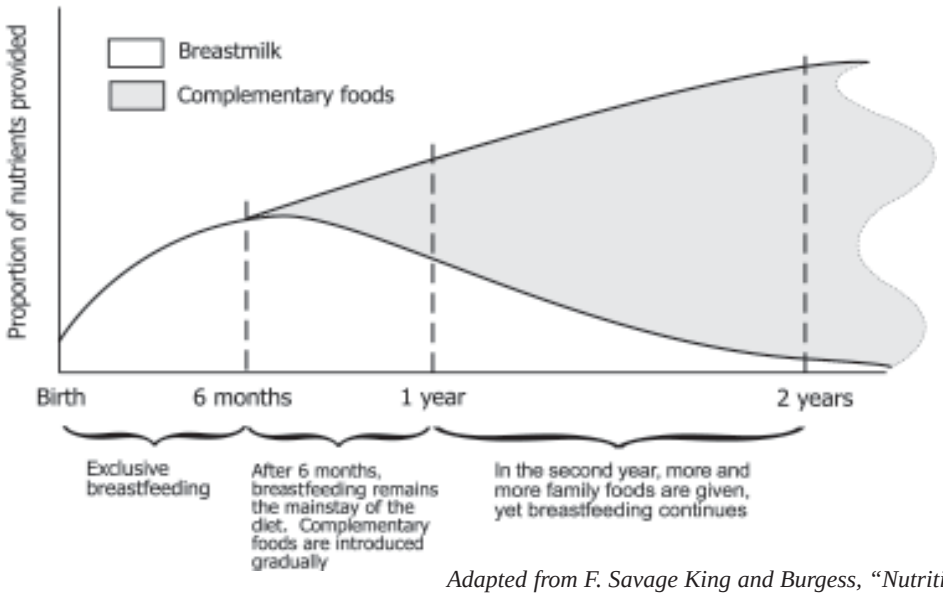
Advertising and other types of product promotion are so common that we rarely think twice about their effect. Yet marketing techniques used to sell many infant food products all over the world are designed to have an effect on women's attitudes and decisions about how to feed their babies; an effect that was serious enough to convince 118 countries to adopt a marketing Code in 1981.

Nations implement the International Code as a measure towards protecting the health of infants and young children through safe and adequate nutrition. This chapter looks at which products, when advertised or promoted to families to use, can impact negatively on optimal infant and young child feeding, and hence, health, growth and development.

What is optimal feeding for infants and young children?

A global consensus has emerged to define the *optimal feeding of infants and young children*. As expressed in the WHO/UNICEF *Global Strategy for Infant and Young Child Feeding* adopted in 2002,

> Infants should be exclusively breastfed for the first six months of life to achieve optimal growth, development and health. Thereafter, to meet their evolving nutritional requirements, infants should receive nutritionally adequate and safe complementary foods while breastfeeding continues for up to two years of age or beyond.[1]



Adapted from F. Savage King and Burgess, "Nutrition for Developing Countries", 2nd Edition, 1993 reprinted 1995, Oxford Medical Publications.

Figure 1: Optimal infant and young child feeding

[1] WHO and UNICEF, *Global Strategy for Infant and Young Child Feeding*, Geneva: WHO, 2003 (adopted 18 May 2002) (*hereinafter* WHO and UNICEF Global Strategy), ¶ 10. *See also* Resolutions WHA54.2 (2001) and WHA58.32 (2005).

To understand the relationship between product marketing and adverse health outcomes, it is crucial to understand the importance of exclusive and prolonged breastfeeding. *Exclusive breastfeeding* means that the baby is fed nothing other than breastmilk, not even water.[2] Policy makers encourage exclusive breastfeeding for the first six months because feeding water, other fluids or foods in addition to breastfeeding increases the risk of disease. Such feeding may also impact growth negatively, reduce the overall duration of breastfeeding and shorten the period of time before the return of the mother's menstrual periods following birth.[3]

It is now well known that exclusive breastfeeding is much safer than breastfeeding mixed with other foods or liquids. The addition of other foods or liquids increases the baby's risk of exposure to bacteria and viruses that can cause diarrhoea, respiratory infections and other life-threatening disorders.[4] In addition, exclusively breastfed infants breastfeed longer because a mother's supply of breastmilk is dependent on frequent suckling.

If a baby is given foods or liquids in addition to breastmilk, the baby will not be as hungry and will suckle at the breast less frequently. When the mother produces less breastmilk, she begins to doubt whether she has enough milk to adequately feed her baby. This lack of confidence further inhibits breastfeeding, because the mother may produce less of the hormone oxytocin, which ejects the milk when the baby sucks (the *let-down reflex).* Reduced milk supply leads to a hungry, crying baby and thus the temptation to further supplement breastmilk with other foods or drinks. It becomes a vicious cycle. An additional benefit of exclusive breastfeeding is that it reduces the risk of another pregnancy soon after a birth.[5]

Babies who are fed by feeding bottle may have problems breastfeeding because of *nipple confusion.* The sucking action required for a bottle is very different from suckling at the breast. Infants who become accustomed to sucking on an artificial teat may become frustrated with breastfeeding. This type of sucking is also likely to cause the mother to have sore nipples, a chief reason mothers cite for giving up breastfeeding. Mothers who express their breastmilk so that someone else can feed the baby when she is not available, should ensure that the expressed milk is fed by a cup, rather than a feeding bottle.

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[2] WHO, Division of Child Health and Development, "Indicators for Assessing Breastfeeding Practices," Reprinted report of an informal meeting, 11-12 June 1991, Geneva. The definition includes infants who receive vitamins, mineral supplements or medicines in drops or syrup.

[3] The development of the recommendation for exclusive breastfeeding for six months is discussed in Chapter 1, pp. 24-26.

[4] *See, e.g.,* Cesar, J.A., Victora, C.G., Barros, F.C. et al., "Impact of Breastfeeding on Admission for Pneumonia during Postneonatal Period in Brazil: Nested case control study", *British Medical Journal*, 1999, 318: 1316-20; Leach, A., McArdle, T. et al., "Neonatal Mortality in Rural area of the Gambia", *Annals Tropical Pediatrics*, 1999, 19: 33-43; Popkin, B.M., Adair, L., Akin, J.S. et al., "Breastfeeding and Diarrhoeal Morbidity", *Pediatrics*, 1990, 86: 874-82; Brown, K.H., Black, R., Romana, G.L. et al., "Infant Feeding Practices and their Relationship with Diarrhoea and other Diseases in Huascar (Lima) Peru", *Pediatrics*, 1989, 83: 31-40; Victora, C.G., Smith, P.G. and Vaughan, J.P., "Evidence for Protection by Breastfeeding against Infant Deaths from Infectious Diseases in Brazil", *Lancet*, 1987, 2: 317-22.

[5] UNICEF, *Facts for Life,* New York: UNICEF, 2002, p. 41 ("Exclusive breastfeeding can give a woman more than 98 per cent protection against pregnancy for six months after giving birth – but only if her menstrual periods have not resumed, if her baby breastfeeds frequently day and night, and if the baby is not given any other food or drinks, or a pacifier or dummy.")

Continued breastfeeding is the second element of optimal infant and young child feeding. It refers to the gradual process of introducing the baby to foods other than breastmilk. At first, breastmilk will continue to be the baby's main source of food. During the second year of life, breastfeeding can still provide one-third or more of a baby's protein and energy needs.[6] Breastmilk during this prolonged period continues to protect the infant from infection. When mothers stop breastfeeding earlier, the child may stop growing or lose weight. This is an important cause of malnutrition.

When drafting legislation to implement the International Code, governments must determine which marketing practices give messages that encourage bottle feeding or that discourage breastfeeding, particularly exclusive breastfeeding during an infant's first six months and continued breastfeeding once complementary foods have been introduced.

The infant food industry has developed a wide array of products. The object of the legislation is not to ban such products, but to control commercial messages that contradict public health messages regarding breastfeeding. The next section looks at the various infant feeding products that are available for sale and considers which ones ought to be included within the scope of national legislation that prohibits or limits advertising and promotion of those products.

The scope in the International Code

The scope of the International Code is defined in Article 2 and can be divided into three categories of included products:

1. *Breastmilk substitutes*, including *infant formula. Breastmilk substitute* is defined as "any food being marketed or otherwise represented as a partial or total replacement for breastmilk, whether or not suitable for that purpose."
2. 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 breastmilk.
3. Feeding bottles and teats.

The term *breastmilk substitute*, used to define the scope of the International Code is ambiguous and requires interpretation. *Figure 1* illustrates that a particular food or drink can either replace or complement breastmilk, depending on when it is given to a baby. It will be recalled from Chapter 1 that the International Code was drafted through a process of compromise and consensus. The compromise is nowhere more evident than in the wording of Article 2, the Scope of the Code. Infant food companies lobbied for a scope that would cover only infant

[6] King, F.S., *Helping Mothers to Breastfeed*, Nairobi: African Medical and Research Foundation, 1987.

formula, whereas health professionals, and other scientists, consumers and NGOs pushed for a much broader scope that would include all the products that discourage breastfeeding.[7]

The scope of the International Code must be interpreted in light of knowledge about optimal infant feeding. As illustrated in *Figure 1*, optimal infant feeding consists of two elements: exclusive breastfeeding for six months and continued breastfeeding for up to two years or more. Thus, in addition to infant formula, a *breastmilk substitute* includes any food marketed or otherwise represented as suitable for feeding an infant up to the age of six months because such foods are being marketed to replace that part of the diet that is best fulfilled by breastmilk. For the same reason, it also includes any product represented as suitable to replace the part of the diet that would be best fulfilled by breastmilk after six months and up to at least two years. The scope also includes feeding bottles and teats.

The rest of this chapter examines common products marketed and used for feeding infants and young children and whether or not they ought to be included within the scope of national measures.

Infant formula

There is no question that *infant formula* is included within the scope of the International Code.[8] Infant formula is also known as baby milk, infant milk food, powdered milk for babies or, in French, *lait industriel* (manufactured milk). The terms *infant formula* or *baby milk* have gradually come to encompass all sorts of modified milks for feeding babies. The distinguishing feature of an infant formula is that it must be formulated to satisfy, by itself, the nutritional requirements of infants during the first months.[9] There has never been any question that infant

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[7] All of the parties that participated in drafting the International Code, including the baby food companies, agreed to call it the *Code of Marketing of Breastmilk Substitutes*, and not the *Code of Marketing of Infant Formula.* Companies persist, however, in claiming that infant formula is the only food product covered by its scope. Nestlé, for example, published instructions for its employees regarding the application of the International Code. Nestlé's instructions state that they apply only to the marketing of infant formula and that other Nestlé products are not covered by the International Code. *See* Nestlé: *Nestlé Instructions for the Implementation of the WHO International Code of Marketing of Breastmilk Substitutes: Instructions to companies of the Nestlé Group and to agents and distributors who market infant formula in developing countries under trade marks owned by the Nestlé Group, updated* July 1996. Some companies also refer to a statement included as *Annex 3* in WHO's publication of the International Code. *Annex 3* consists of excerpts from the introductory statement by Dr. T. Mork (Director-General of Health Services, Norway), which he delivered to the WHA Committee that was about to vote on the adoption of the International Code. Industry references to *Annex 3* routinely leave out the portion of Dr. Mork's statement explaining that whether or not a product is included within the scope of the International Code depends on how it is marketed. *Annex 3* is included in Appendix B of this Handbook.

[8] *Infant formula* is the term used in the International Code. It is also referred to as *baby milk* (particularly in the UK). In this Handbook, the two terms are used interchangeably.

[9] The definition of *infant formula* in Article 3 of the International Code refers to the Codex Alimentarius Standard for Infant Formula and defines it as formulated to satisfy the nutritional requirements of infants "up to between four and six months of age". The World Health Assembly recommended exclusive breastfeeding for six months in 2001 (Resolution WHA54.2), and the Codex Standard for Infant Formula is being revised. *See* Codex Alimentarius Commission, *Draft Revised Standard for Infant Formula and Formula for Special Medical Purposes* (at step 6), *in* Report of 26th Session of the Codex Committee on Nutrition and Foods for Special Medical Purposes, ALINORM 05/28/26, Appendix IV (2004).

formula falls within the scope of the International Code and should be within the scope of any national measure based on the Code.

Specialised formulas for infants

Over the years, companies that manufacture infant formula have introduced a wide variety of formulas ranging from formula designed for premature and low-birth-weight infants to various soy-based and hypo-allergenic milks. Baby milks have become so specialised that manufacturers even market formulas for "hungrier" babies and babies with common problems such as fussiness, gas, spitting up and colic. It is important to ensure that all varieties of infant formula are included within the scope.

Manufacturers have attempted at national and international levels to convince law-makers to exempt various types of formula from marketing restrictions. When the International Code was first adopted, the IFM took the position that specialised formulas such as those for premature infants do not fall within the International Code's definition of *infant formula*, arguing that the definition encompasses only breastmilk substitutes "formulated industrially … to satisfy the *normal nutritional requirements of infants* … ." (emphasis added).[10] According to representives of both WHO and UNICEF, the International Code covers all types of formula, including those for infants with special nutritional requirements or medical needs.[11]

The European Commission Directive on Infant Formulae and Follow-on Formulae differs from the International Code in that it governs only infant and follow-on formulae "intended for use by infants in good health".[12] Members of the European Union base national laws on the marketing of breastmilk substitutes on the 1991 Directive. In 1999, the European Commission adopted a Directive on Dietary Foods for Special Medical Purposes (FSMP).[13] This Directive lays down compositional and labelling requirements for foods intended for the "feeding of patients [including infants] with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary foodstuffs."[14] Unlike the Directive on Infant Formulae and Follow-on Formulae, the 1999 Directive does not restrict product promotion nor does it require any mention of the superiority of breastfeeding on labels of infant food products that fall within its scope.

Proponents of the 1999 Directive argued that marketing restrictions were inappropriate because the Directive would apply only to specialised formulas for *infants who cannot ingest*

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[10] Informal IFM Working Group, *Definitions and Suggested Monitoring Mechanisms Pertaining to the Cessation of Donations and Low-price Supplies of Infant Formula to Maternity Wards and Hospitals in Developing Countries*, Ref. 68.93.

[11] *See* Report of the 25th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses, ALINORM 03/27/26, (2003) ¶ 67 & Report of the 22nd Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses, ALINORM 01/26, (2000), ¶ 62.

[12] European Commission, Directive on Infant Formulae and Follow-on Formulae, 91/321/EEC, 1991, Article 1.

[13] Commission of the European Union Directive on Dietary Foods for Special Medical Purposes, 1999/21/EC, (1999).

[14] *Ibid*., Articles 1 & 2 (b).

breastmilk. Were the Directive truly limited to such formulas for infants who cannot ingest breastmilk, only a very small number of infant formulas would fall within its purview. It has been estimated that only one in 5000 babies are born with a metabolic disorder for which breastfeeding is contraindicated or has to be restricted and (partially) replaced by FSMPs.[15]

Yet because there is no definitive list of which formula products fall within this category, it is left to manufacturers to determine whether or not a product is a FSMP. This has resulted in examples of formulas being marketed for a variety of conditions. For example, in 1999, Nutricia advertised *Infatrini* in a British journal for midwives. *Infatrini* is described as a "prescribable high energy feed" for babies "failing to thrive," a vague condition that is not medically defined.[16] Similarly, Wyeth's UK subsidiary, SMA Nutrition, promoted *SMA High Energy* in advertisements targetted to health visitors in 2004 and 2005. *SMA High Energy* is described by the manufacturer as available on prescription and for infants and young children with medically determined high energy needs.[17]

An incident in the Philippines shows how so-called *special formulas* can be used as marketing devices. In 1987, Wyeth's local subsidiary lobbied the government of the Philippines to exempt formula for low-birth-weight babies from its law banning free supplies. Shortly thereafter, Wyeth-Suaco sent letters to retailers of Wyeth formula announcing that a new low-birth-weight formula would be available, but only as a free service in hospital nurseries. The letter explained to retailers that this new product would boost their sales of infant formula because "mothers will surely buy (Wyeth) S-26 standard right after a short stay on (Wyeth's) LBW (low birth-weight formula); hence more S-26 sales!"[18]

The targets of promotion for special formula are health workers. Breastfeeding is usually down played or not mentioned at all. Yet, health care providers and parents need to know that breastfeeding, the optimal nutrition for nearly all babies, is especially helpful to the most vulnerable babies. Very premature babies are especially likely to benefit more from breastmilk than from a manufactured formula.

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[15] Codex Alimentarius Commission, *Discussion Paper: Foods for Special Medical Purposes Regulated in the Standard for Infant Formula* (Prepared by Germany), *in* Agenda for 23rd Session of Codex Committee on Nutrition and Foods for Special Dietary Uses, Appendix V, CX/NFSCU 01/5-Add.1 (November 2001). In the United States an infant formula that was designed for use in the dietary management of a rare genetic condition known as phenylketonuria (PKU) was one of the first 'medical foods' to be developed. This type of product was regulated originally by the US Food & Drug Administration as a drug. In 1972, however, in order to encourage development of products that are intended for rare conditions and to ensure they would be available at a reasonable cost, the agency decided to regulate the product as a *food for special dietary use* rather than a drug (US Federal Register 61 FR 60661, 29 November 1996).

[16] Baby Milk Action, "Medicalising Infant Feeding – A Marketing Ploy", *Update*, July 1999.

[17] SMA Nutrition UK, http://www.smanutrition.co.uk/products/specialfeeds.htm (accessed 15 May 2005). Some delegations to Codex have lobbied the Codex Commission to create a separate standard for *Infant Formulas for Special Medical Purposes*. The current Codex Standard for Infant Formula applies to infant formula intended to meet the normal nutritional requirements of infants as well as formula intended for infants with special nutritional requirements. *See* Report of the 25th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (2003) ¶ 68.

[18] Wyeth-Suaco Laboratories Inc., Director of Marketing for Philippines, Letter to "valued customers", 27 March 1987.

Drafting examples from other countries: Infant formula

Standard infant formula is included within the scope of all national measures implementing the International Code. Very few national measures refer specifically to specialised formulas. It is important to ensure that all varieties of infant formula are included within the scope because they all are replacements for breastmilk.

The Malaysia Code is one of the few that specifically includes *special formula* within the scope. Malaysia defines *special formula* as formula marketed for premature or low-birth-weight infants or for infants with cow's milk hypersensitivity, carbohydrate intolerance and other metabolic disorders.[19]

The Brazil regulations create a separate category of formula for high-risk newborns. These products are not only subject to the marketing restrictions that apply to normal infant formula, but to stronger restrictions as well. In Brazil, *formula for high-risk newborns* is defined as formula intended for infants born prematurely (less than 34 weeks gestations) or of very low weight at birth (less than 1,500 g) or for an infant who immediately upon birth suffers from pathology that requires intensive care.[20] These products are subject to the general ban on advertising and promotion and samples may not be given.[21] In addition, their use is restricted to hospitals and their sale in pharmacies or supermarkets is not permitted.[22] A number of specific labelling requirements also apply to the products that fall within this category.[23]

The Gabon Decree includes "so-called medicinal milks and drinks covered by legislation on medicines" within its scope.[24] The definition of *infant formula* in the Model Law is broad enough to include all varieties.[25]

Follow-up formula

The marketing of follow-up formula (also called follow-on milk) is also harmful to optimal infant feeding. Follow-up formula is an infant formula recommended by the manufacturer for babies older than six months, and in some cases, for babies older than four months and up to as

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[19] Malaysia, Code of Ethics for Infant Formula Products, *3rd revision*, 1995, § 3.18.

[20] Brazil, Regulamento Técnico para Promoção Comercial dos Alimentos para Lactentes e Crianças de Primeira Infância, Resolução-RDC Nº 222, de 5 de agosto de 2002 (Technical Regulation on Commercial Promotion of Foods for Infants and Young Children), ¶ 2.29. *See also* Norma Brasileira de Comercialização de Alimentos para Lactentes e Crianças de Primeira Infância, Bicos, Chupetas e Mamadeiras, Portaria Nº 2051 de 8 de novembro, 2001 (Brazilian Standard for Marketing of Foods for Infants and Young Children, Teats, Dummies and Feeding Bottles), Article 3(30).

[21] Brazil Technical Regulations, Foods for Infants and Young Children, *supra* note 20, ¶ 4.1; Brazilian Standard for Marketing, *supra* note 20, Article 4 & Article 10.

[22] Brazil Technical Regulations, Foods for Infants and Young Children, *supra* note 20, ¶ 4.20.

[23] *Ibid.*, ¶ ¶ 4.15-4.19.

[24] Décret Nº 000033/PR/MSP portant promotion, protection de l'allaitement maternel et réglementant la qualité, les méthodes de commercialisation ainsi que l'utilisation d'alimentation infantile en République Gabonaise, 27 janvier 2004, (Gabon Decree on the Promotion and Protection of Breastfeeding and on Regulation of the Quality, Marketing Methods and use of Infant Foods), Article 2.

[25] Model Law, § 2 (12).

much as three years. The International Code makes no specific reference to follow-up milks, which were rare in 1981 when the International Code was adopted.

It is not far-fetched to state that the majority of companies created follow-up milks in an attempt to get around the restrictions of the International Code and recapture the customers they knew they would lose with the end to commercial promotion of standard infant formula. A study in the Philippines showed that in the two years after the Philippines adopted its Code, company distribution to health facilities of normal infant formula fell by 95 percent. Yet in the same period, 1986-1988, the proportion of facilities receiving formula for older infants increased by 80 percent.[26]

Manufacturers have lobbied many governments not to include follow-up formula within the scope of their national measures. They base their argument on the wording of the International Code, whose scope covers products "marketed or otherwise represented" as replacements for breastmilk. The manufacturers claim that follow-up milks do not replace breastmilk because they are promoted only for older babies who are no longer breastfeeding.

Yet, as discussed earlier, health authorities worldwide agree that optimal infant feeding includes continued breastfeeding for up to two years and beyond. In fact, more than half of the babies in the world breastfeed for much longer than six months.[27] Any type of milk fed to an infant, whether it is infant formula from birth, or follow-up milk or cow's milk after six months, replaces breastmilk because breastmilk is the first choice for meeting an infant's milk requirements.

Allowing promotion of follow-up formula can easily defeat public health efforts to encourage women to continue breastfeeding for up to two years and beyond. Many of the promotional messages encourage a switch to formula feeding after a period of breastfeeding. Mead Johnson used to advertise *Enfapro* with the slogan "breastfeeding: a hard act to follow". Wyeth uses the brand name *Progress* and Abbott-Ross calls one of its follow-up formulas *Similac Advance* playing on mothers' desire to see their babies get ahead quickly.

There are other reasons why it is important for governments to limit commercial promotion of follow-up milks. Follow-up formulas are usually fed by bottle, and thus pose the consequent dangers. Moreover, the labels of most brands of follow-up milks are nearly identical to the labels of the same company's standard infant formula. The product names are distinguished only by the addition of words like "two" or "plus". Nestlé's follow-up to *Nan 1* is called *Nan 2* and Milupa's follow-up to *Aptamil-1* is *Aptamil-2*. Meiji calls its follow-up milk *Meiji FU* and its standard milk *Meiji FM*. With the similarities in name and package designs, advertisements for the follow-up brands invariably lead to indirect promotion of the company's infant formula and the protection of the International Code or national legislation is lost.

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[26] Popkin, B., Fernandez, M.E. and Avila, J.L., "Infant Formula Promotion and the Health Sector in the Philippines", *American Journal of Public Health,* 1990, 80: 74-75.

[27] Macro International, *Demographic Health Surveys Newsletter,* 1995, vol. 7, No. 2, 1995 (Maryland, USA).

The similarity in labelling between products can also lead to confusion. Follow-up milks are generally higher in protein and are thus inappropriate for younger babies. Some parents, unaware of this difference, use follow-up milks instead of standard formulas for young infants because they are usually less expensive. Even Nestlé, in its instructions to its employees regarding compliance with the International Code, recognised the importance of including such products within the scope. The Nestlé instructions tell employees that follow-up formula is not covered by the International Code "except follow-up formulae which have the same brand name as starter formula (e.g. Nan 1 & Nan 2), and which are subject to the same marketing restrictions as starter formula".[28] It must also be emphasized that, the World Health Assembly declared back in 1986 that follow-up milks are not necessary.[29]

Growing-up milk

In addition to follow-up milks for infants, commercial promotion for milks aimed at young children has burgeoned. Manufacturers refer to these products as *growing-up milks* (GUMS), *junior milks* or 1-2-3 milks because they are intended for babies and young children who are older than one year. These milks represent another example of a product created by companies to get around the restrictions of the Code or the increasing number of national measures that ban the promotion of follow-up formula.

Many companies use brand names, designs, pictures or logos for their growing-up milks that are similar to those for the company's standard infant formulas or follow-up milks. A number of companies have a complete series of milks, similarly named, rendering an advertisement for one product likely to promote any of the others. For example, Mead Johnson's product line includes *Enfalac* (for 0-12 months), *Enfapro* (for 6-18 months), *Enfagrow* (for 1 year plus), and *Enfakid* (for 3-6 years). Dumex markets *Dumex 1 plus*, *3 plus* and *6 plus* in addition to its *Dumex 1* and *Dumex 2* infant and follow-up formulas.

Some companies use attributes of breastmilk as key messages in their advertisements for these milks. A newspaper in Malaysia carried an advertisement for Wyeth *Progress* with the slogan "the growing up milk with 5 nucleotides and natural carotenoids to help strengthen immunity". Abbott-Ross advertised *Gain Plus* in the same newspaper as the "smart choice with DHA from Omega". Advertising for these *junior milks* through the mass media and through all sorts of promotional materials distributed or displayed through the health care system is widespread.

Drafting examples from other countries: Follow-up and growing-up milks

Most of the early countries that implemented the International Code defined the scope using the language of the International Code. Thus, follow-up milks were not included by name.

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[28] Nestlé, *Nestlé Instructions for the Implementation of the WHO International Code of Marketing of Breastmilk Substitutes: Instructions to companies of the Nestlé Group and to agents and distributors who market infant formula in developing countries under trade marks owned by the Nestlé Group, updated* July 1996.

[29] Resolution WHA39.28 (1986).

Follow-up milks were not widespread at the time. Sri Lanka, however, which adopted a national code in 1979, included infant milks manufactured for the use by children up to one year in its scope.[30] When the Philippines adopted its Marketing Code in 1986, the drafters used the language of the International Code to define the scope. In 1989, however, the Interagency Committee created under the Code felt that there was a need to further define the scope to mean "all products given through feeding bottles for children up to the age of one year".[31]

The scope of the Malaysia Code covers *infant formula products*.[32] Malaysia's Code preceded the International Code and was based on the ICIFI *Code of Ethics* that had been promoted by industry as a way to preclude an International Code.[33] Malaysia has revised its Code three times since its adoption in 1979, but has retained the phrase *infant formula products* in its scope. Although *infant formula products* was defined to include all modified milk products for infants up to the age of 12 months,[34] industry interpreted it as not applying to follow-up milk. The code drafters removed any ambiguity with the third revision in 1995 when they further defined *infant formula products* to include *follow-up formula* for infants from six months up to three years.[35] The Malaysia Code is again under revision, but the definition of *follow-up formula* is not expected to change.

In Australia, manufacturers argued that follow-up milk was not covered under the voluntary agreement between the government and infant formula manufacturers. The Agreement covers *infant formula,* which is defined to include "any food described or sold as an alternative for human milk for the feeding of infants up to the age of 12 months."[36] A manufacturer claimed that its follow-up products are marketed as an alternative to cow's milk, and thus, are not within the scope of the Agreement. The Advisory Panel on the Marketing in Australia of Infant Formula, however, confirmed that the definition of *infant formula* clearly covers *follow-up milk*.[37]

Many countries, particularly those that have adopted measures to implement the International Code in recent years, have included *follow-up milk* in the scope.[38] Most of these coun-

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[30] Sri Lanka, Code for the Marketing of Infant Milk Foods, Infant Foods, Feeding Bottles and Teats and Valves for Feeding Bottles, *pursuant to* the Consumer Protection Act, No.1 of 1979, Article 1 and definition of *infant milk food.* The Sri Lanka Code has since been revised and still includes all products for feeding infants up to 1 year old. *See* Sri Lanka, Code for the Promotion, Protection and Support of Breastfeeding and Marketing of Designated Products, 2003, *pursuant to* the Consumer Protection Act, Nº1 of 1979, Definition of *designated product.*

[31] Philippines Department of Health, Country Report on *Action Taken to Give Effect to the International Code of Marketing of Breastmilk Substitutes,* WHO Technical Meeting on Review and Evaluation of Action to Give Effect to the Aims and Principles of the International Code of Marketing of Breastmilk Substitutes, The Hague, 30 September-3 October 1991 (making reference to letter of 11 September 1989 and Memo Circular Nº 42).

[32] Malaysia Code, *supra* note 19, Article 2.

[33] The ICIFI Code is discussed in Chapter 1, p. 7.

[34] Malaysia Code, *supra* note 19, Articles 3.6 & 3.9.

[35] *Ibid.,* Articles 3.4 & 3.9.

[36] Marketing in Australia of Infant Formulas: Manufacturers and Importers, May 1992, Clause 3.

[37] Kerin O'Dea, Chairperson, Advisory Panel, Letter to Baby Food Action Group, 21 January 1993.

[38] These countries include Albania, Benin, Brazil (revised Regulations), Cameroon, Djibouti, Gabon, Georgia, Ghana, Indonesia, Oman, Pakistan, Panama, Tanzania, Uganda, Vietnam (revised Decree) and Zimbabwe. Some articles of the 1991 European Commission Directive on Infant Formulae and Follow-up Formulae, *supra* note 12, apply to both infant formula and follow-on formula. The Directive has been implemented in 14 of the 15 member countries.

tries have included *follow-up formula* as a specific item in a list of products or types of products defining the scope of the national measure. A few, however, have continued to use the term *breastmilk substitute*, but have specifically defined it to include *follow-up formula*. India employs the term *infant milk substitutes,* which is defined as "any food being marketed or otherwise represented as a partial or total replacement for mother's milk for infants [and young children] (*sic*) up to the age of two years".[39] Similarly, in Vietnam, breastmilk substitute is defined as "a milk or milk-like product of animal or vegetable origin formulated industrially and intended to satisfy the nutritional requirements of infants from birth to six months and of young children from 6 to 24 months".[40]

The scope in some countries includes milks marketed for babies and young children up to three or even five years, thus encompassing what companies market as *growing-up milks*. Albania defines *designated products* to include infant formula for infants during the first 6 months and follow-up formula for use after six months as well as any other product sold for nutrition of infants and young children. *Young child* is defined to include a child from 12 months to three years.[41] Similarly, the law in Georgia includes formula intended for infants and young children older than six months and up to three years.[42] Tanzania and Zimbabwe also cover milk for young children within the scope of their laws. Both countries define *young child* to include children up to the age of five years.[43]

Brazil's regulations ban all advertising for infant formula and follow-up formula for infants up to 12 months old. Any form of promotion for follow-up formula for young children up to the age of three years must carry a prescribed warning that must be highlighted in a specific manner.[44] The Vietnam Decree is similar. Vietnam prohibits advertising of breastmilk substitutes for infants up to the age of six months. Advertisements for formulas intended for infants from 6 to 24 months must carry a specified statement regarding the superiority of breastfeeding and comply with other specific requirements in the Decree.[45] The Model Law includes follow-up formulas within the scope and defines them to include those marketed for infants and young children. *Young child* is defined as including a child from the age of 12 months up to three years old.[46]

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[39] India, Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act Nº 41 of 1992, *amended* 2003, § 2, definition of *infant milk substitute.*

[40] Vietnam, Decree on Marketing and use of Breastmilk Substitutes to Protect and Promote Breastfeeding, Nº 74/2000/ND-CP, 2000, Article 4.

[41] Albania, Law for Promotion and Protection of Breastfeeding, Nº 8528, 1999, Article 2.

[42] Law of Georgia on Protection and Promotion of Breastfeeding and Regulated use of Artificial Food, 1999, Article 3.

[43] Tanzania, Food (Control of Quality) (Marketing of Breastmilk Substitutes and Designated Products) Regulations, 1994, Regulation 3, definitions of *designated product* and *young child*; Zimbabwe, Public Health (Breastmilk Substitutes and Infant Nutrition) Regulations, SI 46, 1998, § 2, definitions of *designated product* and *young child.*

[44] Brazil Technical Regulations, Foods for Infants and Young Children, *supra* note 20, ¶¶ 4.1 & 4.2.

[45] Vietnam Decree, *supra* note 40, Article 8.

[46] Model Law, § 2(8) & (24).

Complementary foods

Infant formula and follow-up formula are the first products that come to mind for inclusion in the scope, but many countries are also experiencing harmful consequences from the promotion of commercially processed and packaged infant foods often referred to as *complementary foods*.

Complementary feeding refers to the period when other foods or liquids are given to a baby along with breastmilk. In the International Code, *complementary food* is defined as

> any food, whether manufactured or locally prepared, suitable as a complement to breastmilk or to infant formula, when either becomes insufficient to satisfy the nutritional requirements of the infant.[47]

The period of complementary feeding is represented in *Figure 1* by the shaded portion of the graph. This period, from about 6 to 24 months, is one of the most critical times for preventing malnutrition in children and is the peak age for growth faltering and common childhood illnesses such as diarrhoea.[48]

The *Global Strategy for Infant and Young Child Feeding* emphasises that because babies are particularly vulnerable during this period, complementary foods must be introduced at the right time; be adequate to meet a growing child's nutritional needs; be safe and that meal frequency and feeding method should be suitable for the child's age.[49] The *Global Strategy* also encourages the "widest possible use of indigenous foodstuffs" to "help ensure that *local foods* are prepared and fed safely in the home".[50]

Most families feed infants and young children with a variety of home-prepared foods. First foods are introduced to the baby's diet gradually beginning with soft, pureed or mashed foods and changing to finely chopped foods and finally foods being eaten by the rest of the family as the infant develops. There are also a large variety of commercially processed baby foods available on the market ranging from dried cereals and jarred fruits, vegetables and meats to infant meals, juices and teas.

Because the International Code specifically prohibits companies from advertising infant formula, many companies have put more emphasis on promoting sales of other products for infants and young children. Much of the advertising and labelling of commercially processed

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[47] The definition also says that such foods are commonly called "weaning foods" or "breastmilk supplements". The term *weaning food* is no longer used because *weaning* can be interpreted as stopping breastfeeding. *Complementary food* gives a clearer signal that foods and liquids are given to complement, not replace, breastmilk. The term *breastmilk supplement* is also not equivalent to *complementary food.* A *breastmilk supplement* is a milk given in addition to breastmilk and actually replaces rather than complements breastmilk.

[48] Brown, K., Dewey, K. and Allen, L., *Complementary Feeding of Young Children in Developing Countries: A review of current scientific knowledge*, Geneva: WHO, WHO/NUT/98.1, 1998.

[49] WHO and UNICEF Global Strategy, *supra* note 1, ¶ 13.

[50] *Ibid.,* ¶ 15. The World Health Assembly has also urged improvement in complementary feeding by, among other interventions, the "widest possible use of indigenous nutrient-rich foodstuffs". Resolution WHA54.2 (2001).

complementary foods give the impression that they are essential and that babies who eat them will be happier and healthier. Commercially processed complementary foods are not harmful in and of themselves, but their cost when compared to locally prepared foods can have a major impact on a family's budget. For example, in Swaziland in 1996, Nestlé's dried baby cereal, *Cerelac* cost 17 times the price of locally enriched maize meal.[51]

Some promotional messages contradict the public health goal of encouraging the use of indigenous foods in complementary feeding. For example, a poster for Nestlé *Cerelac* appearing in health care clinics in Pakistan states that it is not possible to achieve a balanced meal with the traditional diet.[52] Similarly, a leaflet promoting *Milupa* cereals in Hong Kong compares the products to traditional porridge in terms of nutritional value, preparation and taste. The leaflet states "Milupa wins on all three counts."[53]

Moreover, infant food companies promote complementary foods in hospitals and clinics leading to the impression that the products are endorsed by the health care system. For example, the blue bear that Nestlé has developed as a symbol for its whole line of complementary food products appears on posters, calendars, leaflets, stickers, pens and notepads in hospitals and clinics around the world.[54] Such items promoting commercial brands of complementary foods flood hospital wards and clinics serving pregnant women, mothers and infants. Many of the mothers utilizing these services have babies still months away from complementary feeding.

The promotion of commercial complementary foods can be harmful when it encourages feeding the product too soon. As discussed earlier in this chapter, complementary foods, while an essential component of an infant's diet, can place a child at risk if given too early. Complementary foods displace breastmilk, which is the safest and most nutritious food for most babies for the first six months. Early complementary feeding increases the risk of infection and food allergy, decreases iron absorption from breastmilk, and increases the mother's risk of pregnancy. Finally, it leads to a reduction and most likely, shorter duration of breastfeeding and all its consequent benefits. The World Health Assembly has addressed this topic on several occasions. It warned in Resolution 39.28 (1986) that

> Any food or drink given before complementary feeding is nutritionally required may interfere with the initiation or maintenance of breastfeeding and therefore should neither be promoted nor encouraged for use by infants during this period.

The 1996 World Health Assembly revisited this topic and in Resolution 49.15 urged Member States "to ensure that complementary foods are not marketed for or used in ways that undermine exclusive and sustained breastfeeding."

Many infant foods and drinks are labelled as suitable for feeding infants of three or four months and sometimes as low as one or two months. Moreover, age recommendations on

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[51] Vitamin-enriched maize meal cost 35 pence per kg, whereas *Cerelac* cost £6.20 per kg. Baby Milk Action, *Update* Nº 18, March 1996, p.4.

[52] The Network, *Feeding Fiasco: Pushing commercial infant foods in Pakistan*, Islamabad: The Network 1998, p. 42.

[53] International Baby Food Action Network, *Breaking the Rules, Stretching the Rules 2004,* Penang, Malaysia: IBFAN-ICDC, 2004, (*hereinafter* Breaking the Rules), p. 47.

[54] *Ibid.,* pp. 66-67.

package labels can be confusing. Companies such as Nestlé, Gerber and Heinz use *steps* or *stages* rather than ages. For example, Gerber vegetable purees in China are sold as 1st or 2nd foods without specific ages. One of Gerber's advertisements for this product pictures a baby wearing a maternity wristband, suggesting that the product may be suitable from birth.[55]

Drafting examples from other countries: Complementary foods

Considering Resolution WHA54.2 (2001) and the global recommendations for optimal infant feeding, food and drink products that are marketed or otherwise represented as suitable for infants below the age of six months should no longer be referred to as *complementary foods*, but as replacements for breastmilk. Countries, such as Ghana and Macedonia have covered all such replacements for breastmilk by including "products marketed or otherwise represented as suitable for feeding infants up to the age of six months" in the scope of their national laws.[56] These countries have not restricted the marketing of *complementary foods* marketed or represented as suitable for feeding infants and young children *after* the age of six months.

Sri Lanka, Colombia and Brazil, however, have placed some restrictions on the promotion of *complementary foods* but have not banned their advertising. This approach balances the need for promotion of nutritious and adequate complementary foods against the dangers of commercial promotion. In Sri Lanka, for example, complementary foods may be advertised to the public (with the approval of a committee) so long as they are not advertised or promoted as suitable for infants under the age of six months.[57] Complementary foods for children from 6 to 12 months old may not be promoted in a health care facility.[58] The Sri Lanka Code specifically prohibits brand names or logos of complementary foods on "any diagnosis card, imunization card, calendar, prescription card or growth chart (sponsored by manufacturers or distributors) used at health care systems".[59] In addition free samples and supplies of complementary foods are prohibited as well as gifts to the public and promotions to health workers that may serve to promote complementary foods.[60]

In Colombia, there is no prohibition on advertising and promotion of *complementary foods* to the general public, but there are many restrictions on promoting these products in the health care system.[61] All promotional materials for complementary foods must encourage mothers to

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[55] *Ibid.,* p. 26.

[56] Ghana, Breastfeeding Promotion Regulations, 2000, Regulation 16; Macedonia, Law on Protection of Consumers, 63/2000, Article 14. *See also* Benin, Décret N°97-643 portant réglementation de la commercialisation des substituts du lait maternel et des aliments pour nourrissons, 1997 (Benin, Decree on the Marketing of Breastmilk Substitutes and Infant Foods), Article 2 (pre-packaged products marketed, presented or used for feeding infants up to 4-6 months of age, including complementary foods).

[57] Sri Lanka Code, *supra* note 30, Article 2.6.

[58] *Ibid.,* Article 4.2.

[59] *Ibid.,* Article 5.7.

[60] *Ibid.,* Articles 3.2, 3.3 & 5.

[61] Colombia, Ministerio de Salud, Decreto N° 1397, 1994 (Colombia, Ministry of Health Decree N° 1397), Articles 8, 10 & 11 (no free samples, gifts or other promotion in a health care facility; no samples to health workers or offers of financial or material benefits to health workers for purpose of promoting products). *See also* Georgia Law, *supra* note 42, Articles 6-9 (advertising of complementary foods permitted; other types of promotion prohibited).

breastfeed for as long as possible and highlight the appropriate time to introduce these foods.[62] Promotional materials may not allude to bottle feeding nor have any representation of a feeding bottle.[63] Labels of complementary foods must clearly state that breastmilk is best, to feed with a cup and spoon and may not refer to feeding with a bottle.[64]

In Brazil, *transition foods and cereal-based foods for infants and young children* may be promoted so long as the promotional material includes the following statement: "The Ministry of Health says 'After the first six months, continue breastfeeding your baby in addition to giving new foods.'"[65] Moreover, the limitation on free samples in the Brazil Regulations also applies to such foods. Free samples may only be provided to paediatricians and nutritionists when the product is launched, and the launch must be completed within 18 months.[66] Labelling requirements in Brazil complement the restrictions on promotion. Labels on these foods must include the following warning:

> The Ministry of Health says: "This product should not be used for children under six months, except upon prescription from a doctor or a nutritionist. Breastfeeding prevents infections and allergies and is recommended up to two years or more." [67]

Other countries have determined that promotion of complementary foods should be prohibited altogether. When the Indian Parliament initially enacted a law to implement the International Code in 1992, all prohibitions applied to *infant milk substitutes*, but only a few of its prohibitions applied to *infant food.*[68] Over the next ten years, monitoring reports indicated that at least six different companies were promoting infant cereals and other foods in ways that were interfering with efforts to promote exclusive and sustained breastfeeding. In 2003, to respond to this situation, the Indian Parliament amended the Act to include infant foods in all of its prohibitions.[69] *Infant food* is defined as "any food (by whatever name called) being marketed or otherwise represented as a complement to mother's milk to meet the growing nutritional needs of the infant after the age of six months and up to the age of two years". Nepal, Pakistan, Tanzania, Djibouti and Oman include products marketed or otherwise represented as suitable for feeding infants up to one year within the scope of their laws.[70]

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[62] Colombia Decree, *supra* note 61, Article 15.
[63] *Ibid.*, Article 16.
[64] *Ibid.*, Articles 17 & 18.
[65] Brazil Technical Regulations, Foods for Infants and Young Children, *supra* note 20, ¶ 4.2.
[66] *Ibid.,* ¶ 5.2.
[67] *Ibid.,* ¶ 4.14.
[68] India, Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, N°. 41 of 1992.
[69] *Ibid.,* § 2(f) (*as amended* 1 June 2003).
[70] Nepal, Breastmilk Substitutes (Marketing Control) Act, N° 39 of 2049, 1992, § 2(d)(3); Pakistan, Protection of Breastfeeding and Child Nutrition Ordinance, N° 93, 2002, § 2(f)(ii); Tanzania Regulations, *supra* note 43 Regulation 3, definition *designated product;* Djibouti, Décret N°97–0011/PB/SB fixant les conditions de commercialisation des substituts du lait maternel, 1997 (Djibouti, Decree on Marketing of Breastmilk Substitutes), Articles 2 & 3; Oman, Ministerial Decision N° 55/98 Regulating the Marketing of Breastmilk Substitutes, 1998, Article 1, definition *breastmilk substitutes*. *See also*, Albania Law, *supra* note 41, Articles 2(c) (scope includes products sold for nutrition of infants and young children, defined as a child up to the age of three years).

Governments should note that including complementary foods in the scope of the law will not prevent parents from feeding their babies complementary foods when they become nutritionally required. Nor will such legislation prevent companies from selling these products. The legislation is meant to control promotion, such as advertising, free samples, and use of the health care system. No country to date has prohibited the sale of any baby food products.

It is important that parents be educated about appropriate complementary feeding through the health care system or other information services within the country. Parents should be informed about inexpensive, nutritious local foods that can be prepared at home and encouraged to feed the baby the same food being served to the rest of the family (enriched in small portions and fed frequently).

Resolution WHA54.2 (2001) urges Member States

> to improve complementary foods and feeding practices by ensuring sound and culture-specific nutrition counselling to mothers of young children, recommending the widest possible use of indigenous nutrient-rich foodstuffs; and to give priority to the development and dissemination of guidelines on nutrition of children under two years of age, to the training of health workers and community leaders on this subject, and to the integration of these messages into strategies for health and nutrition information, education and communication.

The *Global Strategy on Infant and Young Child Feeding* also emphasises culture-specific nutrition counselling for mothers of young children.[71]

Circumstances that affect how complementary foods should be treated in the law differ in each country. Thus, the Model Law presents two options for complementary foods. One option allows promotion for complementary foods so long as the promotion does not take place in a health care facility and the promotional material encourages exclusive breastfeeding for six months and sustained breastfeeding for up to two years and beyond.[72] Any product "marketed or otherwise represented as suitable for feeding infants up to the age of six months" may not be promoted.[73] The other option would prohibit all promotion of complementary foods by including within the definition of *designated products,* any product "marketed or otherwise represented as suitable for feeding infants [or for infants and young children up to the age of two years]."[74]

Other milk products

Policy makers have long been concerned about the effects on infant health of the use of certain other products for infant feeding such as non-modified powdered milks and packaged flours or starches. In some communities, these products are commonly used to feed very young infants. In many Latin American countries it became commonplace to feed young infants with Nestlé's *Nido*, a full-cream powdered milk. And in Sri Lanka, mothers mistakenly

[71] *See* WHO and UNICEF Global Strategy, *supra* note 1, ¶ 15.
[72] Model Law, § 4(1) & 2(6)(b).
[73] *Ibid.,* § 2(6) & note 1.
[74] *Ibid.*

use *Anchor* full-cream milk for their babies because it is so intensely promoted. Such patterns of product misuse often flow from long advertising campaigns that represent certain products as good and healthy for children or for the whole family. This common practice may also be derived from the lower cost and the placement of these milks alongside infant formula in supermarkets, shops and kiosks.

In order to prohibit the promotion of such products for young infants, Benin has included the word *used* in defining part of the scope of its Decree. The scope includes "any other prepackaged product marketed, presented or *used* to feed infants from four to six months of age".[75] Drafters should be aware, however, that employing the term *used* in this manner is, in effect, a form of strict liability. A company would be liable for promoting a product that was *used* for an infant younger than six months whether or not the company "marketed or represented" the product as suitable for infants of that age. For this reason, Tanzania includes within the scope of its Regulations, products "commonly used for feeding infants".[76]

Other countries such as Brazil and Panama have tackled this problem by requiring specific warnings for packages of full-cream and other milks.[77] In 1992, Brazil had already required warnings on labels of whole and skimmed cow's milk.[78] Brazil's revised regulations are even more specific with respect to the labels of these products. Product labels must include warnings about use for infants and include statements encouraging breastfeeding.[79] Moreover, the labels of these products may not include images and expressions that are associated with babies.[80]

If infant teas and juices are marketed for babies below the age of six months, they are breastmilk substitutes. In many countries, HIPP baby teas show a baby face and are recommended for use "from the first week". Samples of such teas are often included in maternity gift packs or promotional mailings. HIPP juices are aggressively advertised in China. A fennel tea by Milupa is recommended from the first week of life.

Milk for mothers

In the 1990s, the major baby food companies introduced milks aimed at pregnant and lactating women. These products are not *breastmilk substitutes*, and thus, not subject to the marketing restrictions of the International Code. Through these brands, the same companies that sell formula and other breastmilk substitutes have direct access to mothers and an excuse to be present in health care facilities. Moreover, the product labels, often pictured in promotional materials, use brand names, designs, pictures or logos that are identical or similar to products included in the scope of the International Code.

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[75] Benin Decree, *supra* note 56, Article 2.
[76] Tanzania Regulations, *supra* note 43, Regulation 3, definition of *designated product.*
[77] Brazil Technical Regulations, Foods for Infants and Young Children, *supra* note 20; Panama, Ley 50 por la cual se Protege y Fomenta la Lactancia Materna, 1995 (Law on the Protection and Promotion of Breastfeeding), Articles 25, 26 & 27.
[78] Brazil, Marketing Regulations for Infant's Foods, Resolution CNS Nº 31, 1992, Article 10.
[79] Brazil, Technical Regulations, Foods for Infants and Young Children, *supra* note 20, ¶ 4.11. The warnings required on the labels of these products are quoted in Chapter 9, p. 133.
[80] *Ibid.,* ¶ 4.10.1.

These products are heavily marketed through the health care system. For example, some companies sponsor pre-natal classes for parents or seminars for health workers using the *milk for mom* brands. New mother's clubs, direct mailing, glossy brochures and mass media advertising are also a major part of the marketing package for these brands.

For years, the New Zealand Dairy Board (now New Zealand Milk Brands) sold *Anmum 1* and *Anmum 2*, milks for pregnant women and breastfeeding mothers respectively, in Asia and the Middle East. The products became popular with mothers and health workers alike. Once those products became known, and the brand entrenched in health care facilities, the company introduced a range of infant and follow-up formulas called *Anmum Infacare.*

Moreover, promotional messages for these milks can discourage breastfeeding. Most mothers worry about eating the right foods during pregnancy and having enough milk to feed their babies. Promotional messages play upon these fears. A leaflet for Abbott-Ross *Formance* for mothers states, "Before delivery, nurture the foetus; after delivery boost milk production."[81] Companies have been selling formulas with fatty acids found in breastmilk and promoting them as essential to the baby's brain development.[82] New Zealand Milk Brands uses the same misinformation to sell *Anmum* for mothers in an advertisement picturing a foetus in the womb holding a can of *Anmum* next to its brain.[83]

No country has yet included milks aimed at pregnant women and breastfeeding mothers within the scope of national legislation. Each country should consider whether commercial promotion of these products ought to be restricted.

Feeding bottles, teats and pacifiers (dummies)

There is no question that feeding bottles and teats should also be included in the scope. Some countries have elected to include feeding cups with spouts as well as other special infant feeding devices.[84] Pacifiers (also known as dummies), are not included in the scope of the International Code, but there is compelling evidence that they can also inhibit breastfeeding and can be harmful to a baby's health and development.[85] Other devices that can interfere with breastfeeding, such as nipple shields are also included in certain countries.[86] Some countries use a catchall phrase to include other implements. For example, the Gabon Decree includes "other utensils that hamper breastfeeding and the use of which may harm the health and development of infants".[87]

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[81] Breaking the Rules, *supra* note 53, p. 91.

[82] The use of these fatty acids to promote infant formulas is discussed in Chapter 7, p. 95.

[83] Breaking the Rules, *supra* note 53, p. 91.

[84] *See, e.g.*, Benin Decree, *supra* note 56, Article 2; Gabon Decree, *supra* note 24, Article 2; Uganda, Food and Drugs (Marketing of Infant and Young Child Foods) Regulations, 1997, Schedule I.

[85] Step 9 of the *Ten Steps to Successful Breastfeeding,* the foundation of the *Baby Friendly Hospital Initiative*, says, "Give no artificial pacifiers to breastfeeding infants".

[86] Brazil, Regulamento Técnico Chupetas, Bicos, Mamadeiras e Protetores de Mamilo, Resolução-RDC Nº 221 de 5 de agosto de 2002 (Brazil, Technical Regulation on Dummies, Teats, Bottles and Nipple Shields), Article 1; Pakistan Ordinance, *supra* note 70, § 2, definition *designated products*; Sri Lanka Code, *supra* note 30, definition *designated product.*

[87] Gabon Decree, *supra* note 24, Article 2.

Model Law

The provision proposed to define the products that are within the scope of the ICDC Model Law is set forth in Section 2(6) (Definitions). The Model Law deliberately avoids the term *breastmilk substitutes* and uses instead *designated products.* The section reads as follows:

Section 2. Definitions

(6) "Designated product" means

(a) infant formula;

(b) any other product marketed or otherwise represented as suitable for feeding infants up to the age of six months;

(c) follow-up formula;

(d) complementary food;

(e) feeding bottles, teats, pacifiers; and

(f) such other product as the Minister of Health may, by Notice in the Official Gazette, declare to be a "designated product" for purposes of this Act

The Model Law permits promotion of complementary foods so long as promotion does not take place in a health care facility and any promotional material encourages exclusive breastfeeding for six months and sustained breastfeeding up to two years and beyond. These conditions are included in Section 4(2) of the Model Law.

Some countries will choose to prohibit promotion of all foods, including complementary foods for infants up to one or even two years. Such countries should use the following alternate text from the Model Law [text in brackets is optional]:

(6) "Designated product" means

(a) infant formula;

(b) any other product marketed or otherwise represented as suitable for feeding infants [and young children up to the age of two years];

(c) follow-up formula;

(d) feeding bottles, teats, pacifiers; and

(e) such other product as the Minister of Health may, by Notice in the Official Gazette, declare to be a "designated product" for purposes of this Act.

These countries should delete Section 4(2) of the Model Law, which allows some types of promotion for complementary foods as well as the reference to Section 4(2) in Section 4(1).

Other relevant definitions from Section 2 of the Model Law are as follows:

(4) "Complementary food" means any food suitable or represented as suitable as an addition to breastmilk, infant formula or follow-up formula for infants from the age of 6 months up to the age of 24 months.

(8) "Follow-up formula" means a milk or milk-like product of animal or vegetable origin formulated industrially in accordance with [*citation to the country's standard for follow-up formula or, in the absence of such standard, citation to the Codex Alimentarius Standard for Follow-up Formula*] and marketed or otherwise represented as suitable for feeding infants and young children older than six months of age.

(12) "Infant" means a child from birth up to the age of 12 months.

(13) "Infant formula" means a milk or milk-like product of animal or vegetable origin formulated industrially in accordance with [*citation to the country's standard for infant formula or, in the absence of such standard, citation to the Codex Alimentarius Standard for Infant Formula*] and intended to satisfy, by itself, the nutritional requirements of infants from birth and/or during the first six months and includes products that continue to meet part of an infant's nutritional requirements after the first six months. [*Explanatory Note: Some brands of infant formula are marketed for infants up to 12 months.*]

(20) "Pacifier" means an artificial teat for babies to suck, also referred to as a "dummy".

CHAPTER 5

Promotion to the Public

Relevant provisions of the International Code

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 breastmilk 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 3. Definitions

*"**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 a product within the scope of this Code. A "primary distributor" is a manufacturer's sales agent, representative, national distributor or broker.*

*"**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.*

Relevant parts of World Health Assembly Resolution

WHA58.32 (2005)
Urges Member States to ensure that "financial support and other incentives for programmes and health professionals working in infant and young-child health do not create conflicts of interest".

Once the scope of the law is settled, the next step is to determine what practices shall be prohibited. Promotion is a very broad term that encompasses all means of encouraging the sale of a product. The most popular methods of promotion employed by the infant food industry are advertising in the mass media; direct mail and newsletters associated with 'baby clubs' and the Internet. Companies also advertise at the retail level by offering free samples, gifts and discounts.

Hospitals and other health care centres are other favourite venues for company product promotion. Materials such as pamphlets, posters, product samples, and gifts are distributed to expectant and new mothers as well as to health workers. Many companies also distribute paraphernalia such as calendars and pencil holders bearing their company or product name or logo.

The original intent was for the International Code to prohibit all sales promotion. The relevant part of the recommendations that resulted from the 1979 WHO/UNICEF *Meeting on Infant and Young Child Feeding* states:

> There should be no sales promotion, including promotional advertising* to the public of products to be used as breastmilk substitutes or bottle-fed supplements and feeding bottles.
>
> . . .
>
> The facilities of the health care system should never be used for the promotion of artificial feeding. Therefore, advertising or promotional distribution of samples of breastmilk substitutes through health service channels should not be allowed.
>
> ---
>
> * This includes the use of mass media and other forms of advertising directly to the mother or general public, designed to increase sales of breastmilk substitutes, to the detriment of breastfeeding.[1]

[1] WHO and UNICEF, "WHO/UNICEF Meeting on Infant and Young Child Feeding", *WHO Chronicle,* 1979, 33: 442-43.

Articles 5 and 6 contain the main provisions of the International Code that deal with all types of promotion to the public. Article 5 covers "the general public and mothers" while Article 6 governs "health care systems". In this chapter, we examine product promotion to consumers other than that which occurs within health care facilities. Promotion that occurs within the health care system is discussed in Chapter 6. Promotion directed specifically to health workers (within the scope of their employment) even though it is often intended to reach families, is discussed in Chapter 7.

Promotion to the general public

Advertising and samples

The first provision of Article 5 broadly prohibits all advertising and other forms of promotion of products within the scope, to the general public. Article 5.2, the second provision of Article 5, is similarly straightforward and clear. It prohibits manufacturers and distributors from giving product samples either directly or indirectly. Article 5.3 gives specific examples of the promotions prohibited in 5.1 and 5.2.

Ever since the International Code was adopted, companies have been adapting their promotional strategies for products under its scope. This trend has continued as more and more countries enact laws and other measures to prohibit advertising and other forms of promotion for breastmilk substitutes. Mass media advertising of infant formula is nowadays confined mainly to wealthy countries that have not implemented the International Code such as the United States, Canada and Japan. Samples and other point-of-sale promotions for infant formula are also rarely seen outside of these countries.

Yet commercial promotion by infant food and feeding bottle companies remains an obstacle to optimal infant feeding, which at its core includes a full six months of exclusive breastfeeding followed by gradual introduction of complementary foods with continued breastfeeding for two years and beyond.[2] Promotional strategies of infant food companies now tend to focus on other infant feeding products, or on infant feeding in general. Advertising of feeding bottles and teats, as well as special displays in shops, however, are still commonplace in nearly all countries.

The Internet has provided every enterprise with a powerful new means of product marketing and offers a way to reach more people than ever before possible. Since the inception of use by the public, the Internet has grown more rapidly than any other media. Today, it is estimated that more than 12 percent of the world's population, over 817 million people, have access to the Internet.[3]

Manufacturers and distributors advertise products on the Internet primarily in two different ways. First, most companies have corporate websites and/or websites dedicated to specific products or topics. Corporate websites for infant food companies typically include information about products as well as educational information about infant and child feeding and general

[2] Recommendations for optimal breastfeeding are more fully discussed in Chapter 4, pp. 44-46.

[3] "Internet Usage Statistics – The Big Picture: World Internet usage and population stats", *Internet World Stats,* updated January 2005, http://www.internetworldstats.com/stats.htm (accessed 3 February 2005).

care.[4] Some companies have also developed websites devoted to infant feeding and care with names like *Very Best Baby* and *Welcome Addition*.[5] The names of these websites do not identify them as associated with a particular company. The sites provide, nonetheless, prime opportunities for the marketing of infant food products. If parents search the web for information on babies and infant feeding, such corporate websites will come up in the list of results.

Infant food companies also advertise their products on other websites. For example, Mead Johnson's *Enfamil* is one of the sponsors of the "pregnancy and family" section of the popular website for medical advice, *WebMD*.[6] Clicking on a banner ad stating "Be a Healthy Mom, have a healthy baby" leads to an enrolment form for the "New Beginnings" programme.[7] The advertisement offers free gifts, newsletters, tips from health experts, and product samples. Another website, *Freegifts4kids* is sponsored by Gerber, Nestlé and Mead Johnson Nutritionals.[8] Company advertisements on the website's home page provide links to the companies' own product or corporate websites.[9]

The targets of promotion

It should be noted that even though all forms of promotion are banned in Article 5, not all potential targets of promotion are given protection. First of all, it is only advertising directed to the *general* public that is banned in Article 5.1. The term *general* public is not defined in the International Code, but seemingly leaves some specialised public outside the reach of its provisions. For example, many companies advertise infant formula and other products in journals for the health professions. Arguably, such advertisements are not directed to the *general public*. They are harmful, nonetheless. Doctors sometimes leave their journals in waiting rooms where they become available to the general public.[10]

The other provisions of Article 5 are limited in similar ways. Article 5.2 applies to "pregnant women, mothers or members of their families." Article 5.3 applies to "the consumer at the retail level", while articles 5.4 and 5.5 apply only to "pregnant women and mothers of infants and young children". Generally, the types of promotion specified in 5.2, 5.4 and 5.5 are directed to mothers and pregnant women, but leaving loopholes only invites companies to devise ways to

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[4] The use of information materials on corporate websites as a way to promote products is discussed in Chapter 8, pp. 113-14.

[5] *See, e.g.*, Nestlé, *VeryBestBaby.com,* US website, http://www.verybestbaby.com (accessed 15 February 2005); Ross Products Division, Abbott Laboratories, *Similac WelcomeAddition.com,* http://www.welcomeaddition.com (accessed 15 February 2005); Dumex, *YoungNutrition.net,* http://www.YoungNutrition.net (accessed 15 February 2005).

[6] "Pregnancy & Family Center", *WebMDHealth*, http://my.webmd.com/health_and_wellness/pregnancy_family/default.htm (acccessed 15 February 2005).

[7] "Let Your Baby Shower Begin: Enfamily family beginnings", *WebMDHealth*, sponsored by Mead Johnson, https://www.webmd.com; Path: WebMDHealth; Pregnancy & Family; Be a healthy mom, have a healthy baby (accessed 22 June 2005).

[8] *FreeGifts4Kids.com,* sponsored by Gerber, Nestlé Infant Nutrition & Enfamil Family Beginnings, http://www.freegifts4kids.com (accessed 16 February 2005).

[9] *Ibid*. At one time, the children's health website *Kidsgrowth* (http://www.kidsgrowth.com) was sponsored by *Similac* infant formula. The website contained advertisements for *Similac* as well as links to Abbott-Ross's *Similac* website. The website no longer includes advertisements.

[10] Advertising in professional journals is further discussed in Chapter 7, pp. 94-98.

take advantage of them. Why should marketing personnel be permitted to contact men or women contemplating a future family or fathers or grandparents? When drafting national legislation, these loopholes can be closed by ensuring that these provisions apply to the entire public.

Gifts

Article 5.4 is concerned with "gifts of articles or utensils which may promote the use of breastmilk substitutes or bottle feeding". Gifts of feeding bottles or items marked with brand names of breastmilk substitutes would not be permitted according to Article 5.4. It could also be argued convincingly that other gifts bearing the name or logo of a manufacturer of breastmilk substitutes such as bibs or bumper stickers that announce "baby on board" promote the use of a breastmilk substitute.

Companies never stop devising creative marketing tactics. In 1999, Mead Johnson launched a compilation of classical music for children entitled *Smart Symphonies*. The company refers to the music collection as "classical music to help stimulate your baby's brain development".[11] The same company later launched a new formula with a 'smarter baby' campaign. The formula contains two fatty acids found in breastmilk that have been linked to brain development.[12]

The company distributed more than five million copies of this classical music CD to mothers around the world.[13] In the US, the CD is distributed in diaper bags given when mothers leave the hospital and features the formula brand name on the cover. In other countries where the formula brand may not be directly advertised, Mead Johnson sponsors a variety of programmes designed to study the relationship between classical music and child mental development. In Vietnam, the company distributed 3,500 CDs to children joining the programme and to more than one million in Turkey.[14] The link between the *Smart Symphonies* and infant formula touted to promote brain development is hard to miss.

Nutricia started a similar campaign in China in 2004. The company produced at least 50,000 CDs of Dutch children's songs translated into Chinese to be distributed to purchasers of their milk products, including the infant formula brands *Kissing My Baby* and *Cow and Gate*. The slogan "For over 100 years, Nutricia has been committed to making babies smarter", appears on the CD cover. After protests and negative press coverage, Nutricia claimed that the CD would only be offered with *growing-up milks*, which are outside the scope of the Chinese Rules.[15] Later, however, mothers of one-to-three month old babies reported receiving the CD with the purchase of *Kissing My Baby* infant formula and by asking for it on the Nutricia hotline.

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[11] Mead Johnson, *Enfagrow,* home page, http://www.meadjohnson.ph/enfagrow/smart_symphonies.htm (accessed 16 February 2005).

[12] Mead Johnson's *Enfamil Lipil* with the fatty acids ARA and DHA. Mead Johnson and at least 15 other companies have added this manufactured blend of fatty acids to their infant formulas in an attempt to make their products closer to breastmilk. The industrial imitation, however, can never compare with the real thing (breastmilk). *See* Chapter 7, pp. 95-96 for discussion of the marketing aspects of the addition of DHA and ARA to formulas in the context of promotion to health professionals.

[13] Grammy Foundation, "Smart Symphonies: Classical music to help stimulate your baby's development", http://www.grammy.com/academy/foundation/smart_symphonies.html (accessed 21 January 2003).

[14] *Turkish Daily News*, 13 May 1999.

[15] *See* China, Rules Governing the Administration of Marketing of Breastmilk Substitutes, 1995, Article 3.

Direct contact with mothers

Article 5.5 forbids company marketing personnel from seeking contact with pregnant women or mothers of infants and young children "in their business capacity". In addition, Article 8.2 prohibits marketing personnel from performing "educational functions in relation to pregnant women or mothers of infants and young children".

To get around this prohibition, companies encourage mothers to contact them or put mothers in contact with so-called product information specialists rather than *marketing* personnel. Companies use devices such as telephone "help lines" or sponsor events including baby shows, children's drawing contests and public forums on topics related to infants or pregnancy. This gives the company an opportunity to have its name associated with babies.

A common and effective strategy that companies have adopted for marketing infant feeding products is by direct mail. Companies used to obtain addresses of pregnant women from hospitals or clinics. Most hospitals will no longer give out private information, but companies have found a way around this obstacle by creating clubs for mothers. Mothers-to-be and new mothers are solicited to sign up for company clubs at their doctor's office or clinic; via leaflets included in discharge packs from hospitals; at maternity and children's shops; in supermarkets; at baby shows and via the Internet.

Companies use the club membership lists to mail newsletters, product samples, discount coupons and a variety of other items to families at their homes. The mailings are sent to women throughout their pregnancy and into the early years of their child's life. Mailings are often timed to coincide with key developmental stages in their baby's life, such as three, six, nine and 12 months − sensitive moments when mothers are wondering about what to feed next.

In the United States and Canada, clubs such as Abbott-Ross's "*Similac* Welcome Addition Club" and Mead Johnson Nutritionals' "*Enfamil* Family Beginnings Program" directly advertise brands of infant formula. In other countries where companies are obligated to restrict their promotion of infant formula, company mothers' clubs are sometimes more generic. Nestlé's "Baby World Club" in Singapore and Malaysia offers its members information on baby care and samples of baby cereals or other products arguably outside of the scope of national measures. Mead Johnson's *EnfaMaMa Club* newsletter distributed in Malaysia, however, prints enthusiastic letters from mothers about their experiences with Mead Johnson formulas. The company justifies the direct promotion of formula by stating that the publication is restricted to club members who are users of their products.

Companies also promote their products indirectly by sponsoring events related to babies, but not necessarily infant feeding. Abbott-Ross, for example, sponsored a public forum in Singapore on *Planning for a Family*. One topic on the agenda was entitled "Understanding milk supplements − are they useful?"[16] In 2005, the same company launched a Maternal Wellness Training & Education Programme in Malaysia for nurses and for expectant mothers.

[16] Public Forum, *Planning for a Family, What does it Take*, 23 September 2000, Singapore General Hospital (sponsored by Abbott Laboratories (Singapore)).

Drafting examples from other countries: Advertising and promotion

Advertising

It is essential to uncover and study the current marketing methods being employed in your country or region before setting the policy that will be expressed in this section of the law. The policy towards promotion and advertising differs among the countries that have legislated or are in the process of legislating. At the same time, much can be learned from how other countries have responded to various promotional practices. Quite a few countries have improved on Article 5 of the International Code by imposing a ban on promotion and advertising regardless of the target audience. You will recall that the ban in the International Code applies only to certain categories of people.

For example, India and Bangladesh prohibit all forms of advertising and promotion without limitation.[17] The Bangladesh Ordinance states, "No person shall promote any breastmilk substitute either by advertisement or by offering or giving any gift, prize, discount coupon, or other free item or by any other means".[18] Cameroon categorically forbids "any kind of advertising of breastmilk substitutes, feeding bottles and teats . . . from the whole of the national territory".[19]

Unfortunately, the European Union has somewhat lessened the impact of Article 5. The Directive for the European Union allows advertising in publications specialising in baby care and in scientific publications.[20] European Union members, however, may further restrict advertising, which France[21] and the Netherlands[22] have done by allowing advertising of infant formula only in publications for health workers.

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[17] India, Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act Nº 41 of 1992, *amended* 2003, § 3; Bangladesh, Breastmilk Substitutes (Regulation of Marketing) Ordinance Nº 33, 1984, *amended* 1990, §§ 3 & 4.

[18] Bangladesh Ordinance, *supra* note 17, § 4.

[19] Cameroon, Arrêté Interministeriel Nº 040 portant sur la réglementation de la commercialisation des substituts du lait maternel, 1993 (Cameroon, Interministerial Decree on the Control of Marketing of Breastmilk Substitutes), Article 4. *See also*, Albania, Law for Promotion and Protection of Breastfeeding, Nº 8528, 1999, Article 3; Law of Georgia on Protection and Promotion of Breastfeeding and Regulated use of Artificial Foods, 1999, Article 7; Macedonia, Law on Protection of Consumers, 63/2000, Article 14; Pakistan, Protection of Breastfeeding and Child Nutrition Ordinance, Nº 93 of 2002, § 7(1); Saudi Arabia, Royal Decree for Handling of Mother's Milk Substitutes, 2004, Article 5; Sri Lanka, Code for the Promotion, Protection and Support of Breastfeeding and Marketing of Designated Products, 2003, *pursuant to* the Consumer Protection Act, Nº 1 of 1979, Article 2.1; Uganda, Food and Drugs (Marketing of Infant and Young Child Foods) Regulations, 1997, Regulations 14(1) & (2)(a); and Vietnam, Decree on Marketing and use of Breastmilk Substitutes to Protect and Promote Breastfeeding, Nº 74/2000/ND-CP, 2000, Article 8.

[20] European Commission, Directive on Infant Formulae and Follow-on Formulae, 91/321/EEC, 1991, Article 8.

[21] France, Loi Nº 94-442 du 3 juin 1994 modifiant le code de la consommation en ce qui concerne la certification des produits industriels et des services et la commercialisation de certains produits, 1994 (France, Law modifying the Consumer Code with regard to the certification of manufactured products and services and the marketing of certain products), Article L.121-51.

[22] Netherlands, Warenwetregeling Zuigelingenvoeding, 1993, (Infant Feeding Product Regulation), Article 13.2.

The terms *advertising* and *promotion* are not defined in the International Code. According to a former Senior Legal Officer of the World Health Organization, these terms were left undefined deliberately so that they are "given their ordinary meaning".[23] Advertising and promotion are part of the broader concept of *marketing*, which is defined in the International Code as "product promotion, distribution, selling, advertising, product public relations, and information services". Even though these terms have ordinary meanings, some countries have elected to define them in their law. The Papua New Guinea Law, the India Act and the Malaysia Code, each include detailed definitions of *advertisement*.[24]

The Pakistan Ordinance prohibits any person to promote a product within the scope of its law. Pakistan defines promotion as "introducing a person to or familiarizing a person with a designated product or inducing a person to buy or use a designated product".[25]

Brazil has chosen to ban what it calls *commercial promotion* and defines it as follows:

> Information and persuasion activities deployed by companies involved in the production and/or handling, distribution and marketing [of products], with the purpose of leading to the purchase or sale of a product, including the dissemination of information by written or audio-visual means, and direct or indirect contact with health professionals or students of health professions.[26]

In Brazil, commercial promotion is banned

> by any means of communication, including merchandising, dissemination via electronic, written or audio-visual means, promotional strategies aimed at increasing retail sales, such as special displays, discount coupons, below-cost price, prizes, gifts, sales linked to products not covered by this Regulation and special presentations.[27]

It is useful to enumerate examples as in the Bangladesh Ordinance, the Brazil law and in Article 5.3 of the International Code, but the drafter must take care to make it clear that the specific provisions are examples rather than the only forbidden practices. Otherwise, such a provision may create ambiguity.

In each country, the extent of the prohibition on advertising depends on the scope of the national measure. In some countries, advertising is only prohibited for certain products. Other products may be advertised within certain conditions. For example, in Brazil, formula intended for one-to-three year olds may be advertised, but only if the advertisement includes the following statement: "Breastfeeding prevents infections and allergies and is recommended up to two

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[23] Shubber, S.,"The International Code of Marketing of Breastmilk Substitutes", *International Digest of Health Legislation*, 1985, 36: 885.

[24] Papua New Guinea, Baby Feed Supplies (Control) Act, N° 21 of 1977, § 1; India Act, *supra* note 17, § 2(a); Malaysia, Code of Ethics for Infant Formula Products, 3rd revision 1995, § 3.1.

[25] Pakistan Ordinance, *supra* note 19, §§ 7(1) and 2(w).

[26] Brazil, Regulamento Técnico para Promoção Comercial dos Alimentos para Lactentes e Crianças de primeira Infância, Resolução-RDC Nº 222 de 5 de agosto de 2002 (Technical Regulation on Commercial Promotion of Foods for Infants and Young Children), ¶ 2.28.

[27] *Ibid*., ¶ 4.1.

years of age or more."[28] Similarly, promotion for complementary foods in Brazil must include the following text: "After the first six months continue breastfeeding your baby in addition to giving new foods."[29] Advertising of infant and follow-up formula for infants up to one year old is prohibited.[30]

In Vietnam, the prohibition on advertising falls short of what is expected under the International Code, as it applies only to formula for infants up to the age of six months.[31] Advertisements for breastmilk substitutes intended for infants aged from 6-24 months, while not prohibited, must meet certain conditions. First, such advertisements must include the statement, "breastmilk is the best food for healthy growth and all-sided development of infants and young children".[32] In addition, the advertisement must comply with all of the restrictions that apply to information materials. Finally, the advertisement must not be false and may not use pictures of products for infants up to the age of six months.[33]

An innovative provision in the Malaysia Code provides that labels of one product may not be used as vehicles for advertising another product.[34] For example, a tin of infant formula may not include an insert, under the lid advertising follow-up formula, a practice that some companies have instituted. As in the International Code, the term *label* is defined to include inserts as part of the label.[35]

Some countries where the national constitution does not permit a complete prohibition of advertising have made the policy decision to allow advertising and promotion that has been prescreened by a government body. In Costa Rica, advertisements or information about breastmilk substitutes must be submitted to the Ministry of Health prior to publication or distribution. The law provides strict criteria for approval, which, if applied diligently, should serve to minimise promotion.[36] In the Philippines, advertising and promotional materials must be approved by a special inter-agency committee prior to release to the public.[37]

In general, screening is a time-consuming and exacting process that requires a very committed and knowledgeable group of people. In a review of implementation of the Philippine Code, a Department of Health official stated that it is much harder to screen advertising than to ban it. The author explained that screening was difficult because screening criteria were not clear-cut, members of the committee were not trained for the task and levels of awareness among commit-

[28] *Ibid*., ¶ 4.2.1
[29] *Ibid*., ¶ 4.2.2
[30] *Ibid*., ¶ 4.1.
[31] Vietnam Decree, *supra* note 19, Article 8(1).
[32] *Ibid*., Article 8(2).
[33] *Ibid*.
[34] Malaysia Code *supra* note 24, § 6.2(vii).
[35] *Ibid*., § 3.10 (definition of *label*).
[36] Costa Rica, Leyes Nº 7430: Fomento de la Lactancia Materna, 1994 (Law on the Promotion of Breastfeeding), Articles 10 & 11.
[37] Philippines, National Code of Marketing of Breastmilk Substitutes, Breastmilk Supplements and other Related Products, Executive Order Nº 51, 1986, § 6(a).

tee members were not the same.[38] The Philippines issued new guidelines in 2004 for advertising and promotion of products under the Code. Even the new guidelines do not have very specific screening criteria. The advertisements are to be judged according to the "over-all impact of the ad on the public to which it is addressed or to those who would generally have access to the publication". In addition, all advertisements must include standard messages about the superiority of breastfeeding and warnings about the use of breastmilk substitutes in both English and Filipino.[39]

In Nicaragua, advertising for breastmilk substitutes and feeding bottles is permitted, but "shall not induce the substitution of breastmilk".[40] This type of provision is very difficult to apply because it requires proof of causation. A judge would have to determine whether or not an advertisement was the reason a particular mother used a breastmilk substitute.

Advertising on the Internet

When countries prohibit advertising of certain infant feeding products to protect their citizens, they expect that it will apply to all advertisements, no matter what the media. The advent of the Internet has posed new questions across all domains. Just as advertisements placed in a magazine in a country that does not prohibit such advertising can easily find its way into a country where such advertising is prohibited, Internet advertisements are created in one country and appear on the screen of a person in any other country throughout the world. Countries may act to enforce their law within their territory, but not extraterritorially.

To date, no country has brought an action against a manufacturer or distributor for advertising a breastmilk substitute on the Internet. There is, however, precedent for legal actions concerning other types of prohibited activity that occurred over the Internet. For example, a French court ruled that US based, Yahoo, Inc. was liable under French law for allowing French citizens to view Nazi memorabilia contrary to its law.[41]

Some companies try to limit promotions on their websites to residents of particular countries. For example, one of Nestlé's websites, *VeryBestBaby.com* includes the following notice: "The content of this site is intended for US residents only". Residents of other countries are asked to click to read a special notice, which gives information about Nestlé and the International Code.[42]

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[38] Philippine Department of Health, *Country Report on Action Taken to Give Effect to the International Code of Marketing of Breastmilk Substitutes*, Report presented for the WHO Technical meeting on Review and Evaluation of Action Taken to Give Effect to the International Code of Marketing of Breastmilk Substitutes, The Hague, 30 September-3 October 1991.

[39] Philippines, Guidelines on Advertising, Promotion and other Marketing Materials of Breastmilk Substitutes, Breastmilk Supplements and other Related Products *pursuant to* Executive Order No. 51, 2004.

[40] Nicaragua, Ley N° 295 de Promoción, Proteción y Mantenimiento de la Lactancia Materna y Regulación de la Comercialización de Sucedáneos de la Leche Materna, 1999 (Law on the Promotion, Protection and Support of Breastfeeding and Regulating the Marketing of Breastmilk Substitutes), Article 16.

[41] *La ligue contre le racisme et l'antisémitisme (LICRA) et Union des étudiants juifs de France (UEJF) vs. YAHOO! Inc. and YAHOO France*, Order of 20 November 2000 by the Superior Court of Paris.

[42] Nestlé, *VeryBestBaby.com*, US website, http://www.verybestbaby.com/default.asp (accessed March 2005). Similarly, the "Enfamil family beginnings" banner on the WebMD website leads to a sign-up form, which states that the program is limited to US residents. "Let Your Baby Shower Begin: Enfamil family beginnings", *WebMDHealth,* sponsored by Mead Johnson, https://www.webmd.com; Path: WebMDHealth; Pregnancy & Family; Be a healthy mom, have a healthy baby (accessed 22 June 2005).

It remains to be seen if this type of disclaimer would protect a company from liability in a court of law.

Many Internet websites regulate themselves by following codes or guidelines. A number of health-related websites, for example, abide by the Health on the Network (HON) Code of Conduct for medical and health websites.[43] The HON Code is monitored by the Health on the Net Foundation. The HON Code does not preclude advertising, but requires transparency in identification of any sponsorship. The Code also states that advertising on a website should be presented in a way that makes it clearly distinguishable from original material created by the site's operating institution.[44]

Direct marketing and other promotions

Under Article 5.5 of the International Code, marketing personnel should not seek contact with mothers and pregnant women. Most countries have incorporated Article 5.5 of the International Code in their national measures. In Brazil, marketing personnel are not permitted in health care facilities, except for the purpose of providing technical product information to paediatricians and nutritionists.[45] In Pakistan, manufacturers and distributors may not contact members of the general public in a health care facility for business purposes.[46] Uganda has the same provision, but it is not limited to health care facilities.[47]

Although instances of personal solicitation by company personnel have decreased, companies have vastly stepped up attempts to contact mothers via clubs, telephone help lines and public events such as baby contests and shows. Companies get around national measures by creating educational departments that handle customer queries and develop educational materials for mother or baby clubs. Employees in these departments are not referred to as marketing personnel and companies claim that they are thus not precluded from seeking contact with mothers.

The Zimbabwe law closes this loophole by prohibiting manufacturers and distributors from employing any person to provide education or instruction on the use of a designated product or the nutrition of babies and young children up to the age of five years.[48] An exception is provided for informational materials that have been approved by a designated Committee.

Manufacturers and distributors of products under the scope of the Georgia law are not allowed to contact pregnant women and new mothers directly, through third parties, or by mail, Internet or telephone.[49] Georgia specifically prohibits the introduction and promotion of tele-

[43] "HON Code of Conduct (HONcode) for medical and health Web sites", *Health on the Net Foundation,* http://www.hon.ch/HONcode/ Conduct.html (accessed 14 April 2005).
[44] *Ibid*.
[45] Norma Brasileira de Comercialização de Alimentos para Lactentes e Crianças de Primeira Infância, Bicos, Chupetas e Mamadeiras, Portaria Nº 2051 de 8 de novembro, 2001 (Brazilian Standard for Marketing of Foods for Infants and Young Children, Teats, Dummies and Feeding Bottles), Article 13.
[46] Pakistan Ordinance, *supra* note 19, § 7(6).
[47] Uganda Regulations, *supra* note 19, Regulation 14(2)(e).
[48] Zimbabwe, Public Health (Breastmilk Substitutes and Infant Nutrition) Regulations 1998, §§ 9 & 2.
[49] Georgia Law *supra* note 19, Article 6 (2).

phone help lines.[50] The Georgia law does not use the phrase marketing personnel but instead applies to contacts by manufacturers or distributors "with the aim to fulfil their official duties".[51]

Singapore's Code of Ethics states that the infant food industry will not solicit contacts with pregnant women or mothers of infants and young children.[52] In Malaysia, the infant formula industry may not obtain directly or indirectly, the names and addresses of pregnant and lactating mothers for purposes of promoting their products.[53] This provision is complemented by a direction to health personnel not to allow company personnel to obtain names and addresses of mothers from the health care system.[54]

Albania has a specific provision that could be applied to prohibit promotional activities that come in the guise of educational events such as the public forum on family planning held in Singapore, where a discussion of infant formula products was included as one of the topics. In Albania, manufacturers and distributors may not sponsor activities related to the health of mothers and children other than activities that "have a scientific character".[55] It should be noted that in 2005, the WHA adopted Resolution 58.32, which urges Member States to ensure that "financial support and other incentives for *programmes* and health professionals working in infant and young-child health do not create conflicts of interest". (emphasis added)

The voluntary codes in Malaysia and Singapore each include provisions that relate to baby shows. The Malaysia Code states that the infant formula industry "should not be involved in any manner with baby shows (0-36 months)".[56] The Singapore Code states "the infant food industry will not be associated in any manner with Baby Shows for products within the scope of this Code".[57]

Model Law

The relevant provisions of the ICDC Model Law are as follows:

Section 4. Promotion

(1) Except as provided in Subsection 4(2), a manufacturer or distributor shall not him or herself, or by any other person on his or her behalf, promote any designated product. Prohibited promotional practices include but are not limited to−

(a) advertising;

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[50] *Ibid*.
[51] *Ibid*.
[52] Singapore, Code of Ethics on the Sale of Infant Formula Products, Revised July 2002, Article 8.3.
[53] Malaysia Code, *supra* note 24, § 4.10.
[54] *Ibid*., section 5.5.
[55] Albania Law, *supra* note 19, Article 5.
[56] Malaysia Code, *supra* note 24, § 4.7.
[57] Singapore Code of Ethics, *supra* note 52, Article 8.3.

(b) sales devices such as special displays, discount coupons, premiums, rebates, special sales, loss-leaders, tie-in sales, prizes or gifts;

(c) giving of one or more samples of a designated product to any person;

(2) A manufacturer or distributor may promote a complementary food provided that–

(a) such promotional practice does not take place in a health care facility; and

(b) any material promoting complementary food encourages exclusive breastfeeding for six months and sustained breastfeeding for up to two years and beyond.

(3) A manufacturer or distributor shall not him or herself, or by any other person on his or her behalf–

(d) sponsor events, contests, telephone counselling lines or campaigns related to reproductive health, pregnancy, childbirth, infant or young child feeding or related topics;

The relevant definitions are as follows:

Section 2. Definitions

(1) "Advertise" means to make any representation by any means whatsoever for the purpose of promoting the sale or use of a designated product including but not limited to–

(a) written publication, television, radio, film, electronic transmission including the Internet, video or telephone;

(b) display of signs, billboards, or notices; or

(c) exhibition of pictures or models.

(7) "Distributor" means a person, corporation or other entity engaged in the business, whether wholesale or retail, of marketing any designated product.

(17) "Manufacturer" means a person, corporation or other entity engaged in the business of manufacturing a designated product whether directly, through an agent, or through a person controlled by or under an agreement with it.

(18) "Market" means to promote, distribute, sell, or advertise a designated product and includes product public relations and information services.

(22) "Promote" means to employ any method of directly or indirectly encouraging a person to purchase or use a designated product.

(23) "Sample" means a single or small quantity of a designated product provided without cost.

CHAPTER 6

Promotion in Health Care Facilities

Relevant provisions of the International Code

Article 6. Health care systems

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.

6.6 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 breastmilk 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 4. Information and education

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 3. Definitions

"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.*

"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.*

Relevant parts of World Health Assembly Resolutions

WHA39.28 (1986)

Urges Member States . . . to ensure that the small amounts of breastmilk substitutes needed for the minority of infants who require them in maternity wards and hospitals are made available through the normal procurement channels and not through free or subsidized supplies.

WHA47.5 (1994)

Urges Member States . . . to ensure that there are no donations of free or subsidized supplies of breastmilk substitutes and other products covered by the International Code of Marketing of Breastmilk Substitutes in any part of the health care system; and to exercise extreme caution when planning, implementing or supporting emergency relief operations, by . . . ensuring that donated supplies of breastmilk substitutes or other products covered by the scope of the International Code be given only if all the following conditions apply:

(a) infants have to be fed on breastmilk substitutes, as outlined in the guidelines concerning the main health and socioeconomic circumstances in which infants have to be fed on breastmilk substitutes,

(b) the supply is continued for as long as the infants concerned need it;

(c) the supply is not used as a sales inducement.

Probably the greatest success of the International Code has been the reduction in direct promotion of infant formula and other products through the mass media and retail outlets. When it comes to promotion that takes place within health care facilities, however, the same cannot be said.

Company materials in health care facilities

Clinics, doctors' offices and hospital wards that serve pregnant women, mothers, infants and young children are attractive to companies that market infant foods or feeding utensils. These are places where product promotion is bound to reach its target audience. Moreover, posters and other materials promoting products or the companies that sell those products, when displayed in or distributed through a hospital or clinic, have the tacit or overt endorsement of the medical establishment in which parents place their trust.

At its conception, it was intended that the International Code would put an end to product promotion through the health care system. The relevant recommendation that came out of the 1979 WHO/UNICEF *Meeting on Infant and Young Child Feeding* states:

> The facilities of the health care system should never be used for the promotion of artificial feeding. Therefore, advertising or promotional distribution of samples of breastmilk substitutes through health service channels should not be allowed.[1]

As discussed in Chapter 5, Article 5 of the International Code bans advertising and other forms of promotion of products within the scope of the Code. Article 6.2 prohibits the use of a health care facility for "the purpose of promoting infant formula or other products within the scope of this Code". In addition, Article 6.3 prohibits the display of products or placards or posters concerning such products within the scope as well as the distribution of materials provided by a manufacturer or distributor in a health care facility.

In countries where the International Code has not been implemented or where national measures are either not enforced or inadequate, company-produced booklets, pamphlets, posters, calendars, note pads, cot cards, pens, pencil holders, toys and a variety of other materials are displayed or distributed in health care facilities that cater to mothers and children. The materials are usually imprinted with *pack shots* or brand names of infant formulas, follow-up formulas, feeding bottles or other products within the scope of the International Code.

In addition, companies use health care facilities to distribute gift packs and product samples to mothers after they have given birth. Gift packs usually contain booklets, coupons for nappies and other child care products as well as product samples. In the US and Canada, companies design gift packs especially for the breastfeeding mother. These usually contain a booklet on breastfeeding and packets of formula for 'just in case'.

Even where the International Code has been implemented or in countries where companies claim to comply, health care facilities are full of materials that have the effect of promoting

[1] WHO and UNICEF, "WHO/UNICEF Meeting on Infant and Young Child Feeding", *WHO Chronicle*, 1979, 33: 443.

products within the scope of the Code. Many of the promotional tactics found in health care facilities show that infant food companies work hard to find loopholes in the provisions of the International Code. Even though Article 6.3 prohibits the *distribution* of all materials provided by a manufacturer or distributor [other than informational or educational materials] in a health care facility, Article 6.8 allows certain donations. According to Article 6.8, equipment and materials *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". Companies take advantage of this discrepancy in the International Code.

Instead of producing materials displaying product brand names, companies produce a wide array of posters, clocks, stickers, cot cards and countless other items that display only the name of the company. The items are given to hospital and clinic staff who put them out for display in the waiting rooms, examination rooms and on the wards. In one large hospital in Taiwan, for example, the walls of the maternity unit were full of clocks with the names of various companies that produce breastmilk substitutes. Other floors of the hospital had only a few regular clocks on the walls.

More often, the company-produced posters and calendars feature happy, healthy babies, or a breastfeeding mother along with a prominent display of the company name and/or logo. Sometimes companies use images associated with babies such as colourful toys or cartoon animals. Many companies have developed symbols, mascots or logos that they associate with a particular brand or line of products. These symbols, rather than product brand names, are printed on items that are distributed or displayed in the health care facilities.

For example, Abbott-Ross uses the *Rosco bear* to represent *Similac* and other formulas, and Gerber uses its famous baby face on all of its products for infants and young children. Wyeth formulas *SMA* and *S-26* are associated with colourful building blocks, cartoon carrots or a yellow duck. Nestlé uses a blue bear to symbolise its line of cereals and other complementary foods. Some of these symbols have become better known than the companies themselves.[2]

Companies have realised that they do not need to mention specific brand names in order to promote products. Company names, company logos or product symbols, especially when appearing in association with images of babies, breastfeeding mothers or cartoon animals serve, by themselves, to promote the associated product or products. Moreover, the lovely images of mothers and babies alongside the company name, visible in maternities and clinics where mothers bring their babies, do much to enhance the corporate image. The association between the company and babies will stay in the mother or father's mind in the supermarket, or even in the doctor's mind when recommending feeding options. Companies would not spend the money to produce and distribute so many of these materials if they did not generate additional sales.

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[2] For additional examples *see* International Baby Food Action Network, *Look What They're Doing: Hospitals and Clinics*, *Monitoring trends – An IBFAN summary,* Penang, Malaysia: IBFAN-ICDC, 2001; International Baby Food Action Network, *Breaking the Rules, Stretching the Rules 2004*, Penang, Malaysia: IBFAN-ICDC, 2004; International Baby Food Action Network, *Breaking the Rules, Stretching the Rules 1998*, Penang, Malaysia: IBFAN-ICDC, 1998, pp. 8-9.

This distribution through health care facilities of information and educational materials such as posters about infant care, growth charts, booklets and pamphlets on infant feeding is another way in which companies use health care facilities to promote their products. Like the baby posters, these items serve to promote commercial products because they are always imprinted with the company name and logo. As educational materials, their distribution is subject to Article 4.3, which requires that they be given only upon request and approval of a government agency, but permits the company's name or logo. Informational and educational materials are more fully discussed in Chapter 8.

Companies also take advantage of Article 6.8 by donating equipment or materials to hospitals or practitioners such as incubators and air conditioners or smaller but useful items like feeding bottles, towels, diapers or baby cots. Companies have even been known to donate a new nursery to hospitals or clinics. The donated items nearly always display the donor company's name. Larger items will have the donor's name embossed on a plaque. In some cases the companies give on condition that the hospital use and distribute its products exclusively. Other times there is no express *quid pro quo* but health workers tend to feel an implicit obligation to repay the donor company with product recommendations.

Such donations can lead to a reliance on the "generosity" of companies, enabling them to influence hospital practices. Many health workers, government officials and hospital administrators feel dependent on assistance from companies to obtain the medical equipment, textbooks and hospital fixtures they need.

Drafting examples from other countries: Promotion in health care facilities

Any national measure that prohibits advertising and other forms of product promotion would necessarily prohibit materials found in health care facilities that refer to a product within its scope. Such displays of product names, logos or *pack shots* fall within the meaning of *advertising*. Ghana, in addition to its prohibition on advertising, has a provision specifically related to health care facilities. Materials that bear the name, logo, trademark or any other description of a designated product may not be displayed in a health care facility or in any other public place.[3]

Yet a ban on advertising or showing the brand names of specific products does not close the loophole whereby companies display their *company* name, logo or symbol on items like posters, clocks or incubators without referring to a particular product. Georgia has drafted its law to close this loophole. The law not only prohibits the display in health care facilities of advertising, informative or teaching materials related to products within the scope but also prohibits the use of items that bear a mark, logo, name or symbol of a manufacturer or distributor of products within the scope of the law.[4]

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[3] Ghana, Breastfeeding Promotion Regulations, 2000, Regulation 4.

[4] Law of Georgia on Protection and Promotion of Breastfeeding and Regulated use of Artificial Foods, 1999, Article 19.

Countries that adopt a similar provision must note, however, that prohibiting a mention of the company name will surely mean that companies will no longer donate equipment or materials to health care facilities. Companies are profit-making ventures and do not spend money unless they can count on some return such as a boost in corporate image. Moreover, a provision in the law forbidding all reference to a company name or logo on materials distributed within a health care facility would also apply to materials by the same manufacturers that are unrelated to infant food products. Thus, for example, a general food company that sells infant formula as one product in its range of products would not be permitted to display its name on an oven it donates to the hospital kitchen and a pharmaceutical company that also sells infant foods within the scope would not be permitted to have its name on a poster promoting child vaccines.

Governments must determine if this is their intended outcome. Uganda, like Georgia, has chosen to do without this type of company assistance. Uganda prohibits altogether manufacturers and distributors from donating equipment or services to a health care facility.[5] Yemen and Zimbabwe have taken a different approach that does not preclude all donations from manufacturers and distributors. In Yemen, manufacturers and distributors are prohibited from distributing to the public only materials "that can promote the use of milks or foods other than breastmilk."[6] In Zimbabwe, it is prohibited to display a poster or placard "depicting or intended to promote a designated product".[7] The Model Law is similar and prohibits manufacturers from donating or distributing equipment, services or materials, which "refer to or may promote the use of a designated product".[8]

The phrase "which refer to or may promote the use of a designated product" gives scope to regulators and courts to interpret industry's actions based on the purpose of the law. It casts the burden on industry to prove that its donation is not likely to promote the use of a designated product, which burden will be difficult to discharge if the donation is made to maternity or paediatric facilities. The Zimbabwe regulations specifically state that the onus of proving that the donation was not given for the purpose of promoting a designated product lies with the manufacturer or distributor.[9] It should be noted that the Model Law also prohibits promotion of complementary foods within a health care facility, even though such foods may be advertised in the mass media.[10] The promotion of complementary foods is more fully discussed in Chapter 4.

Free and low-cost supplies

The long-established industry practice of donating large quantities of baby milk, other foods for infants below six months and feeding bottles to hospitals and other health care facilities has been both the most damaging to breastfeeding and the most successful marketing technique. It is for this reason that for many years *free supplies* had been the focus of attention for international agencies, non-governmental organisations and industry.

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5 Uganda, Food and Drugs (Marketing of Infant and Young Child Foods) Regulations, 1997, Regulation 15(3).
6 Yemen, Prime Minister Decree N°18 on Regulation of Breastfeeding Promotion and Protection, 2002, Article 12(3).
7 Zimbabwe, Public Health (Breastmilk Substitutes and Infant Nutrition) Regulations, SI 46 of 1998, § 18(1)(b).
8 Model Law, § 4(3)(b).
9 Zimbabwe Regulations, *supra* note 7, § 18(6).
10 *See* Chapter 4, pp. 59 & 62.

The practice of donating what have become known as *free supplies*[11] to hospitals worldwide is longstanding and goes hand-in-hand with the industry's tendency to market its products through the health care system. Companies would provide as much formula as a hospital could use, often with the understanding that each mother would be discharged with a product sample. Later many hospitals, desiring to get some order in their storage rooms and dissociate themselves from any particular company, established monthly rotations of the various companies' products, the so-called "flavour of the month" system.

Hospital practices, along with the availability of free milk, entrench the practice of formula feeding, thus guaranteeing sales to the industry. There are still many hospitals, particularly private hospitals and hospitals in industrialised countries that have not become *baby-friendly*.[12] These hospitals still separate mothers from their new-borns. It is thought to be more convenient for the staff to prepare 20-30 feeding bottles six times a day for the babies in the nursery, than to bring the babies to 20-30 mothers for each feeding.

For a number of reasons, the majority of mothers whose babies were bottle-fed from birth in the hospital will continue to bottle feed their babies after discharge. The absence of suckling will delay or prevent the adequate secretion of prolactin, which is necessary for the production of breastmilk. At the same time, maternal confidence in exclusive breastfeeding is eroded by hospital use of supplemental bottles. Babies' suckling reflexes become confused. Moreover, families interpret hospital use of infant formula as an endorsement not only of formula feeding, but also of the particular brand that was fed to their baby. This becomes, for the company, an excellent way to build brand loyalty, as parents will often buy the same brand after leaving the hospital. One free tin of baby milk can grow into six months of sales.

From the huge amounts of money companies are willing to spend to donate these products to hospitals, it is obvious that the practice is a successful marketing technique. Companies vie for the opportunity to give milk to hospitals. In Canada, companies are known to enter into contractual arrangements to provide, free of charge, hospitals' entire needs for infant feeding products in return for each hospital's exclusive use of the particular company's products. One company included in the deal an additional payment of C$43.26 for each birth over the hospital's reported number of annual births. In Taiwan, on top of the free formula, companies pay hospitals US$25 for each baby fed on their brand. In Thailand, at least seven different companies supply formula to hospitals. Private hospitals are offered so much free formula that many still use the system of monthly brand rotations.

Far from being charity, companies use free supplies as a direct route to consumers, the more affluent the better. They also serve to gain an edge over competitors. In Brazil, there were no free supplies until several other manufacturers of infant formula entered the market, ending Nestlé's virtual monopoly. There have never been free supplies in some of the poorest countries where purchasing power is too low to make it worthwhile for companies.

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[11] The terms *free supplies* and *donations* also refer to low-cost or subsidised supplies.
[12] The concept of *baby-friendly hospitals* is discussed in Chapter 2, pp. 21-22.

Free supplies and the International Code

The term *supplies* is defined in the International Code as "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 6.6 says that donations or low-price sales of supplies of infant formula to institutions and organisations *may be made* but they should only be used or distributed for *infants who have to be fed on breastmilk substitutes.* Article 6.6 also says that donations or low-price sales should not be used by manufacturers as a sales inducement.

Chapter 2 recounts how companies used a variety of interpretations of this fairly straightforward language to justify giving regular and large quantities of supplies to hospitals. It was hoped that the practice would finally end after the WHA urged Member States in Resolution 47.5 (1994) to

> ensure that there are no donations of free or subsidized supplies of breastmilk substitutes and other products covered by the International Code of Marketing of Breastmilk Substitutes in any part of the health care system.

Even though a large number of countries implemented Resolution WHA47.5 in national laws, directives, circulars or other measures forbidding free supplies in the health care system, the practice has not stopped. In addition, many industrialised countries do not yet have legislation or other measures banning supplies. A 2004 IBFAN survey showed that 8 of the 16 baby food companies surveyed were still giving free supplies of infant formula, follow-up formula or other foods for babies under six months old to health care facilities.[13]

Free supplies in the context of HIV

Chapter 2 discusses the development of international guidelines regarding infant feeding in the context of HIV. This section looks at guidelines for providing breastmilk substitutes to HIV-positive mothers who have decided not to breastfeed.

The discovery in the early 1990s that some babies born to HIV-positive mothers may become infected with the virus via breastfeeding has given renewed importance to the International Code and particularly the WHA resolutions calling for an end to free supplies in the health care system. Because of HIV transmission via breastfeeding, there are more infants who *have to be fed on breastmilk substitutes*, but in relation to all babies born around the world, that number is still very small. Implementation of the International Code can ensure that breastfeeding is not undermined for the majority of infants for whom breastfeeding greatly improves the chances of better health and survival.

Some governments have decided to provide or are considering providing breastmilk substitutes for HIV-positive mothers who have made an informed choice not to breastfeed in con-

[13] International Baby Food Action Network, *State of the Code by Company 2004,* Penang, Malaysia: IBFAN-ICDC 2004.

junction with programmes to reduce mother-to-child transmission of HIV. The programmes usually include voluntary HIV testing and counselling; the administration of anti-retroviral drugs as well as free infant formula. When planning a programme that includes giving breastmilk substitutes to mothers, governments should carefully ensure that certain conditions are met. Most importantly, breastmilk substitutes should only be offered to women who are known to be HIV-positive and for whom replacement feeding is acceptable, feasible, affordable, sustainable and safe (AFASS). In addition, the government must be able to ensure that the mother will have access to enough formula without interruption, even in the remotest areas, for as long as her baby needs it.[14]

The provision of free formula should not be done in a way that undermines breastfeeding for the majority of infants nor in a way that promotes breastmilk substitutes. Governments should not accept offers of donations of breastmilk substitutes from manufacturers or distributors, but should purchase what they need. It will be recalled that the World Health Assembly resolved in 1986 that breastmilk substitutes should not be donated to hospitals or maternity wards because there are so few infants who need them for physiological or socioeconomic reasons.[15] The WHA reaffirmed this with Resolution WHA47.5 in 1994 and expanded the ban on free supplies to the entire health care system.

The International Code aims to prevent the use of free supplies as a marketing technique. As noted above, when companies are allowed to donate products to health care facilities, the products become too easily available. Medical staff are likely to distribute them even to mothers who do not need them or who cannot use them safely. There is already a strong belief in many communities and governments that HIV-positive women should not breastfeed their babies even though for many, the risk of transmitting HIV is outweighed by the risk of replacement feeding.[16] There is also the risk that the use of breastmilk substitutes might 'spill over' to women who do not know their HIV status or are uninfected.

As a measure to deter free formula from becoming an incentive for HIV-positive women to choose replacement feeding, governments could consider providing nutritional or related support for women, who choose to breastfeed. Such a measure can help to ensure that the health care system is not seen as promoting one feeding option over another.

Drafting examples from other countries: Free supplies

At least 100 countries have taken some action to end or prevent infant food and feeding bottle companies from giving free or low-price supplies to health care facilities.[17] A number of countries allow manufacturers and distributors to donate the relevant products to orphanages or

[14] International guidelines for replacement feeding and the necessary conditions (AFASS) in the context of HIV-positive mothers are more fully discussed in Chapter 2, pp. 29-30.

[15] Resolution WHA39.28 (1986).

[16] The risk of breastfeeding as compared to replacement feeding for HIV-positive mothers is more fully discussed in Chapter 2, pp. 27-29.

[17] UNICEF, *Progress Report, Baby Friendly Hospital Initiative,* New York: UNICEF, 1995.

other charitable organisations, even if these institutions or organisations are considered part of the health care system.[18]

In Guatemala and Nicaragua, companies may donate breastmilk substitutes or provide them at low cost with the permission of the Ministry of Health.[19] Countries that give such discretion to the Ministry should draft clear guidelines delineating the circumstances under which a request for free supplies will be approved.

Other countries have made exceptions to the ban on free supplies in health care facilities for cases of need as was intended in Article 6.6 of the International Code. In Zimbabwe, for example, a manufacturer or distributor may donate breastmilk substitutes or feeding bottles with permission of the Secretary for Health. The Zimbabwe Regulations specify that the Secretary may not give such permission, unless 1) the products are needed due to the medical condition of the infant or mother; 2) the product is for orphaned or abandoned infants or 3) is intended for multiple births. Donated products may not bear a product brand name. In addition, if donated for infants outside of a health care facility, the supply must be enough to last as long as the infant requires the product and those providing care for the infant must receive appropriate training to prevent health hazards.

In India, donations from manufacturers and distributors are not allowed even in cases of need, but health care institutions may distribute breastmilk substitutes and feeding bottles to a mother who is unable to breastfeed and who cannot afford to purchase these products. [20]

In the Model Law, reflecting the policy of WHO and UNICEF, manufacturers and distributors may not provide free supplies of designated products, or sell them at less than the published wholesale price, or in its absence less than 80 percent of retail price, to health care facilities.[21] For cases of need, including HIV-positive mothers who choose not to breastfeed, governments are encouraged to purchase the formula and distribute it according to developed guidelines.

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[18] *See, e.g.*, France, Décret N° 98-688 relatif à la distribution gratuite des préparations pour nourrissons, à la documentation et au matériel de présentation les concernant, 1998 (Decree on the free distribution of infant formula, documentation and the presentation of material concerning such products), Article 3 (donations only to philanthropic, social or humanitarian organisations); Philippines, National Code of Marketing of Breastmilk Substitutes, Breastmilk Supplements and other Related Products, Executive Order N° 51, 1986, §§ 6(b) & (f) and Philippines, Guidelines for Implementation of Executive Order N° 51, Department Circular N° 24 s. 1987, *as amended by* Department Circular N° 122-A s., 1987, § IV. B (Philippine Code requires approval of Ministry of Health for donations. Guidelines state that donations may be given only to non-profit institutions such as orphanages or in times of disaster); Uganda Regulations, *supra* note 5, Regulation 15(1) (donations permitted for orphanages or institutions devoted exclusively to caring for abandoned children); Vietnam, Decree on Marketing and use of Breastmilk Substitutes to Protect and Promote Breastfeeding, N° 74/2000/ND-CP, 2000, Article 12(1)(b) (free supplies only for orphanages and charitable organisations).

[19] Guatemala, Reglamento para la Comercialización de los Sucedáneos de la Leche Materna, Acuerdo Gubernativo N° 841-87, 1987 (Guatemala, Rules for the Marketing of Breastmilk Substitutes), Article 9; Nicaragua, Ley N° 295 de Promoción, Protección y Mantenimiento de la Lactancia Materna y Regulación de la Comercialización de Sucedáneos de la Leche Materna, 1999 (Nicaragua Law for the Promotion, Protection and Support of Breastfeeding and Regulation of the Marketing of Breastmilk Substitutes), Article 22.

[20] India, Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act N° 41 of 1992 *amended* 2003, §§ 5(a) & 8(4).

[21] Model Law, § 4(3)(a).

Donations of breastmilk substitutes in emergency situations

According to the WHO, every year for the last century some 150 million people worldwide have been affected by some type of emergency. These may be natural or human-induced calamities such as drought, floods, earthquakes, tsunamis, famine, epidemics, agricultural or ecological catastrophes, wars, civil unrest and severe political and economic decline.[22] Of the 40 million refugees and displaced persons, 5.5 million are children under five years old.[23] In such situations, breastfeeding takes on an even greater importance as mothers and babies are often the most vulnerable victims. Principles of the International Code and relevant subsequent WHA resolutions are vital to protect infants in emergency situations.

Studies have shown that in emergency situations, children under five years old are more likely to die than the rest of the population.[24] Under normal circumstances, around the world, two-thirds of the deaths of children under five years old occur during the child's first 12 months. The proportion of deaths occurring during those first 12 months in emergency situations depends, in part, on how the infant is fed.[25]

In disaster situations, when food is lacking, milk is frequently requested or donated in various forms for distribution to affected populations. Donations of infant foods and feeding bottles and teats come from many sources, usually with good intentions but often stemming from a lack of information. Media coverage can create the impression that breastfeeding in such situations is impossible and that bottles and breastmilk substitutes are therefore needed. Yet, it has been found that use of milk products in such situations, especially for infants, can result in even greater suffering and loss of children's lives.

One study of large unsolicited donations of infant formula and other feeding products during the crisis in the Balkans in the 1990s found that too much formula was sent because there had been little or no assessment of need.[26] A NATO representative in Macedonia estimated that during the initial weeks of the crisis, the organisation received and transported 3,500 metric tonnes of donated aid of which an estimated 40 percent was baby food.[27] The study in the Balkans also noted that feeding bottles and teats were donated even though a cup is the recommended feeding implement. In addition, preparation and feeding instructions were not provided in local languages, donations served to advertise commercial brands and some donated formulas had expired.[28]

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[22] WHO, *Guiding Principles for Feeding Infants and Young Children during Emergencies,* Geneva: WHO, 1997.
[23] WHO, *The Management of Nutrition in Major Emergencies*, Geneva: WHO, 2000.
[24] *Infant Feeding in Emergencies: Manual for orientation reading and reference*, Module 1 for Emergency Relief Staff, (Revision 1), November 2001 (*hereinafter* Infant Feeding in Emergencies), p. 4 (material developed through collaboration of WHO, UNICEF, Linkages, IBFAN and Emergency Nutrition Network).
[25] *Ibid.,* p. 5.
[26] Phelps, L. and Wilkenson, C., *Infant Feeding Practices: Observations from Macedonia and Kosovo,* UK: Action Against Hunger, 1999 (*hereinafter* Phelps & Wilkenson). *See also* Infant Feeding in Emergencies, *supra* note 24, p. 19.
[27] Borrel, A., Taylor, A., McGrath, M. et al., "From Policy to Practice: Challenges in infant feeding in emergencies during the Balkan crisis", *Disaster*, 2001, 25: 149-63.
[28] Phelps and Wilkenson, *supra* note 26.

In every emergency situation there will be infants who, for one reason or another, will not be breastfed. These include infants who have become separated from their mothers, infants whose mothers are ill or have died, those whose mothers' milk production has become very low, whose mothers have chosen not to breastfeed after testing positive for HIV or babies who were being artificially fed prior to the emergency situation.

Article 6.6 of the International Code allows donations of breastmilk substitutes for social welfare purposes to institutions and organisations such as orphanages or other social welfare institutions so long as the donations are used and distributed to infants who have to be fed on breastmilk substitutes. Article 6.7 says that the institution that distributes the products must ensure that the supply can be continued as long as the infants need it.

Resolution WHA47.5 (1994), in addition to urging an end to free supplies in the health care system, also addressed supplies in the context of emergency situations. Resolution 47.5 urges governments to

> exercise extreme caution when planning, implementing or supporting emergency relief operations . . . by ensuring that donated supplies of breastmilk substitutes . . . be given only if all the following conditions apply:
>
> (a) infants have to be fed on breastmilk substitutes, as outlined in the guidelines concerning the main health and socioeconomic circumstances in which infants have to be fed on breastmilk substitutes; [see WHA39.28]
> (b) the supply is continued for as long as the infants concerned need it; and
> (c) the supply is not used as a sales inducement.

UNICEF, WHO and a large group of NGOs have been actively working to find ways to ensure that the provisions of the International Code and Resolution 47.5 are applied. Guidelines developed for staff and policy makers in emergency situations include detailed recommendations regarding procurement, distribution and management of the use of breastmilk substitutes during emergencies.[29]

The guidelines recommend that all donations of breastmilk substitutes, feeding bottles, teats and commercial baby foods should be refused. Generically branded formula should be procured for infants who have to be fed on breastmilk substitutes. If such formula is unavailable, the guidelines recommend that staff purchase locally products that are manufactured and packaged in accordance with Codex Alimentarius standards. Staff should choose brands that are labelled in a language that may be understood by the users and whose label is in compliance with the other requirements of the International Code. In some cases products may need to be relabelled prior to distribution.[30]

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[29] Interagency Working Group on Infant Feeding in Emergencies, *Operational Guidance for Emergency Relief Staff and Policy-Makers*, November 2001. These practical guidelines were drafted by Save the Children, Institute of Child Health (London), Linkages and IBFAN. Comments from many other agencies were incorporated over a long consultation process. *See also* WHO, *Guiding Principles for Feeding Infants and Young Children during Emergencies*, Annex to WHO, *The Management of Nutrition in Major Emergencies*, Geneva: WHO, 2000.

[30] *Operational Guidance for Emergency Relief Staff and Policy-Makers, supra* note 29, § 6.

The guidelines also stipulate conditions that reduce the dangers of artificial feeding. Breastmilk substitutes should only be distributed on an individual basis after assessment of need and the supply should be enough to last as long as the infant needs it. There should be no promotion for the product at the place where it is distributed. It is recommended that the product be dispensed in regular short intervals, such as every week. In addition to the milk product, staff should supply feeding cups and soap for cleaning them, ensure that there is a clean place for preparation and a safe place for storage, a way of properly measuring the water and milk powder as well as adequate fuel for safe preparation of feeds.[31]

Sri Lanka, which was hard hit during the tsunami disaster at the end of 2004, had already legislated similar guidelines for donations of infant formula and related products in emergency relief operations. The Sri Lanka Code limits such donations to infants who have lost or have become separated from their mother and only if the supply can be continued for the duration of need; is not used as a sales inducement and has been requested upon medical advice.[32]

Model Law

The relevant provisions of the ICDC Model Law are as follows:

Section 4. Promotion

(1) Except as provided in Subsection 4(2), a manufacturer or distributor shall not him or herself, or by any other person on his or her behalf, promote any designated product. Prohibited promotional practices include but are not limited to–

(a) advertising;

(d) donation or distribution of information or educational material referring to infant or young child feeding or performance of educational functions related to infant or young child feeding except as provided in Section 14.

(2) A manufacturer or distributor may promote a complementary food provided that–

(a) such promotional practice does not take place in a health care facility; and
(b) any material promoting complementary food encourages exclusive breastfeeding for six months and sustained breastfeeding for up to two years and beyond.

(3) A manufacturer or distributor shall not him or herself, or by any other person on his or her behalf–

(a) donate or provide at lower than the published wholesale price where one exists, and in its absence, lower than 80 percent of the retail price, any quantity of a designated product to a health worker or a health care facility;
(b) donate to or distribute within a health care facility equipment, services or materials such as pens, calendars, posters, notepads, growth charts and toys, which refer to or may promote the use of a designated product;

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[31] *Ibid.* § 6.2.

[32] Sri Lanka, Code for the Promotion, Protection and Support of Breastfeeding and Marketing of Designated Products, 2003, *pursuant to* the Consumer Protection Act, No 1 of 1979, Article 4.7.

The relevant definitions are as follows:

Section 2. Definitions

For purposes of this Act−

(1) "Advertise" means to make any representation by any means whatsoever for the purpose of promoting the sale or use of a designated product including but not limited to −
  (a) written publication, television, radio, film, electronic transmission including the Internet, video or telephone;
  (b) display of signs, billboards, or notices; or
  (c) exhibition of pictures or models.

(3) "Brand name" means a name given by the manufacturer to a product or range of products.

(7) "Distributor" means a person, corporation or other entity engaged in the business, whether wholesale or retail, of marketing any designated product.

(9) "Health care facility" means a public or private institution or organisation or private practitioner engaged directly or indirectly in the provision of health care or in health care education. It also includes day-care centres, nurseries or other infant-care facilities.

(16) "Logo" means an emblem, picture or symbol by means of which a company or a product is identified.

(17) "Manufacturer" means a person, corporation or other entity engaged in the business of manufacturing a designated product whether directly, through an agent, or through a person controlled by or under an agreement with it.

(22) "Promote" means to employ any method of directly or indirectly encouraging a person to purchase or use a designated product.

CHAPTER 7

Promotion to Health Workers

Relevant provisions of the International Code

Article 7. Health Workers

7.1 Health workers should encourage and protect breastfeeding; 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 breastfeeding. 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 3. Definitions

*"**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.*

*"**Samples**" means single or small quantities of a product provided without cost.*

Relevant parts of World Health Assembly Resolutions

WHA49.15 (1996)

Concerned that health institutions and ministries may be subject to subtle pressure to accept, inappropriately, financial or other support for professional training in infant and child health; . . .

Urges Member States . . . to ensure that the financial support for professionals working in infant and young child health does not create conflicts of interest, especially with regard to the WHO/UNICEF Baby Friendly Hospital Initiative.

WHA58.32 (2005)

Urges Member States to ensure that financial support and other incentives for programmes and health professionals working in infant and young-child health do not create conflicts of interest.

Concerned that nutrition and health claims may be used to promote breastmilk substitutes as superior to breastfeeding: urges Member States to ensure that nutrition and health claims are not permitted for breastmilk substitutes, except where specifically provided for in national legislation.

Perhaps the legislative provisions most difficult to draft will be those concerning the control of marketing to health workers. Well-entrenched marketing practices used by most of the baby food companies include providing product samples to health workers, advertising in journals for the health professions, visits from marketing representatives armed with promotional materials and gifts, and providing financial and in-kind benefits to individual health workers and their associations.

In drafting legislation, each country will have to weigh the merits and harms of allowing each of these different types of interactions between companies and health workers. It would be beneficial to include members of the health care professions, independent marketing experts and representatives of public interest groups in any such discussions both to gain their perspec-

tive and to forge a consensus. Measures to prevent gift giving and sponsorship may be viewed by some health practitioners as an attack on their integrity. It is therefore important that the real motives for such measures are clarified and understood.

The provisions of the International Code apply to *health workers*, which are defined to include *health professionals*. Some countries have imposed standards and responsibilities only for health professionals, usually defined to include doctors, some nurses and midwives, pharmacists and other positions requiring a professional degree. This Handbook uses the term *health worker* as it is defined in the International Code. The term *health professional* is only used when the provision relates to the narrower class of health workers.

Most infant food companies devote a large part of their marketing budgets to designing ways to reach individual health workers. Health workers, such as obstetricians, paediatricians, midwives and nurses can have a major influence in a mother's decision whether or not she will breastfeed her baby, whether breastfeeding will be exclusive and how long it will last. Similarly, health workers influence a mother's decision to give infant formula and other breastmilk substitutes, often including which brand she will choose.

Companies know that health workers present an ideal channel through which they can reach mothers. A health worker's recommendation of a product is worth its weight in gold. If a doctor gives a sample of an infant formula, or even a company-produced booklet about infant feeding, the mother will see it as a product or company endorsement. Dr. Derrick Jelliffe coined the term "endorsement by association" referring to the "age-old psychosocial mechanisms employed cheaply and effectively by commercial concerns, including both pharmaceutical companies and infant food manufacturers".[1]

The relationship between health workers and the infant food companies is long-standing.[2] At the time the International Code was adopted, and still in some countries today, a majority of doctors, nurses, midwives and other health workers had come to believe that bottle feeding is practically equivalent to breastfeeding and, consequently, did little to encourage breastfeeding. Many were never taught the basics about breastfeeding. In some medical textbooks, the authors of chapters on breastfeeding could even be traced back to infant food companies.

A 1999 survey of US paediatricians' attitudes and practices regarding breastfeeding revealed that only 65 percent recommend exclusive breastfeeding in the first month and only 37 percent recommend breastfeeding to continue for one year. The survey also found that the majority agree or are neutral regarding the statement that breastfeeding and formula feeding are equally acceptable methods of infant feeding.[3] Paediatricians' attitudes towards breastfeeding in developing countries is similar. The lack of enthusiasm for breastfeeding may be due to a tendency of professional classes to adopt western practices perceived as modern. Many of the doctors

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[1] Jelliffe, D.B. and Jelliffe, P., *Human Milk in the Modern World*, Oxford University Press, 1978, p. 237.

[2] Minchin, M., *Breastfeeding Matters: What we need to know about infant feeding*, Alfredton, Australia: Alma Publications, 2nd edition, 1989, Chapter 10. The history of the relationship between health workers and infant food companies is discussed in greater detail in Chapter 3 of this Handbook.

[3] Schanler, R., O'Conner, K. and Lawrence, R., "Pediatrician's Practices and Attitudes Regarding Breastfeeding Promotion," *Pediatrics*, 1999, 103: e35.

are trained in the West or according to western curricula, which placed an emphasis on artificial feeding.

Today, thanks to overwhelming evidence from research and the *Baby Friendly Hospital Initiative*, many health workers have accepted the superiority of breastfeeding and the need for its promotion. These attitudes have yet to gain a strong foothold, however, in many parts of the world. Routines are slow to change. Standard practice in many maternity wards, particularly in private hospitals, continues to consist of separating mother and baby after birth and feeding routinely with glucose and water, followed by formula feeds, alone or as supplements to breastfeeding.

Product information for health professionals

This topic touches on two considerations that often compete with one another: the need for health professionals to have product *information* from the manufacturers of the products and the harm that comes from product *promotion*. While there is certainly a role for baby food companies to play in providing information about their products to health professionals, these companies routinely cross the line between providing product information and blatant advertising .

Article 7.2 of the International Code permits manufacturers and distributors to provide information to *health professionals* regarding their products. The information must be restricted to matters that are *factual and scientific* and may not imply or create a belief that bottle feeding is equivalent or superior to breastfeeding. *Factual* means pertaining only to something known to have happened. *Scientific* means knowledge ascertained by systematic study involving observation and experimentation.[4] The operative word in Article 7.2, however, is *restricted.*

Infant food companies inundate health professionals with full-colour glossy brochures touting the qualities of infant formulas and other products. The information is rarely limited to scientific and factual matters. Promotional slogans and images usually take up the most conspicuous portions of the material. For example, a full-page advertisement for a Nutricia infant formula (*Vital Infantil 1*) on the back cover of the bulletin of the Argentine Perinatal Association features a cartoon bear breaking through a barrier. The advertisement uses the slogan, "The formula with a strong impact on infant feeding from birth" and the bear proclaims, "If baby takes this milk, he will also be strong".[5]

Product advertisements directed at health professionals often violate Article 7.2 in other ways. Article 7.2 states that product information for health professionals may not "imply or create a belief that bottle feeding is equivalent or superior to breastfeeding". Similarity to breastmilk, however, is the dominant theme of many company materials for health professionals. A Wyeth advertisement for *S-26 Gold* in a professional journal in Uruguay, for example, states that the product "contains long-chain polyunsaturated fatty acids, the same as breastmilk".[6] A Nestlé leaflet in Ghana pictures a tin of *Lactogen 2* with the slogan "Two feeds of *Lactogen 2* a day provides the daily protection needs of the infant".[7] Nestlé is indirectly comparing its product to

[4] "Factual", "scientific", *Cambridge International Dictionary of English*, Cambridge, 1995.
[5] International Baby Food Action Network, *Breaking the Rules, Stretching the Rules*, Penang, Malaysia: IBFAN-ICDC, 2004, p. 74.
[6] *Ibid*., p. 80.
[7] *Ibid*., p. 61.

breastmilk because only breastmilk has anti-infective properties that can provide the *protection* a baby needs.

When manufacturers succeeded in adding DHA and ARA, fatty acids found in breastmilk, to infant formula, companies around the world introduced "new and improved" infant formulas with attributes closer to that of breastmilk and marketed them heavily to health professionals. DHA and ARA are long-chain polyunsaturated fatty acids associated with mental and visual development of breastfed infants. Marketing materials targeted to health professionals picture babies with computers or wearing graduation caps and with slogans such as "raising an intelligent baby is no longer an impossible dream",[8] or "the smart formula for smart babies".[9]

Companies sometimes attempt to make their product information more *scientific* by including references to published studies to support assertions about the product. Yet, the studies referenced do not always support the particular representations about the product, are sometimes out-dated and are frequently funded by the product's manufacturer.

For example, a glossy Abbott-Ross leaflet promoting DHA-ARA supplemented *Similac Advance* infant formulas distributed for health workers in the United Arab Emirates in 2003 references three studies to support the assertion "Clinically shown to provide visual and mental development like that of the breastfed infant". Each of the three studies cited concludes, however, that no benefits in visual development or mental development were demonstrated for babies fed the supplemented formula.[10] The statement on the leaflet was technically borne out by the three studies only because neither the breastfed infants nor the infants fed the supplemented formulas showed improved visual or mental functioning for the particular tests that were performed in the study.[11] The three studies were supported by the Ross Products Division of Abbott Laboratories.

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[8] Leaflet for Nestlé *Nan* in China. See *Breaking the Rules, Stretching the Rules, supra* note 5, p. 60.

[9] Magazine advertisement for Abbott-Ross *Similac Advance* in Singapore. See *Ibid*., p. 11.

[10] The following studies were referenced in the *Similac Advance* leaflet: Auestad, N., Halter, R. and Hall, R.T., "Growth and Development in Term Infants Fed Long-chain Polyunsaturated Fatty Acids: A double-masked, randomised, parallel, prospective, multivariate study", *Pediatrics*, 2001, 108: 372-81 (no demonstrable advantage to infant development from the widespread addition of AA and DHA to infant formula; study supported by Ross Products Division of Abbott Laboratories); Auestad, N., Montalto, M.B. and Hall, R.T., "Visual Acuity, Erythrocyte Fatty Acid Composition, and Growth in Term Infants Fed Formulas with Long Chain Polyunsaturated Fatty Acids for One Year", Ross Pediatric Lipid Study, *Pediatric Research* 1997, 41: 1-10 (no differences in growth or in visual function during this 12-month feeding study; study supported by Ross Pediatrics); Scott, D.T., Janowsky, J.S. and Carroll, R.E., "Formula Supplementation with Long-chain Polyunsaturated Fatty Acids: Are there developmental benefits?" *Pediatrics*, 1998 102: e59 (no significant differences in Bayley scales across supplemented and non-supplemented formula groups; study supported by Ross Products Division, Abbott Laboratories). A follow up to the 2001 study, cited in other Abbott-Ross advertisements for *Similac Advance*, found the same results. *See* Auestad, N., Scott, D.T. and Janowsky J.S.,"Visual, Cognitive, and Language Assessments at 39 Months: A follow-up study of children fed formulas containing long-chain polyunsaturated fatty acids to 1 year of age," *Pediatrics*, 2003, 112: e177-83 (follow-up evaluation of growth, visual development, and neurodevelopmental outcomes at 39 months found no adverse effects or benefits of infant formula supplemented with DHA or with both DHA and ARA; work supported by Ross Products Division, Abbott Laboratories).

[11] A number of other studies have, however, demonstrated that the fatty acids found in **breastmilk** lead to optimal brain development.

Moreover, statements comparing the effects of a breastmilk substitute to breastmilk or a known attribute of breastmilk are inherently deceptive. Breastmilk is the *gold standard*. In order to be truthful, in addition to mentioning the few breastmilk ingredients that the manufacturer has managed to put in the formula, the advertisement should also mention the other ingredients found in breastmilk that are lacking in the formula as well as the many risks associated with not breastfeeding.[12] Even then, an advertisement comparing a product to breastmilk would not be completely forthcoming because the complete make-up of breastmilk is yet to be discovered; because it is not possible to know the correct amount of each ingredient that should be in a dose of formula[13] and because it is not known if the ingredient will have the same effect on the baby as when it occurs in breastmilk. Governments that are considering allowing product information for health professionals should keep in mind standard consumer protections laws that require truth in advertising and prohibit advertisements that are deceptive or misleading.

In a related matter, the Canadian Food Inspection Agency advised Mead Johnson in 2004 to stop making claims about improved cognitive development in infants being fed its formula *Enfamil A+* because the clinical data did not substantiate such claims.[14]

Finally, although Article 7.2 also states that the materials must include the points specified in Article 4.2, a good number of the product advertisements do not include all, or sometimes any of that information. When the information is there, it is often too small to read: miniscule in comparison to the print size used for the advertisement.

Drafting examples from other countries: Product information for health professionals

Although the International Code only prohibits advertising of products within the scope to the "general public," most countries have implemented Article 5 by prohibiting product advertising completely. A complete prohibition on such advertising necessarily includes advertisements placed in professional journals. In most countries, however, companies are allowed to provide *information* about products either to all health workers or only to health professionals.

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[12] The increased risks for formula fed babies as compared to breastfed babies include increased risk of asthma; allergy; reduced cognitive development; acute respiratory disease; infection from contaminated formula; childhood cancers; chronic diseases; diabetes; cardiovascular disease; obesity; gastrointestinal infections; mortality; otitis media; and side effects of environmental contaminants. International Baby Food Action Network, *Fourteen Risks of Formula Feeding: A brief annotated bibliography,* Penang, Malaysia: IBFAN-ICDC, *reprinted* with thanks to INFACT Canada for compiling the abstracts, July 2004. *See also* the website of the US National Women's Health Information Centre, the programme of the US DHHS that developed the National Breastfeeding Awareness Campaign in 2003, "Science behind the Campaign", http://www.4women.gov/Breastfeeding/bf.cfm?page=ref (accessed 31 May 2005).

[13] For example, worldwide concentrations of DHA in breastmilk range from 0.07% to greater than 1.0% of total fatty acids, with a mean (±standard deviation) of about 0.34% (±0.23%). Brenna, J.T., "Infant Formula Containing DHA and ARA", *Cornell Cooperative Extention, Food and Nutrition: Ask the nutrition expert,* updated 4 April 2003, http://www.cce.cornell.edu/food/expfiles/topics/brenna/brennaoverview.html (accessed 22 June 2005).

[14] A Cochrane Review published in 2004 concluded that no long term benefits were demonstrated for infants who received formula supplemented with long chain fatty acids. Simmer, K. and Patole, S., "Long Chain Polyunsaturated Fatty Acid Supplementation in Preterm Infants", *The Cochrane Database of Systematic Reviews*, 2004, Issue 1.

Most of these national provisions have been modelled after Article 7.2 of the International Code. In Georgia, for example, information about products must be restricted to scientific and factual matters and may not imply or create a belief that artificial feeding is equivalent or superior to breastfeeding.[15] Georgia has added to the International Code provision by also requiring that such information emphasise the priority of breastfeeding.[16]

In Brazil, dissemination of information to health professionals and students of the health profession is prohibited as a form of commercial promotion except for the provision of "technical-scientific materials about products".[17] Technical-scientific materials are defined as "any material containing proven technical and/or scientific data about products or related to knowledge of nutrition and paediatrics, intended for health professionals and health workers".[18] Such materials must comply with detailed regulations that apply to product labels.[19]

In Ghana, manufacturers and distributors may provide product information to health personnel if the information "is restricted to scientific and factual matters that relate to the technical aspects and methods for the use of the designated product". Copies of such materials must be submitted to the Food and Drugs Board.[20]

In the Philippines, advertisements directed to health professionals are permitted but must be approved by an inter-agency committee according to established guidelines.[21] Printed materials given directly to certain health care institutions and health workers in private practice need not be vetted, but must be restricted to scientific and factual matters and include the information required by the Rules.[22]

Some countries already have laws that limit the use of certain types of health or nutrition claims in advertisements for food products. In the Philippines, the criteria for screening advertisements for products within the scope of its Code state, "All health and nutrition claims for products which have high potential of misleading the public shall not be allowed".[23] Moreover, in 2005, the WHA adopted Resolution 58.32, which urges Member States to "ensure that nutrition and health claims are not permitted for breastmilk substitutes, except where specifically provided for in national legislation". The Codex Alimentarius Commission is drafting guide-

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[15] Law of Georgia on Protection and Promotion of Breastfeeding and Regulated use of Artificial Foods, 1999, Article 9.

[16] *Ibid*., Article 9.

[17] Brazil, Regulamento Técnico para Promoção Comercial dos Alimentos para Lactentes e Crianças de primeira Infância, Resolução- RDC N° 222 de 5 de agosto de 2002 (Brazil, Technical Regulation on Commercial Promotion of Foods for Infants and Young Children), definition 2.28.

[18] *Ibid*., definition 2.26 "technical/scientific material".

[19] *Ibid*., ¶ 4.21.

[20] Ghana, Breastfeeding Promotion Regulations, 2000, Regulation 7(2).

[21] Philippines, National Code of Marketing of Breastmilk Substitutes, Breastmilk Supplements and other Related Products, Executive Order N° 51, 1986, § 6(a) and Philippines, Guidelines on Advertising, Promotion and other Marketing Materials of Breastmilk Substitutes, Breastmilk Supplements and other Related Products *pursuant* to Executive Order N° 51, 2004.

[22] Philippines, Rules and Regulations covering the Advertising, Promotion and Marketing of Breastmilk Substitutes, Breastmilk Supplements and Related Products, 1987, §§ 1(d) & 20.

[23] Philippines Guidelines on Advertising, *supra* note 21, §11.

lines for the use of health and nutrition claims in food labelling. In the most recent draft, the guidelines apply to claims in advertising as well.[24]

The Model Law allows information about products for health professionals, but only if the information is restricted to scientific and factual matters regarding technical aspects and methods of use of the product and complies with the Model Law's requirements for other information materials about infant feeding.[25] In addition, the material must provide references to published studies to support any "representation that states or suggests that a relationship exists between the product or constituent thereof and health, growth or development".[26] This provision is intended to prohibit promotional advertisements and unsupported claims, yet allow technical information including ingredients, composition and relevant warnings.

Product samples for health workers

Another common promotional method is the distribution of product samples to health workers. The practice of giving samples to health workers is governed by Article 7.4 of the International Code. The Code allows samples in only two situations: "for the purpose of professional evaluation or research at the institutional level". If companies heeded this restriction, one would expect to find few instances of professional samples. First of all, it is rare for clinical health workers to perform professional evaluations of products that fall within the scope of the International Code. Secondly, research at the institutional level must be performed according to an approved research protocol and would not account for samples left indiscriminately at a doctor's door.

Yet, monitoring of this provision worldwide shows that sampling to health professionals is a widespread and regular practice. Company sales representatives have been known to visit clinics and private practitioners regularly and leave a carton or two of product samples for the doctor or nurse. The doctors' common response is to hand the samples out to patients. The 1997 study by the Interagency Group on Breastfeeding Monitoring (IGBM) of marketing practices in South Africa, Poland, Bangladesh and Thailand showed that "across the four cities, from 3 out of 40 (8 percent) to 20 out of 40 (50 percent) health facilities had received free samples which were not being used for research or professional evaluation".[27] Another study in Togo and Burkina Faso found that health providers received free samples and that none of the recipients were involved in research or professional evaluation.[28] Companies hope to get around Article 7.4 by printing on the labels "for professional evaluation only" or by distributing standard retail-size tins that are unmarked and, therefore, unrecognisable as samples.

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[24] Codex Alimentarius Commission, *Draft Guidelines for use of Health and Nutrition Claims* § 1.4. (at step 8), *in* Report of the 32nd Session of the Codex Committee on Food Labelling, ALINORM 04/27/22, Appendix III (2004), § 11. Health claims in the context of labelling are discussed in Chapter 9, pp. 131-32.

[25] Model Law, § 14.

[26] *Ibid*.

[27] Taylor, A., "Violations of the International Code of Marketing of Breastmilk Substitutes: Prevalence in four countries", *British Medical Journal*, 1998, 316: 1117.

[28] Aguayo, V., Ross, J., Souleyman, K. et al., "Monitoring Compliance with the International Code of Marketing of Breastmilk Substitutes in West Africa: Multisite cross sectional survey in Togo and Burkina Faso", *British Medical Journal*, 2003, 326: 127-30.

Drafting examples from other countries: Product samples for health workers

Many countries ban all samples to health workers or to health professionals, tightening up Article 7.4 of the International Code, which allows samples under certain circumstances.[29] Brazil has taken a different approach. In Brazil, manufacturers and distributors may give samples of most food products within the scope of its regulations to paediatricians and nutritionists, but only at the time of the launch of the product.[30] In the case of an infant formula or follow-up formula for infants up to one year old, only one sample is allowed and only to health professionals who have requested the sample. A national launch must be completed with 18 months.[31] To deter companies from frequently launching 'new and improved' products, Brazil prohibits samples when a product is re-launched or re-named. The regulations also require samples to be labelled as professional samples not to be distributed to mothers, pregnant women or their families. Samples of formula for high-risk newborns are not permitted.[32] Samples of feeding bottles and teats are also prohibited.[33]

Zimbabwe also allows free samples to health workers only at the time of a product launch and only to institutions or organisations for purposes of professional analysis, evaluation or research.[34] In Malaysia, samples of new products may be given to health professionals upon approval of the Medical Research Ethics Committee.[35] In order to prevent companies from abusing the privilege of providing samples, the Model Law prohibits product samples to any person, whether a member of the general public or a health worker.[36]

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[29] *See, e.g.*, Albania, Law for Promotion and Protection of Breastfeeding N° 8528, 1999, Art 6(b); Cameroon, Arrêté Interministeriel N° 040 portant sur la réglementation de la commercialisation des substituts du lait maternel, 1993 (Cameroon, Interministerial Decree on the Control of Marketing of Breastmilk Substitutes), Article 5(1); Law of Georgia on Protection and Promotion of Breastfeeding and Regulated use of Artificial Foods, 1999, Article 18; Ghana, Breastfeeding Promotion Regulations, 2000, Regulation 1(2)(b); Macedonia, Law on Protection of Consumers, 63/2000, Article 29(2); Niger, Arrête N° 215 MSP/DSF portant réglementation de la commercialisation des substituts du lait maternel, 1998 (Niger, Decree Regulating the Marketing of Breastmilk Substitutes), Article 7(1); Philippines, Guidelines for the Implementation of Executive Order N° 51, Department Circular N° 24 s.1987, *as amended by* Department Circular N° 122-A s., 1987, § III, 1; Saudi Arabia, Royal Decree for Handling of Mother's Milk Substitutes (2004), Article 5(b); Sri Lanka, Code for the Promotion, Protection and Support of Breastfeeding and Marketing of Designated Products, 2003, *pursuant to* the Consumer Protection Act, N° 1 of 1979, Article 5.3; Uganda, Food and Drugs (Marketing of Infant and Young Child Foods) Regulations, 1997, Regulation 12(c); Vietnam, Decree on Marketing and use of Breastmilk Substitutes to Protect and Promote Breastfeeding, N° 74/2000/ND-CP, 2000, Article 12(2)(c).

[30] Norma Brasileira de Comercialização de Alimentos para Lactentes e Crianças de Primeira Infância, Bicos, Chupetas e Mamadeiras, Portaria N° 2051 de 8 de novembro, 2001 (Brazilian Standard for Marketing of Foods for Infants and Young Children, Teats, Dummies and Feeding Bottles), Article 10 and Brazil Technical Regulations, Foods for Infants and Young Children, *supra* note 17, ¶ 5.

[31] Brazil Technical Regulations, Foods for Infants and Young Children, *supra* note 17, ¶ 5.

[32] *Ibid.*

[33] Brazil, Regulamento Técnico Chupetas, Bicos, Mamadeiras e Protetores de Mamilo, Resolução-RDC N° 221 de 5 de agosto de 2002 (Brazil Technical Regulations, Dummies, Teats, Bottles and Nipple Shields), Article 6.1.

[34] Zimbabwe, Public Health (Breastmilk Substitutes and Infant Nutrition) Regulations, 1998, § 19(2)(a).

[35] Malaysia, Code of Ethics for Infant Formula Products, 3rd revision, 1995, § 4.4.

[36] Model Law, § 4(1)(c).

Benefits to health workers

Another method the companies use to achieve goodwill and endorsement, particularly by the medical profession, is to provide benefits either to a health worker directly or to a professional association. Direct benefits can include gifts, financial or in-kind; professional or personal items; and meals, accommodation or travel. Companies are also known to try to influence future doctors by providing medical students with free textbooks, graduation gifts such as stethoscopes and sponsorship to attend professional society or educational events.

In 1999, the Network, a consumer organisation in Pakistan, published *Milking Profits*, which reveals how a Nestlé subsidiary in Pakistan, Nestlé Milkpak, used gifts and benefits to "buy" doctors' loyalty. The report describes how company salespeople maintain a system that classifies health workers according to the size of their practice, patient income levels and influence. Gifts to health workers vary in value according to their classification.[37] Another example of gift giving to health workers comes from Indonesia, where a Nutricia-owned company, Sari Husada, held a "lucky draw" for midwives. One of the prizes was a fully paid trip to perform the Islamic Hajj in Mecca.

Companies also shower health workers with small gifts such as pens, pencil holders, desk calendars, diaries, prescription pads and note pads. Nestlé amended its internal marketing instructions in 1984 to state that it would no longer consider appropriate "personal gifts of a non-professional nature, such as chocolates, key rings and pens".[38] Yet its current internal marketing instructions allow Nestlé employees to give health workers gifts from a list of "low-cost items of professional utility", such as diaries and wall charts as well as "culturally appropriate gifts". These items may bear the company name or logo.[39]

Even though such gifts lack any great monetary value, they act as promotional devices. These items are almost always imprinted with company names and logos and are left on desks or shelves in full view of patients and visitors to maternity and paediatric wards and doctors' examination rooms. "Minor gifts showered by retail persons on individual health personnel, while ostensibly to generate goodwill and information, also serve to keep the name of the company in constant view and play a critical role in moulding opinion and influencing decisions."[40] A study of the effects of gifts to physicians from industry states:

> small gifts may be surprisingly influential. The sheer ubiquity of trinkets given by pharmaceutical companies is evidence of their effectiveness; why else would profit-minded companies continue to provide them?[41]

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[37] The Network, *Milking Profits: How Nestlé puts sales ahead of infant health*, Islamabad: The Network, 1999.

[38] Nestlé, WHO *International Code of Marketing of Breastmilk Substitutes, Instructions to all Companies of the Nestlé Group and to Agents and Distributors who Market Infant Formula under Trade Marks owned by the Nestlé*, Vevey, February 1982; Addendum, September 1984.

[39] Nestlé, *Nestlé Instructions for Implementation of the WHO International Code of Marketing of Breastmilk Substitutes: Instructions to companies of the Nestlé Group and to agents and distributors who market infant formula in developing countries under trade marks owned by the Nestlé Group, updated* July 1996, Annex 4.

[40] Administrative Petition to United States Food and Drug Administration, *LULAC et. al vs. Secretary of Health & Human Services*, 17 June 1981.

[41] Dana, J., "A Social Science Perspective on Gifts to Physicians from Industry," *Journal of the American Medical Association*, 2003, 290: 252-55.

A number of studies have shown that gifts from pharmaceutical companies to health workers, whether or not expressly given as inducements to promote products, influence health workers' decisions regarding their patients. A 1989 study published in the *Journal of the American Medical Association* on the subject of gift giving between drug companies and doctors states:

> Whenever a physician accepts a gift from a drug company, an implicit relationship is established between the physician and the company or representative. Inherent in the relationship is an obligation to respond to the gift . . . .[42]

According to the authors, gifts may influence the physician's decisions regarding patient care. In 2003, the *British Medical Journal* devoted an entire issue to the increasing entanglement between physicians and drug companies and the effect of these relationships on prescribing behaviour, research and the consequences for patients.[43]

The same idea, in the context of baby food companies, translates into a gift influencing the health worker's advice about infant feeding. The recipient may feel obligated to recommend the donor company's products, or will simply recommend them out of familiarity with the company's name, its brands and its sales personnel. This is especially harmful in the context of breastmilk substitutes because the competition is breastmilk. Thus, company gifts may influence health workers to more easily recommend a supplement to or replacement for breastfeeding, not merely one product over another. While most health professionals laugh at the idea that they might be *bought*, it must be borne in mind that companies are motivated by profit. "No drug company gives away its shareholders' money in an act of disinterested generosity."[44]

Article 7.3 of the International Code does not prohibit gifts outright, trusting professional ethics to protect the public. Article 7.3 prohibits "financial or material inducements to promote products". The phrase *inducements to promote products* makes the provision difficult to monitor and enforce. It will never be easy to prove the intent with which a benefit was given. Neither the donor nor the recipient will be willing to come forward and admit that a particular gift or sponsorship was meant as an inducement to promote products. Furthermore, the term *financial or material inducement* could be interpreted so as not to include small gifts like pens and prescription pads that advertise company or product names.

It should be noted that aside from the creation of a relationship with implied obligations, the physician's acceptance of gifts has another major repercussion. Gifts, although free to the physician, have a cost to the company. The company passes that cost on to the consumer, in effect giving the professional a benefit at the expense of his or her patients.

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[42] Chren, M., Landefeld, C.S. and Murray, T.H., "Doctors, Drug Companies and Gifts", *Journal of the American Medical Association*, 1989, 262: 3448 (*hereinafter* Chren, Landefeld and Murray). See also Wazana, A., "Physicians and the Pharmaceutical Industry: Is a gift ever just a gift?", *Journal of the American Medical Association*, 2000, 283: 373-80; Tenery, R.M. Jr., "Interactions Between Physicians and the Health Care Technology Industry", *Journal of the American Medical Association*, 2000, 283: 391-93; Madhavan, S., Amonkar, M.M., Elliott, D. et al, "The Gift Relationship between Pharmaceutical Companies and Physicians: An exploratory survey of physicians", *Journal of Clinical Pharmacy & Therapeutics*, 1997, 22: 207-15.

[43] *British Medical Journal*, vol. 326, Issue 7400, 31 May 2003 (Theme issue on the relationship between doctors and the drug industry). *See also* Relman, A. and Angell, M., "America's Other Drug Problem", *New Republic*, 16 December 2002, pp. 27-41 (Harvard University professor and former editor of the *New England Journal of Medicine* critiques industry influence in health care).

[44] Chren, Landefeld and Murray, *supra* note 42, p. 3449.

Sponsorship and assistance for professional purposes

Another way in which baby food companies influence health workers is by providing individuals with contributions ostensibly towards professional development such as study grants, fellowships or funds to attend professional meetings, conferences or educational courses. Companies also pay for cocktail parties, meals and vacations that happen to coincide with a conference. In 1993, for example, Nestlé paid for paediatricians in Brazil to attend a continuing education course aboard a luxury cruise liner.

Aside from sponsoring individual health workers, companies frequently sponsor, in whole or in part, meetings, conferences, educational endeavours, and professional society events. Sponsorship may entail underwriting the major costs of the event, paying for dinners and entertainment during the event or controlling the choice of topics, speakers and attendance list. Professional events are replete with company promotional booths offering free gifts, samples or promotional materials about products.

Product displays and programme advertisements may also accompany sponsorship. Such congresses, symposia and educational events under company sponsorship tend to be lavish. They can take place in elegant hotels, aboard cruise ships or in exotic locations. "Medical congresses have widely served to spread scientific information while at the same time rewarding loyal physicians for their attachment to a given pharmaceutical company."[45]

Companies may even sponsor entire organisations. For example, Nestlé sponsors the Mexican Academy of Paediatrics. In return, Nestlé obtains publicity because its corporate logo appears on the Academy's publications, notices, announcements and its website.[46] Abbott-Ross, which is one of the top corporate funders of the America Academy of Pediatrics, received a similar pay-off when it got permission from the AAP to print its name and logo on the cover of the AAP's *New Mother's Guide to Breastfeeding*.[47]

Unless such contributions can be shown to be *inducements* to promote products, they are not prohibited by the International Code. Article 7.5 states that manufacturers and distributors must disclose to a health worker's affiliated institution any contributions to him or her for "fellowships, study tours, research grants, attendance at professional conferences, or the like".

The International Code does not address the issue of sponsorship of organisations or events, even though such events serve in many ways to promote products within the scope of the Code. In 1996, however, the World Health Assembly expressed concern about *inappropriate* financial support for professional training in infant and child health. Resolution WHA49.15 warns about the conflicts of interest that can be created by financial support for professionals working in infant and young child health. In 2005, the WHA reemphasised in Resolution WHA58.32 the potential for financial support of health professionals to create conflicts of interests.

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[45] "Italy: An end to the fun and games", *The Lancet, vol.* 338, 21 September 1991.

[46] International Baby Food Action Network, *Using International Tools to Stop Corporate Malpractice-Does it Work?: Checks and balances in the global economy*, Cambridge: Baby Milk Action, 2004, p. 35.

[47] This incident is discussed in Chapter 8, p. 115.

Drafting examples from other countries: Benefits to health workers

Many countries have followed Article 7.3 of the International Code and prohibit financial or material inducements for the purpose of promoting specified products.[48] In Zimbabwe, the donor shoulders the burden of proof. The law states that the donor must show that the donation or benefit "was not given for the purpose of promoting or inducing use of a designated product".[49]

Some countries have moved away from the language of Article 7.3 and prohibit gifts whether or not there is proof of a link between the gift and product promotion. In Albania, Brazil, Georgia, Pakistan, and Uganda, manufacturers and distributors are barred from giving any gift to an individual health worker.[50] In Albania, the provision pertains only to health workers engaged in maternal and child health.

In Australia, the Advisory Panel that implements the voluntary code has interpreted the ban on financial inducements to include small gifts such as pens and papers with company logos designed for use at conferences when the gifts are intended or likely to be taken home. The Panel also considers it unacceptable to leave such materials in a hospital ward.[51]

Some countries have legislation prohibiting gifts and other benefits to health professionals from pharmaceutical companies. These laws are relevant because some of the largest infant food companies are divisions of pharmaceutical companies. In France, medical professionals may not accept and pharmaceutical companies may not offer any kind of gift other than certain small gestures of hospitality. Violators are subject to heavy penalties including two years imprisonment, fines of up to € 75,000 or a temporary suspension of the professional licence for up to 10 years.[52]

In Italy, pharmaceutical companies are limited to giving only gifts of low commercial value. In 2004, thousands of doctors and a major pharmaceutical company faced charges of corruption. The company was reported to have spent $278 million on incentives for doctors to pre-

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[48] *See e.g.*, Ghana Regulations, *supra* note 20, Regulation 6(2); Guatemala, Decreto-Ley Nº 66-83: Ley de Comercialización de Sucedáneos de la Leche Materna, 1983 (Guatemala, Decree–Law on Marketing of Breastmilk Substitutes), Article 10; India, Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act Nº 41 of 1992 *amended* 2003, § 9(1), Malaysia Code, *supra* note 35, § 4.9; Philippines Code, *supra* note 21, § 8(c); Saudi Arabia Royal Decree, *supra* note 29, Article 5; Sri Lanka Code, *supra* note 29, Article 5.2; Tanzania, Food (Control of Quality) (Marketing of Breastmilk Substitutes and Designated Products) Regulations, 1994, Regulation 10(1)(a) (health worker not to accept financial assistance to promote products); Yemen, Prime Minister Decree Nº 18 on Regulation of Breastfeeding Promotion and Protection, 2002, Article 19; Zimbabwe Regulations, *supra* note 34, § 18(2).

[49] Zimbabwe Regulations, *supra* note 34, § 18(6).

[50] Albania Law, *supra* note 29, Article 5(c); Brazil Technical Regulations, Foods for Infants and Young Children, *supra* note 17, ¶ 4.1 and definition 2.8 "commercial promotion"; Georgia Law, *supra* note 29, Article 18(a); Pakistan, Protection of Breastfeeding and Young Child Nutrition Ordinance, Nº 93, 2002, § 6(3); Uganda Regulations, *supra* note 29, Regulation 15(4).

[51] Advisory Panel for the Marketing in Australia of Infant Formula (APMAIF), *Annual Report*, July 2002-June 2003, p. 29.

[52] France, Code de la Santé Publique, Article L.4113-6, Loi Nº 2002-303 du 4 mars 2002, Article 25, (France, Public Health Code, Article L.4113-6).

scribe the companies drugs.[53] During the investigation, police discovered that the company used a complex software system, which allowed sales representatives to monitor the prescribing behaviour of doctors they had compensated. The more highly placed professionals had been sent on "medical tours" to Monte Carlo during the Grand Prix and to other exotic destinations.[54]

The United States has not implemented the International Code, but the US Anti-kickback Statute, a criminal prohibition against payments (in any form) made purposefully to induce or reward referrals of health care business, has wording similar to that of Article 7.3.[55] The US DHHS has guidelines for pharmaceutical companies regarding compliance with the Anti-kickback Statute and other federal health laws.[56] The DHHS guidelines can serve as an example for how laws based on Article 7.3 might be enforced.

According to the DHHS, several types of remuneration by pharmaceutical companies and their employees to physicians or others in a position to prescribe the manufacturer's products or to influence such prescriptions may implicate the Anti-kickback statute. Types of payments that may be suspect include those for entertainment, recreation, travel, meals, or other benefits in association with information or marketing presentations as well as gifts, gratuities and other business courtesies.[57]

The DHHS advises companies to pose the following questions to assist in determining if certain gifts or other arrangements might be illegal under the Anti-kickback statute:

- What degree of influence does the physician have, directly or indirectly, on the generation of business for the manufacturer?
- Does the remuneration take into account, directly or indirectly, the volume or value of business generated (*e.g.*, is the remuneration only given to persons who have prescribed or agreed to prescribe the manufacturer's product)? Is the remuneration conditioned in whole or in part on referrals or other business generated?
- Is the remuneration more than trivial in value, including all gifts to any individual, entity, or group of individuals? Do fees for services exceed the fair market value of any legitimate, reasonable, and necessary services rendered by the physician to the manufacturer?
- Would acceptance of the remuneration diminish, or appear to diminish, the objectivity of professional judgment? Are there patient safety or quality of care concerns? If the remuneration relates to the dissemination of information, is the information complete, accurate, and not misleading?[58]

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[53] Hooper, J., "Over 4,000 doctors face charges in Italian drugs scandal", *The Guardian*, 27 May 2004.
[54] *See* Turone, F., "Italian Police Investigate GSK Italy for Bribery", *British Medical Journal*, 2003, 326: 413.
[55] 42 United States Code §1320a-7b(b).
[56] United States Department of Health and Human Services, Office of Inspector General, "Compliance Program Guidance for Pharmaceutical Manufacturers", *Federal Register*, 5 May 2003, vol. 68, Nº 86, pp. 23731-43.
[57] *Ibid*., p. 23738.
[58] *Ibid*., p. 23737.

Drafting examples from other countries: Sponsorship

As noted above, while the International Code forbids *inducements to promote products*, it does not prohibit manufacturers or distributors from giving certain forms of financial assistance to health workers for professional purposes like fellowships or attendance at professional conferences so long as there is some disclosure to relevant authorities. Some countries have taken the same approach as the International Code.[59] Other countries have either prohibited completely this type of financial assistance or established some type of control such as channelling contributions through a professional association or requiring government approval.

In India, manufacturers and distributors are not allowed to give any benefit to an individual health worker or to an association of health workers including funding for events such as seminars and meetings.[60] Georgia and Azerbaijan prohibit manufacturers and distributors from sponsoring health workers to attend scientific or training activities such as conferences, meetings, study tours and continuing medical education.[61]

In Brazil, companies may provide assistance to associations of paediatricians or nutritionists that are nationally recognised but the recipient organization must ensure that companies do not promote their products at sponsored events.[62] In addition, materials distributed at sponsored events must include a sentence explaining that the organisation received sponsorship from private companies for the particular event.[63]

In Cameroon, Ghana and Niger, fellowships, research grants or sponsorship of health workers to attend professional meetings, seminars or conferences require the approval of the Minister of Health.[64] Italy restricts infant food companies from sponsoring meetings, courses, workshops and other events unless authorised by the Ministry of Health.[65] The Italian Decree

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[59] *See, e.g.*, Décret N° 000033/PR/MSP portant promotion, protection de l'allaitement maternel et réglementant la qualité, les méthodes de commercialisation ainsi que l'utilisation d'alimentation infantile en République Gabonaise, 2004, (Gabon Decree on the Promotion and Protection of Breastfeeding and on Regulation of the Quality, Marketing Methods and Use of Infant Foods), Article 29; Guatemala Law, *supra* note 48, Article 11; Tanzania Regulations, *supra* note 48, Regulation 13(1).

[60] India Act, *supra* note 48, § 9(2).

[61] Georgia Law, *supra* note 29, Article 18(3); Law of the Azerbaijan Republic on Feeding of Infants and Young Children, 2003, Article 10.0.1.

[62] Brazil Standard for Marketing, *supra* note 30, Article 11 and Brazil Technical Regulations on Infant Foods, *supra* note 17, ¶ ¶ 5.7 & 5.8. *See also* Brazil Technical Regulations, Dummies, Teats, Bottles and Nipple Shields, *supra* note 33, Articles 6.7-6.9 (suppliers and distributors of dummies, teats and bottles may make financial and/or material contributions to scientific bodies but institutions receiving contributions must ensure no product promotion at sponsored events. Distributed materials at sponsored events must include statement disclosing sponsorship)

[63] Brazil Standard for Marketing, *supra* note 30, Article 11 § 2 and Brazil Technical Regulations, Foods for Infants and Young Children, *supra* note 17, ¶ 5.9.

[64] Cameroon Decree, *supra* note 29, Article 7; Ghana Regulations, *supra* note 29, Regulation 6(b); Niger Decree, *supra* note 29, Article 8.

[65] Italy, Decreto 22 febbraio 2005, N° 46, Regolamento recante norme per la pubblicita' dei prodotti sostitutivi del latte materno - Modifica dell'articolo 7 del decreto del Ministro della sanita' 6 aprile 1994, N° 500 (Italy Decree, New rules regarding the norms for the promotion of breastmilk substitutes), Article 7.

includes an innovative provision forbidding continuing medical education credits to be awarded to health workers who participate in meetings for which there has been a financial contribution from producers of breastmilk substitutes.[66]

Uganda, Philippines and Sri Lanka require that contributions to health workers be channelled through specific associations or organisations. Uganda allows companies to make such contributions only to a nationally recognised trust fund under management of the Ministry of Health.[67] In the Philippines, assistance for individuals to attend courses, conventions and seminars must be channelled through the local chapters of national professional organisations.[68] In Sri Lanka, manufacturers may make contributions to nationally recognised medical associations.[69]

Because of the widespread use by industry of gifts and financial assistance as a way to influence health workers, the Model Law proposes a complete ban on the offer or giving of "any gift, contribution or benefit to a health worker or to associations of health workers engaged in maternal and child health, including but not limited to fellowships, research grants or funding for meetings, seminars, continuing education courses or conferences".[70] Moreover, a health worker may not accept "any gift, contribution or benefit, financial or otherwise, of whatever value from a manufacturer or distributor or any person on his or her behalf".[71]

Health workers themselves and through their professional associations can make a difference by refusing to accept industry funding. At the 1992 Congress of the International Paediatric Association, the late James Grant, then Executive Director of UNICEF, called on the IPA to "seriously debate the impact of accepting financial support from infant formula manufacturers on your ability to lead a movement for a massive return to breastfeeding".[72]

Even before India enacted its law on the marketing of infant milk substitutes, the Indian Academy of Paediatrics (IAP) refused to accept sponsorship in any form from infant food companies.[73] The Indian Paediatric Association also has a complete ban on conference sponsorship by infant food companies.[74] In 1999, the International Society for Research on Human Milk and

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[66] *Ibid*., Article 7. In May 2005, just before this Handbook was going to press, the Italian Ministry of Health issued a press release stating that it would annul this provision of Decree N° 46. In Italy, another Decree controls sponsorship of scientific congresses by pharmaceutical companies. Pursuant to the Decree, scientific congresses organised or financially supported by pharmaceutical companies, even indirectly, must aim only at the improvement of knowledge in medical disciplines. Advertising, distribution of free samples and displays of promotional exhibits during the meeting are forbidden. Moreover, application must be made to the Ministry of Health in advance with conference details and a detailed budget that does not include expenses for travel and lodging for participants other than speakers. Legislative Order 541, Article 12, 1992.

[67] Uganda Regulations, *supra* note 29, Regulation 16(b).

[68] Philippines, Guidelines for Assistance/Sponsorship by Manufacturers of Products covered by Executive Order 51, Administrative Order N° 3-B s.2000, § IV.A(1.4).

[69] Sri Lanka Code, *supra* note 29, Article 5.4.

[70] Model Law, § 4(3)(c).

[71] Model Law, § 4(4)(a).

[72] Grant, James P., *Twentieth International Congress of Paediatrics*, Rio de Janeiro, 7 September 1992.

[73] Indian Academy of Paediatrics, Special Committee on Breastfeeding, Recommendations of the Executive Board, *Indian Paediatrics*, 1988, 25: 873-74.

[74] Indian Paediatric Association Conference Guidelines Committee, *IAP Guidelines on Conference Organisation*, 2000.

Lactation, broke with years of commercial sponsorship and held its ninth annual professional conference in Munich, Germany with funding only from non-commercial sources.

Other professional organisations have guidelines for relations between physicians and pharmaceutical companies. In the United States, where the culture of gift giving and sponsorship between pharmaceutical companies and physicians is long-standing, it is encouraging to see that the American College of Physicians published recommendations to individual physicians in 2002 regarding acceptance of gifts and other financial relationships with industry.[75]

The recommendations strongly discourage acceptance of gifts, hospitality, trips and all subsidies from industry by an individual physician. The recommendations also address conflicts of interest that arise when health practitioners have financial relationships with industry. These can comprise speaking, researching or consulting on behalf of a company as well as investment in particular companies. Physicians with such financial relationships are urged not to "compromise their objective clinical judgment" and to "disclose the financial interest".[76]

This 'weaning' from company funding is encouraging, but admittedly still exceptional worldwide. For the most part, governments, professional organisations and individual health professionals are reluctant to give up industry funding out of concern for who will fund research and conferences. Dr. R. K. Anand, a paediatrician in India with a long history of involvement in promotion and protection of breastfeeding states the following:

> Professional and voluntary bodies that believe in complete independence from the baby food industry, even if it means acute shortage of resources, must either raise money from their own members or through publications. Governments, international organisations (including independent charitable trusts and other appropriate sources that do not create conflict of interest) will need to step into the breach. In India, the Indian Council of Medical Research, the Department of Science and Technology, the Ministry of Health, and the Department of Women and Child Development, several charitable trusts, and UNICEF have been meeting such needs.[77]

Years later, Dr. Anand emphasised that conferences need not be lavish and can be organised without industry funding. In 2005, several Indian paediatricians organised a medical conference for professionals wanting to "acquire skills without frills" and emphasised sound academics in modest surroundings with a small registration fee.[78]

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[75] Coyle, S., "Physician-Industry Relations, Part 1:Individual physicians," *Annals of Internal Medicine*, 2002, 136: 396-402.

[76] *Ibid*., p. 399. Guidelines on the relationship between physicians and companies have also been developed by other organisations. *See* World Medical Association (WMA), "Statement concerning the Relationship between Physicians and Commercial Enterprises", approved by the WMA General Assembly, Tokyo 2004, http://www.wma.net/e/policy/r2.htm (accessed 27 April 2005); Royal College of Physicians, "The Relationship between Physicians and the Biomedical Industries: Advice from the Royal College of Physicians", December 2004, http://www.rcplondon.ac.uk/college/statements/advice_biomedIndustry.htm (accessed 23 May 2005).

[77] Anand, R.K., "Health Workers and the Baby Food Industry", Editorial, *British Medical Journal*, 1996, 312:1556.

[78] Academics With Excellence, Science Only Minus Extravagance (AWESOME), Organised by the Society for Rational Therapeutics, September 2005.

Model Law

The relevant provisions of the ICDC Model Law are as follows:

Section 4. Promotion

(1) Except as provided in Subsection 4(2), a manufacturer or distributor shall not him or herself, or by any other person on his or her behalf, promote any designated product. Prohibited promotional practices include but are not limited to–

(a) advertising;

(c) giving of one or more samples of a designated product to any person; and

(d) donation or distribution of information or educational material referring to infant or young child feeding or performance of educational functions related to infant or young child feeding except as provided in Section 14.

(3) A manufacturer or distributor shall not him or herself, or by any other person on his or her behalf–

(b) donate to or distribute within a health care facility equipment, services or materials such as pens, calendars, posters, notepads, growth charts and toys, which refer to or may promote the use of a designated product;

(c) offer or give any gift, contribution or benefit to a health worker or to associations of health workers engaged in maternal and child health, including but not limited to fellowships, research grants or funding for meetings, seminars, continuing education courses or conferences;

(4) A health worker engaged in maternal and child health shall not–

(a) accept any gift, contribution or benefit, financial or otherwise, of whatever value from a manufacturer or distributor or any person on his or her behalf;

(b) accept or give samples of designated products to any person; or

(c) demonstrate the use of infant formula except to individual mothers or members of their families in very special cases of need, and in such cases, shall give a clear explanation of the risks of the use of infant formula as well as the other information required by Chapter IV.

Section 14. Product information for health professionals

Manufacturers and distributors may give materials about designated products to health professionals if such materials−

(1) are restricted to scientific and factual matters regarding the technical aspects and methods of use of the product;

(2) provide references to published studies to support any representation that states or suggests that a relationship exists between the product or constituent thereof and health, growth or development; and

(3) are otherwise in accordance with Sections 12 and 13 of this Act.

CHAPTER 8

Information and Education

Relevant provisions of the International Code

Article 4. Information and education

4.1 Governments should have the responsibility to ensure 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 clear information on all the following points:

(a) the benefits and superiority of breastfeeding;
(b) maternal nutrition, and the preparation for and maintenance of breastfeeding;
(c) the negative effect on breastfeeding of introducing partial bottle feeding;
(d) the difficulty of reversing the decision not to breastfeed; 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 breastmilk substitutes. Such materials should not use any pictures or text which may idealize the use of breastmilk 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 4 of the International Code implements the recommendation of the 1979 *WHO/UNICEF Meeting on Infant and Young Child Feeding* that "Every citizen has the right to have access to correct, consistent information and education."[1] This right was reinforced in 1990 when the Convention on the Rights of the Child, adopted unanimously by the United Nations General Assembly, entered into force. The Convention states that all countries are obliged to "ensure that all segments of society, in particular parents and children, are informed, have access to education and are supported in the use of basic knowledge of . . . the advantages of breastfeeding . . . ".[2]

According to Article 4.1 of the International Code, governments 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". Thus, the International Code envisions that in some countries, a government body would publish and distribute information on infant and young child feeding. Other countries would control the production and dissemination of information materials through detailed regulations or by vetting.

Public education about infant nutrition in general, and breastfeeding in particular, is an essential part of any government policy to promote breastfeeding. The methods governments use to achieve this objective, however, is a subject beyond the scope of this Handbook. The focus of this chapter is on developing legal measures to ensure that educational materials are not misused by the commercial sector as a means to promote commercial infant food products. The chapter also examines measures to ensure that such materials provide objective and consistent information on infant and young child feeding.

Article 4.2 of the International Code states that any materials dealing with information or education about infant feeding must include clear information about,

- the benefits and superiority of breastfeeding;
- maternal nutrition and preparing for breastfeeding;
- the negative effect on breastfeeding of partial bottle feeding;
- the difficulty of reversing a decision not to breastfeed; and
- the proper use of infant formula, when needed.

Article 4.3 allows manufacturers and distributors of products within the scope of the International Code to donate information or educational materials, but only upon request and with approval of an appropriate authority. In almost every country where infant food manufacturers sell their products, they produce or distribute materials that contain information about infant feeding. These materials range from simple pamphlets about products to full books on the how's and why's of breastfeeding and weaning. Companies also produce and distribute specialised materials for doctors, nurses and other health professionals.[3] Experience shows

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[1] WHO and UNICEF, "WHO/UNICEF Meeting on Infant and Young Child Feeding", *WHO Chronicle*, 1979, 33: 439.

[2] UN Convention on the Rights of the Child, *adopted by* UN General Assembly Resolution 44/25, 20 November 1989, Article 24.2(e).

[3] Product information for health professionals is discussed in Chapter 7.

that companies often use so-called information materials to promote their products. There is a grey area between information and promotion and some companies take advantage of this subtlety. Others are more blatant about using such materials as marketing devices.

Company booklets and pamphlets are common sights in maternity and paediatric wards, where they are usually distributed. They are, as a rule, attractive and can be informative. New mothers appreciate the booklets, often the only information about infant care they receive. It is difficult, however, to find a company-produced booklet that does not in some way promote products within the scope of the International Code, promote bottle feeding in general, or otherwise discourage breastfeeding.

While nearly every booklet collected during several international monitoring surveys informed mothers that breastfeeding is best, most also pointed out that supplementing breastmilk with a commercial milk, fed by bottle, would be necessary at some stage. Many of the materials devote substantially more text to the topic of bottle feeding than to breastfeeding. The company's name or logo is always displayed on the cover or in other eye-catching places. Although prohibited by Article 4 of the International Code, some companies advertise formulas and other products within the pages of the booklets or leaflets. For example, Wyeth's *El Libro de mi bebe (My Baby Book)* distributed to mothers at a paediatric clinic in 2003 in the Dominican Republic states, "your doctor recommends a Wyeth formula (*S-26 or SMA*)".[4]

A large number of company information booklets are written in a manner that casts doubts on a woman's ability to breastfeed or that portrays breastfeeding as a more difficult and less attractive feeding method than bottle feeding. A 1986 Gerber booklet told newly delivered mothers, "You may opt to room in [with your baby] or to get all the rest you can before going home" making the choice to breastfeed sound unduly negative.[5] A 1990 booklet by Mead Johnson stated "even though health care professionals strongly favour breastfeeding, the decision to breastfeed or bottle feed is still yours".[6]

Company booklets on breastfeeding can be harmful when information is incorrect or misleading. Each drawing of a mother breastfeeding her baby in a Nestlé booklet produced in Ghana, shows the baby poorly attached to the breast.[7] Mothers using this booklet to learn to breastfeed would most likely end up with sore nipples and an unsatisfied baby, leading the mother to believe she does not have enough milk and that she must supplement her milk with a purchased product.

Several different company booklets on breastfeeding or infant care use the technique of juxtaposing a photograph of a mother bottle feeding her baby with a breastfeeding mother. In these

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[4] *See* International Baby Food Action Network, *Breaking the Rules, Stretching the Rules 2004*, Penang, Malaysia: IBFAN-ICDC, 2004 (*hereinafter* Breaking the Rules, Stretching the Rules), p. 82.

[5] *Quoted in* Auerbach, K., "Beyond the Issue of Accuracy: Evaluating patient education materials for breastfeeding mothers", *Journal of Human Lactation,* 1988, 4: 109.

[6] Mead Johnson, *Breastfeeding, the Best Start for your Baby,* Canada, 1990.

[7] Nestlé, *I am Breastfeeding my Baby. A guide to breastfeeding* (undated booklet). The back cover of the booklet states, "Presented with the compliments of Nestlé". Ghanaian authorities removed the booklet from circulation in 2003 after complaints by health workers. *See* Breaking the Rules, Stretching the Rules, *supra* note 4, p. 61.

publications, the bottle-feeding mother looks happy and loving while holding her baby closely. The breastfeeding mother, on the other hand, appears indifferent and the baby is often far from the mother's face.[8] In some instances the mother's head is cropped from the photo.

One reviewer of company information materials produced and distributed in the United States in the year 2000 stated:

> content analysis of "educational" materials today shows a slant towards making formula appear equivalent to breastmilk, telling mothers not to feel guilty if they choose to bottle-feed, assume that breastfeeding mothers will want or need to supplement, portrayal of mixed feeding as the norm, encouragement to supplement, and limiting exclusive breastfeeding to as little as four weeks so formula can be introduced as soon as possible. (examples omitted)[9]

Sometimes companies comply only superficially with the content requirements of Article 4.2 of the International Code. For example, it is not uncommon to find the required information printed on the inside or back cover in print too small to read comfortably. Other booklets, instead of explaining implications of using infant formula, merely include the statement "social and financial implications should be considered." Such quoting of the Code in fine print is not compliance.

Distribution of free information booklets through health care facilities is the most common way that companies give information to new and expectant mothers. Company websites are also a popular communication tool used to provide information on infant and young child feeding.

An Internet search using an American-based search engine and the key words "infant or baby feeding and nutrition" turned up five infant food company websites in the first fourteen results.[10] The same search on an Asian-based search engine yielded nine different infant food company websites in the first five pages of the search results.[11] Several of the websites are not immediately identifiable as commercial websites with names such as *Very Best Baby* and *Wel-*

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[8] *See, e.g.,* Wyeth-Ayerst International Inc., *The Baby Book*, Malaysia, March 1990.

[9] Walker, M., *Selling out Mothers and Babies, Marketing of breastmilk substitutes in the USA*, Weston, Massachusetts, Natinal Alliance for Breastfeeding Action, 2001, pp. 50-51.

[10] A search using *Yahoo!* on 16 February 2005, using the search terms "infant or baby feeding and nutrition" came up with the following websites: Beechnut, *Beechnut,* http://www.beechnut.com; Infant Formula Council, *Infant Formula Council*, April 2004, http://www.infantformula.org, (members include Mead Johnson Nutritionals; Nestlé USA, Inc., Nutrition Division; PBM Products, LLC; Ross Products Division, Abbott Laboratories; Solus Products; and Wyeth Nutrition); Nestlé, *VeryBestBaby.com*, US website, http://www.verybestbaby.com; Ross Products Division, Abbott Laboratories, *SimilacWelcomeAddition.com*, http://www.welcomeaddition.com; and Gerber, *Gerber,* http://www.gerber.com/home.

[11] The search using *MSN Malaysia* for "infant and baby and feeding and nutrition" on 16 February 2005 came up with the following websites: Infant Formula Council, *Infant Formula Council*, April 2004, http://www.infantformula.org (members listed *supra* note 10); Nutricia, *Nutricia,* Malaysian website, http://www.nutricia.com.my; Wyeth, "Welcome Malaysia", *Wyeth Nutrition*, Malaysian website, http://www.wyethnutrition.com.my; three different Nestlé websites, Nestlé, *Baby Milk Issue Facts,* http://www.babymilk.nestle.com; Nestlé, *VeryBestBaby.com,* US website, http://www.verybestbaby.com; Nestlé, "Welcome to Nestlé Baby", *NestléBaby*, Canadian website, http://www.nestle-baby.ca; Heinz, *HeinzForBaby,* website for Australia and New Zealand, http://www.heinzforbaby.com.au; and SMA Nutrition, *SMA Nutrition,* UK website, http://www.smanutrition.co.uk/.

come Addition. Moreover, the commercial websites do not, at first glance, appear to be selling products. The opening pages present information on topics ranging from pregnancy and birth to general infant care and feeding. For example, Wyeth Nutrition's Malaysian website presents the *Aunty Wyeth Careline.* The site encourages questions and states,

> It's reassuring for new parents to know there's someone they can turn to for complete childcare and nutrition information. Family, friends, and healthcare professionals can all help - and so can **Aunty Wyeth Careline**.[12]

In these websites, readers can find information about breastfeeding side by side with advice on the use of formula and on bottle feeding. The information is not always encouraging for breastfeeding. The breastfeeding section of the *Welcome Addition* website includes a topic entitled "Is Your Baby Getting Enough Milk?" The column mentions the normal stage of fussiness in the baby's first few days of life, which may coincide with the "normal softening of the mother's breast after normal engorgement." It goes on to state that mothers may question the adequacy of their milk supply. Instead of firmly reassuring mothers, *Welcome Addition* states, "It does not necessarily mean you don't have enough milk. The fussiness may only be temporary."[13] Companies know very well that sowing a seed of doubt in the mother's mind can lead to breastfeeding failure.

An article on Nutricia's Malaysian website encourages early mixed feeding as well as bottle feeding. A section subtitled "When it's time for a bottle" begins by stating that "breastfeeding is best begun immediately after birth" and goes on to say "all babies eventually drink milk from a bottle, as they are gradually weaned off milk and onto solids".[14]

Baby food companies are also involved in sponsoring paediatric information found on other Internet websites. For example, the website of Medem Inc., an internet health care company that provides information to the public and internet services to physicians is sponsored by Ross Pediatrics.[15] The *Similac Welcome Addition Club* icon appears on the home page of Medem's Website. Clicking on the icon brings the reader to *WelcomeAddition.com,* the Abbott-Ross website that promotes *Similac* formula. Abbott-Ross also supports home pages for paediatricians who register for Medem's services. The *Welcome Addition* icon will also appear on each paediatrician's website.[16]

[12] Wyeth, "Contact Aunty Wyeth Careline: What is the right thing to do?", *Wyeth Nutrition,* Malaysian website, http://www.wyethnutrition.com.my; Path: Welcome Malaysia; Contact Aunty Wyeth Careline (accessed 16 February 2005).

[13] Ross Products Division, Abbott Laboratories, "Is Your Baby Getting Enough Milk?", *SimilacWelcomeAddition.com,* http://www.welcomeaddition.com; Path: Feeding & Nutrition; Breastfeeding; Is Your Baby Getting Enough Milk (accessed 16 February 2005).

[14] Nutricia, "When it's Time for a Bottle", *Nutricia*, Malaysian website, http://www.nutricia.com.my; Path: Resources; Baby Nutrition; The First Four Months: Milk... and more milk (accessed 16 February 2005).

[15] Medem, *The Medem Network: Connecting physicians and patients online,* http://www.medem.com (accessed 16 February 2005). Medem was founded by the American Medical Association; American Academy of Pediatrics; American Academy of Ophthalmology; American Society of Plastic Surgeons; American College of Allergy, Asthma and Immunology; American College of Obstetricians and Gynecologists and American Psychiatric Association.

[16] Medem, www.medem.com; Path: For physicians; Example sites; Franklin Park Pediatrics. The example site for Franklin Park Pediatrics includes the *Similac Welcome Additoin Club* icon, above which is stated "supported in part by a grant to Medem from [Similac Welcome Addition Club]" (accessed 16 February 2005).

The baby clubs mentioned in Chapter 5 are also a popular technique that companies use to provide information to mothers and their families. When a person signs up for membership in a company baby club, he or she will receive a variety of information materials. These materials are mailed directly to the home and thus are not reviewed by a health worker. The materials rarely comply with all of the requirements of Article 4.2 and are often slanted towards encouraging artificial feeding products.

Some companies produce magazines that contain articles about infant foods and nutrition. In Canada, Nestlé produces and distributes *Good Start Magazine,* which uses the name of one of Nestlé's infant formula products as its title. Articles about nutrition are interspersed with advertisements for infant formula and complementary foods.

Abbott-Ross found another way of delivering its promotional message to hundreds of thousands of American breastfeeding mothers. In 2002, the AAP produced the *New Mother's Guide to Breastfeeding*. Abbott-Ross bought 300,000 copies of the book from the AAP and was given permission to imprint "Ross Pediatrics" along with the company logo (the Ross teddy bear) on the front cover. The Ross logo creates the impression that the AAP endorses Ross's formula products and that the products have some role in breastfeeding. The book's authors objected and the AAP received many complaints, yet the solution was not much better. On the next lot of books that Ross purchased, the company placed its name and logo on the book's inside cover with the phrase "a gift from Ross."

Drafting examples from other countries: Information and educational materials

Procedure

Most national measures that implement the International Code give the government the obligation to provide information on infant and young child feeding to families. Yet the obligation is usually drafted in general terms and is often not carried out with specific action. The Gabon decree is much more specific. It states:

> The Ministry of Health shall ensure the production, distribution and display of placards, posters, booklets, leaflets or other means of information in maternity wards, clinics, doctors' offices, ante-natal consultation and pediatric clinics, health centres and health posts, as well as any other appropriate place, with a view to drawing the attention of pregnant women, mothers and families to: the benefits of breastfeeding and the risks of early weaning; and the appropriate use of complementary foods.[17]

In addition to creating a governmental obligation to provide information about infant and young child feeding, national measures also regulate the provision of such information by other parties. Governments have used three different approaches to ensure that information about infant and young child feeding is objective and consistent.

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[17] Décret N° 000033/PR/MSP portant promotion, protection de l'allaitement maternel et réglementant la qualité, les méthodes de commercialisation ainsi que l'utilisation d'alimentation infantile en République Gabonaise, 2004 (Gabon, Decree on the Promotion and Protection of Breastfeeding and on Regulation of the Quality, Marketing Methods and Use of Infant Foods), Article 25.

Some countries prohibit manufacturers and distributors of products within the scope of their national measure from producing such materials. Other countries have allowed infant food companies to produce and distribute information materials, but require government approval prior to publication. The third option for governments is to set forth detailed regulations delineating requirements and prohibitions for materials on infant and young child feeding.

The governments that prohibit the production of materials on infant and young child feeding by manufacturers and distributors have recognised the potential for misinformation and direct or indirect product promotion. Commercial entities are unlikely to make large expenditures on the production of information materials unless they lead to benefits such as increased sales or an improved corporate image. Constitutional or other legal protections, however, may preclude the option of such a ban in some countries.

Brazil and Pakistan prohibit companies from producing or distributing materials on infant or young child feeding.[18] The Brazil Regulations also include detailed provisions for the content of information and educational materials produced by others and distributed within the country.[19] In Pakistan, persons other than manufacturers and distributors of products within the scope of the Ordinance must submit copies of any material on infant feeding to the National Infant Feeding Board and comply with the content requirements of the Ordinance.[20]

Governments that prohibit materials produced by manufacturers and distributors should ensure that there are other sources of materials to fill the gap. Are there enough local resources to produce materials? Can the government distribute information produced by sources such as WHO, UNICEF, local and foreign universities and relevant non-governmental organisations?

Guatemala takes the second approach and requires review and approval by the Ministry of Health and Social Welfare before any information on feeding of infants and children less than two years old can be produced and distributed.[21] Approval from the Minister is also required for the production of any material on infant and young child feeding in Ghana and the material

[18] Norma Brasileira de Comercialização de Alimentos para Lactentes e Crianças de Primeira Infância, Bicos, Chupetas e Mamadeiras, Portaria Nº 2051 de 8 de novembro, 2001 (Brazilian Standard for Marketing of Foods for Infants and Young Children, Teats, Dummies and Feeding Bottles), Article 8, §2. In Brazil, information dealing with feeding bottles, teats, dummies or nipple shields may not be produced or sponsored by manufacturers or distributors of those products. Brazil, Regulamento Técnico Chupetas, Bicos, Mamadeiras e Protetores de Mamilo, Resolução-RDC N° 221 de 5 de agosto de 2002 (Brazil Technical Regulations, Dummies, Teats, Bottles and Nipple Shields), Article 6.6; Pakistan, Protection of Breastfeeding and Young Child Nutrition Ordinance, Nº 93, 2002, § 7.7.

[19] Brazil Standard for Marketing, *supra* note 18, Articles 8 & 9; Brazil, Regulamento Técnico para Promoção Comercial dos Alimentos para Lactentes e Crianças de primeira Infância, Resolução-RDC N° 222 de 5 de agosto de 2002 (Brazil, Technical Regulation on Commercial Promotion of Foods for Infants and Young Children) ¶ 4.21; Brazil,Technical Regulations, Dummies, Teats, Bottles and Nipple Shields, *supra* note 18, Articles 6.4 & 6.5.

[20] Pakistan Ordinance, *supra* note 18, § 9.

[21] Guatemala, Reglamento para la Comercialización de los Sucedáneos de la Leche Materna, Acuerdo Gubernativo Nº 841-87, 1987 (Guatemala, Rules for the Marketing of Breastmilk Substitutes), Article 6. *See also* Albania, Law for Promotion and Protection of Breastfeeding, Nº 8528, 1999, Article 11; Uganda, Food and Drugs (Marketing of Infant and Young Child Foods) Regulations, 1997, Regulation 17(1); Yemen, Prime Minister Decree Nº 18 on Regulation of Breastfeeding Promotion and Protection, 2002, Article 21; Zimbabwe, Public Health (Breastmilk Substitutes and Infant Nutrition) Regulations, SI 46 of 1998, Part III.

may not refer to a product or contain the name or logo of a manufacturer or distributor.[22] In Malaysia, the voluntary Code provides that educational materials may be distributed only with the approval of the Vetting Committee, which is established pursuant to the Code. Approved materials may only be distributed to certain listed categories of health professionals.[23]

Vetting boards or committees can be a good mechanism, but might prove to be impractical if the volume of materials is excessive and the members do not have the required training and dedication. Moreover, a vetting committee will only be as strong as its mandate. Regulations must establish clear and complete criteria for the evaluation of materials. Approval of materials should be for a specified duration followed by required resubmission so that materials do not become out-dated. The committee should be required to meet regularly and continuously.

A number of countries have taken the third option and have drafted detailed regulations governing the production and distribution of materials on infant and young child feeding. Companies can then be subject to penalties for failing to comply with the regulations.[24] Most of these countries prohibit a reference in the material to a particular product. Some prohibit references to the name or logo of the manufacturer or distributor as well as to particular products.[25]

In France manufacturers and distributors may donate information materials on infant feeding, but only upon request of a health care facility or another social agency.[26] The company must inform the Regional Director for Health and Social Affairs in writing regarding such a request. Such materials may not refer to a specific product and may be distributed to individual mothers only by health workers.[27]

In the Model Law manufacturers and distributors of products within the scope are not permitted to donate or distribute educational or information materials on infant and young child feeding. An exception is made for product information distributed to health professionals. The Model

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[22] Ghana, Breastfeeding Promotion Regulations, 2000, Regulations 7(4) & 8(d).

[23] Malaysia, Code of Ethics for Infant Formula Products, *3rd revision*, 1995, § 4.5.

[24] *See e.g*, Gabon Decree, *supra* note 17, Articles 26 & 27; Ghana Regulations, *supra* note 22, Regulations 7 & 8; Nicaragua, Ley Nº 295 de Promoción, Protección y Mantenimiento de la Lactancia Materna y Regulación de la Comercialización de Sucedáneos de la Leche Materna, 1999 (Nicaragua Law for the Promotion, Protection and Support of Breastfeeding and Regulation of the Marketing of Breastmilk Substitutes), Articles 11 & 12; Niger, Arrêté Nº 215 MSP/DSF portant réglementation de la commercialisation des substituts du lait maternel, 1998 (Niger Decree Regulating the Marketing of Breastmilk Substitutes), Article 17; Sri Lanka, Code for the Promotion, Protection and Support of Breastfeeding and Marketing of Designated Products, 2003, *pursuant to* the Consumer Protection Act, Nº 1 of 1979, Article 7.7 and Vietnam, Decree on Marketing and use of Breastmilk Substitutes to Protect and Promote Breastfeeding, Nº 74/2000/ND-CP, 2000, Article 6.

[25] *See* Ghana Regulations, *supra* note 22, Regulation 8(d); Uganda Regulations, *supra* note 21, Regulation 17(2)(c); Vietnam Decree, *supra* note 24, Article 6(2)(c); Tanzania, The Food (Control of Quality) (Marketing of Breastmilk Substitutes and Designated Products) Regulations, 1994, Regulation 5(3).

[26] France, Décret Nº 98-688 relatif à la distribution gratuite des préparations pour nourrissons, à la documentation et au matériel de présentation les concernant, 1998 (France, Decree on the free distribution of infant formula, documentation and the presentation of material concerning such products), Article 2.

[27] *Ibid.*

Law sets forth detailed requirements governing the content of materials on infant and young child feeding for others who may produce such materials.[28]

Content

The principles discussed here concerning content of information materials are applicable to all information, whether produced by industry, government or other organisations. Article 4.2 of the International Code provides a list of elements, noted at the beginning of this chapter, that must be included in all information or educational materials that deal with infant feeding.

Article 4.2 is not as protective as it might be because these points need only be included in materials that "are intended to reach pregnant women and mothers of infant and young children". Such a restriction, as in other parts of the International Code, is unnecessary and counterproductive. Why is it that pamphlets targeted to new fathers or grandmothers need not comply with restrictions on content? Regulations should apply to all materials, regardless of the intended audience.

Article 4.2 can provide a blueprint for countries drafting legislation, regulations or other measures. Sections 12 and 13 of the Model Law borrow from Article 4.2 of the International Code with some modifications and additions.

First, all educational materials should be required to explain the benefits of breastfeeding and its superiority over bottle feeding. In information materials, the statement "breastfeeding is superior to bottle feeding" should not be considered sufficient. The author should be required to explain the reasons in detail. Thus, the material should discuss the known benefits of breastfeeding as compared to the deficiencies of feeding with a substitute.

The second point required in Article 4.2 is information about preparation for and maintenance of breastfeeding, including a discussion of maternal nutrition both before and during breastfeeding. Note, however, that in some materials maternal nutrition is over-emphasised. Mothers who cannot afford to eat all the foods advised may be led to doubt their own ability to breastfeed. Nutrition charts ultimately discourage breastfeeding. For this reason, the Model Law simply requires information on how to initiate and maintain breastfeeding.[29] Third, the text must explain why bottle feeding, even for a short duration, can make breastfeeding difficult and in some cases impossible, and finally, why a decision not to breastfeed may be difficult to reverse.

The legislation should also mandate the inclusion of other points if the material includes the topic of bottle feeding, such as the following:

- The proper preparation and use of the product;
- The approximate financial cost of feeding with the particular product in the recommended quantities as compared to the cost of breastfeeding;

[28] Model Law, § 4(1)(d) & § 12-15.
[29] Model Law, § 12(5)(c).

- The health hazards of bottle feeding, including that of improper preparation, to be discussed in a manner that can be readily grasped; and
- How to feed infants with a cup.

The legislation should prohibit the text or illustrations from idealising or making the idea of bottle feeding seem more attractive than breastfeeding. The Model Law states that the materials "shall not use any pictures or text that encourage bottle feeding or discourage breastfeeding".[30]

Most countries that have legislation on this topic have included all the criteria from Article 4 of the International Code. Some countries have additional requirements. For example, in India, information and educational materials related to breastmilk substitutes, infant foods or feeding bottles may only be distributed through the health care system if "it is found necessary for healthy growth of the infant by a medical practitioner".[31] In addition, information must be provided in writing about the benefits of breastfeeding, that breastfeeding helps space children, and that bottle feeding carries a danger of microbial contamination.[32]

When the information deals with the pre- or post-natal care or with infant feeding, the India Rules require the author to include all of the information required by Article 4.2 of the International Code, as well as many specified details concerning colostrum, breastmilk, and the advantages and management of breastfeeding.[33] Several countries require that information materials mentioning formula feeding must explain how to feed the baby using a cup rather than a feeding bottle.[34]

In Guatemala, the regulations about information apply to materials concerning feeding infants up to the age of two years. The information may not include any photographs or other representations of children under two years. Further, the materials may not show images of health professionals or any symbol that might suggest that a product is endorsed by the health authorities.[35] Similarly, in Georgia, any material related to feeding children younger than two years may not include any image or text that may imply that a food has been approved by a health worker.[36] In addition, the material may not state that breastmilk could be insufficient or lack a necessary ingredient.[37]

Kenya specifically prohibits "misinformation" and any suggestion that breastmilk will be insufficient in quantity or quality.[38] In the Philippines, the regulations set forth "favoured themes" for information materials.[39]

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[30] Model Law, § 12(1).
[31] India, Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Rules, 1993, *amended* 2003, § 5(b).
[32] *Ibid.*, § 5(a).
[33] *Ibid.*, § 9.
[34] *See e.g.*, Vietnam Decree, *supra* note 24, Article 6; Ghana Regulations, *supra* note 22, Regulation 9(1)(d); Uganda Regulations, *supra* note 21, Regulation 17(3)(e); Zimbabwe Regulations, *supra* note 21, § 11(3)(d)(v).
[35] Guatemala Rules, *supra* note 21, Article 5.
[36] Law of Georgia on Protection and Promotion of Breastfeeding and Regulated use of Artificial Foods, 1999, Article 15.
[37] *Ibid.*
[38] Kenya, Code for Marketing of Breastmilk Substitutes, Standard 05-429, 1983, *revised* 1999, § 8.2.1(g).
[39] Philippines, Rules and Regulations covering the Advertising, Promotion and Marketing of Breastmilk Substitutes, Breastmilk Supplements and Related Products, 1987, § 20.

In Tanzania, materials must be written in Kiswahili, the national language, but those intended for academic purposes may be written in English.[40] The International Code does not address the language for information materials. It merely states that the information must be clear.

Several countries require information about exclusive and sustained breastfeeding as well as about the proper introduction of complementary foods. In Ghana, all materials on infant and young child feeding must mention the global recommendation of exclusive breastfeeding for six months as well as sustained breastfeeding for two years or more.[41] Such materials must also mention how and why bottle feeding or early complementary feeding interferes with breastfeeding.[42] Materials concerning complementary feeding distributed in Ghana must explain the hazards of introducing such foods earlier than six months and that complementary foods can be easily prepared at home.[43]

Gabon also requires a mention of the negative effect on breastfeeding of introducing complementary foods before the age of six months.[44] In Zimbabwe, materials that address complementary feeding must include clear and accurate information about preparation, cost, health hazards, cup feeding and home preparation using family foods.[45]

The establishment of a National Breastfeeding Committee, as recommended by the *Innocenti Declaration*, can be instrumental in ensuring that good information gets produced and distributed. It can also be used as a vetting agency for commercially produced materials. Ultimately, information materials should enable parents to make informed decisions about feeding their infants.

Model Law

The relevant provisions of the ICDC Model Law are as follows:

Section 4. Promotion

(1) Except as provided in Subsection 4(2), a manufacturer or distributor shall not him or herself, or by any other person on his or her behalf, promote any designated product. Prohibited promotional practices include but are not limited to–

(d) donation or distribution of information or educational material referring to infant or young child feeding or performance of educational functions related to infant or young child feeding except as provided in Section 14.

[40] Tanzania Regulations, *supra* note 25, Regulation 5(2).
[41] Ghana Regulations, *supra* note 22, Regulation 8(a)(iii).
[42] *Ibid.*, Regulation 8(a)(vi).
[43] *Ibid.*, Regulation 9(2).
[44] Gabon Decree, *supra* note 17, Article 26.
[45] Zimbabwe Regulations, *supra,* note 21, § 11(3)(e).

Section 12. Information and educational materials about infant feeding

Information or educational materials, whether written, audio or visual, which refer to infant feeding shall–

(1) contain only correct and current information and shall not use any pictures or text that encourage bottle feeding or discourage breastfeeding;

(2) be written in [*insert appropriate language(s)*];

(3) not give an impression or create a belief that a designated product is equivalent to, comparable with or superior to breastmilk or to breastfeeding;

(4) not contain the brand name or logo of any designated product nor of any manufacturer or distributor of a designated product;

provided that this clause shall not be applicable to information about designated products provided to health professionals as authorised by Section 14 of this Act; and

(5) clearly and conspicuously explain each of the following points:

(a) the benefits and superiority of breastfeeding;

(b) the value of exclusive breastfeeding for six months followed by sustained breastfeeding for two years or beyond;

(c) how to initiate and maintain exclusive and sustained breastfeeding;

(d) why it is difficult to reverse a decision not to breastfeed;

(e) the importance of introducing complementary foods from the age of six months;

(f) how and why any introduction of bottle feeding or early introduction of complementary foods negatively affects breastfeeding; and

(g) that complementary foods can easily be prepared at home using local ingredients.

Section 13. Information and educational materials about infant formula, follow-up formula or feeding bottles

If the material referred to in Section 12 includes the topic of bottle feeding, it must also include the following points:

(1) instructions for the proper preparation and use of the product including cleaning and sterilisation of feeding utensils;

(2) how to feed infants with a cup;

(3) the health risks of bottle feeding and improper preparation of the product; and

(4) the approximate financial cost of feeding an infant with such a product in the recommended quantities.

Section 14. Product information for health professionals

Manufacturers and distributors may give materials about designated products to health professionals if such materials–

(1) are restricted to scientific and factual matters regarding the technical aspects and methods of use of the product;

(2) provide references to published studies to support any representation that states or suggests that a relationship exists between the product or constituent thereof and health, growth or development; and

(3) are otherwise in accordance with Sections 12 and 13 of this Act.

Section 15. Submission of materials to Advisory Board

Any person who produces or distributes any materials referred to in this Chapter shall submit copies to the Advisory Board according to procedures as shall be prescribed.

CHAPTER 9

Labelling

Relevant provisions of the International Code

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 breastfeeding.

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 breastfeeding;
(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. They may, however, have graphics for easy identification of the product as a breastmilk 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 3. Definitions

"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.*

"Container" *means any form of packaging of products for sale as a normal retail unit, including wrappers.*

Relevant parts of World Health Assembly Resolution

WHA58.32 (2005)

Urges Member States "to ensure that nutrition and health claims are not permitted for breastmilk substitutes, except where specifically provided for in national legislation".

Urges Member States to "ensure that clinicians and other health-care personnel, community health workers and families, parents and other caregivers, . . . are informed that powdered infant formula may contain pathogenic microorganisms and must be prepared and used appropriately; and, where applicable, that this information is conveyed through an explicit warning on packaging".

Many countries have general food labelling laws that set forth requirements and prohibitions for labels of all food products. Article 9 of the International Code is devoted to requirements for the labels of infant formula that may not appear in general food labelling laws. To implement Article 9, countries could draft a specific labelling provision in the law or other measure. Alternatively, general labelling laws can be amended to include the requirements of Article 9.

A good labelling provision in the legislation is vital, as the label is often the only opportunity for a consumer to obtain essential information about the product's content and use. Moreover, when advertising is restricted, labels are often the first and only contact parents have with a product. The attractiveness of the label may be what pushes an indecisive mother to opt for using a commercial infant food product.

Drafting examples from other countries: Labelling

Article 9 of the International Code is a starting point for drafting the section of legislation concerning product labelling. Article 9.2 contains detailed requirements for labels. Drafters should note carefully, however, that Article 9.2 applies only to infant formula. Article 9.1 is the only labelling provision that applies to all products within the scope, including feeding bottles and teats. It states that labels should include necessary information about the appropriate use of the product, and should be designed so as not to discourage breastfeeding. Article 9.4 governs all food products within the scope, but covers only general information such as ingredients and storage conditions. In addition to Article 9, it is instructive to analyse the laws of various countries that make improvements to Article 9 in numerous respects.

One such improvement is the addition in many national measures of labelling requirements for products other than infant formula. The regulations in Brazil are by far the most specific, delineating requirements for labels of infant formula, follow-up formula for infants, follow-up formula for young children, formulas for high-risk newborns, transition and cereal-based foods, varieties of animal milks, feeding bottles, teats, nipple shields and pacifiers.[1] Many other national measures also include requirements for labels of products in addition to infant formula.

Clear and understandable message

Article 9.2 states that the label of *infant formula* must have a message that is "clear, conspicuous, easily readable and understandable . . .". This general provision would be appropriate for labels of all products under the scope, not only for infant formula.

Several countries have removed the manufacturer's discretion in ensuring clarity of labelling by specifying certain ways the warnings and notices must appear. For example, in India, the statement "Mother's milk is best for your baby" must appear on every label of infant milk substitute or infant food in capital letters.[2] An additional detailed warning must be written in letters at least five millimetres in size in a colour that contrasts with that of the background of the label and must appear in the central panel of the label.[3]

Guatemala specifies that the statement "Breastmilk is the best food for infants" must appear on all labels of breastmilk substitutes "in visible font and colour with characters not smaller than five mm".[4] In Malaysia, those same words must appear in Malay in bold lettering, in not less than 10-point size for a 500-gram tin. The lettering size must increase proportionally with the size of the tin.[5]

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[1] Brazil, Regulamento Técnico para Promoção Comercial dos Alimentos para Lactentes e Crianças de Primeira Infância, Resolução-RDC N° 222 de 5 de agosto de 2002 (Brazil, Technical Regulation on Commercial Promotion of Foods for Infants and Young Children) ¶¶ 4.3-4.19 and Brazil, Regulamento Técnico Chupetas, Bicos, Mamadeiras e Protetores de Mamilo, Resolução-RDC N° 221 de 5 de agosto de 2002 (Brazil Technical Regulations, Dummies, Teats, Bottles and Nipple Shields), Article 5.

[2] India, Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act N° 41 of 1992 *amended* 2003, § 6(1)(a).

[3] India, Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Rules, 1993 *amended* 2003, § 7(a-d). *See also*, Brazil Technical Regulations, Foods for Infant and Young Children, *supra* note 1, ¶ 4.7 (warning must appear on front of label and in contrasting colours); Law of Georgia on Protection and Promotion of Breastfeeding and Regulated use of Artificial Foods, 1999, Article 25(1) ("breastmilk is the best food for your child" must be written in a colour that is clearly different from the background); Zimbabwe, Public Health (Breastmilk Substitutes and Infant Nutrition) Regulations, SI 46 of 1998, § 13(3)(c)(viii) (notices must be written in black against a white background).

[4] Guatemala, Reglamento para la Comercialización de los Sucedáneos de la Leche Materna, Acuerdo Gubernativo N° 841-87, 1987 (Guatemala, Rules for the Marketing of Breastmilk Substitutes), Article 11(a).

[5] Malaysia, Code of Ethics for Infant Formula Products, *3rd revision*, 1995, § 6.2 (xiv). *See also* Georgia Law, *supra* note 3, Article 25(2) (notice in colour clearly different from background; size not less than 1/3 size of product name and no less than 5mm); Pakistan, Protection of Breastfeeding and Young Child Nutrition Ordinance, N° 93, 2002, § 8(3)(b) (warnings not less than 3mm); Sri Lanka, Code for the Promotion, Protection and Support of Breastfeeding and Marketing of Designated Products, 2003 *pursuant to* the Consumer Protection Act, N° 1 of 1979, Article 2.3(g) (letters not less than 5 mm); Uganda, Food and Drugs (Marketing of Infant and Young Child Foods) Regulations, 1997, Regulation 19(2)(b) (notice on front in bold conspicuous characters); Vietnam, Decree on Marketing and use of Breastmilk Substitutes to Protect and Promote Breastfeeding, N° 74/2000/ND-CP, 2000, Article 10(1)(a) (size of type for each warning specified); Zimbabwe Regulations, *supra* note 3, § 13(3)(c)(viii) (notice bold, conspicuous, non-serif, not less than 10-point in black against a white background).

Some countries also mandate the size of characters in a warning or notice relative to the size of other text on the label. For example, in Georgia, the size of the "important notice" cannot be less than one-third the size of the product name.[6] In Uganda, the characters in the "important notice" may not be less than 50 percent of the size of the largest word on the label, with the minimum size no less than 2 millimeters.[7] In Brazil the font used for the required warning must be the same as that used for the product designation.[8]

Appropriate language

Article 9.2 requires that the messages on the label of infant formula be written "in an appropriate language". Drafters of national laws can ensure that this important requirement applies to all products within the scope of the legislation. The term *appropriate language* is not defined. In countries that have not implemented the International Code, companies have had to determine what is meant by the term *appropriate language*. Companies often use the country's official language for product labels. Yet, in many countries, large parts of the population do not understand the country's official language.

National measures should specify the language in which the label should be written. Some countries require labels to be written in several languages to accommodate a diverse population. For example, in Sri Lanka, labels must be written in Sinhala, Tamil and English.[9] Countries that face industry objections to such requirements can be reminded that in Switzerland, the home of Nestlé, one of the world's largest infant food manufacturers, labels for all products are written in three national languages: French, German and Italian.

When labels are written in more than one language, it is also important that the translation be the same. Mead Johnson had to recall a ready-to-use infant formula in the US because the English version of the instructions called for use without dilution but the instructions in Spanish directed dilution with water.[10] A report from Yemen showed that the English text of a label of follow-up milk recommended the product from the sixth month while the Arabic text recommended it from the fourth month. Similarly, in Armenia, the statement on a *Nestogen* (Nestlé) label states in Armenian, "breastmilk is the ideal nutrition for a baby". The Russian text however, reads, "breastmilk is the ideal nutrition for a newborn", (meaning, in Russian, a baby below one month).[11] The Kenya Code addresses this problem by requiring all product information to be given the same meaning in English and in Kiswahili.[12]

In India, a criminal complaint was filed against Nestlé in 1995 for printing the words, "Breastmilk is best for your baby" on labels of its infant formula *Lactogen* rather than the

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[6] Georgia Law, *supra* note 3, Article 25(1).
[7] Uganda Regulations, *supra* note 5, Regulation 19(2)(b).
[8] Brazil Technical Regulations, Foods for Infant and Young Children, *supra* note 1, ¶ 4.7.
[9] Sri Lanka Code, *supra* note 5, Article 2.3(f).
[10] Warning Letter from District Director, Detroit District, US Food & Drug Administration to President, Bristol-Myers Squibb, 29 August 2001 (concerning Mead Johnson Nutritionals, *Enfamil Nutramigen Hypoallergenic Formula*, Ready to Use/Do Not Add Water in one quart cans).
[11] International Baby Food Action Network, *Breaking the Rules, Stretching the Rules 2004,* Penang, Malaysia: IBFAN-ICDC, 2004, (*hereinafter* Breaking the Rules, Stretching the Rules 2004), p. 58.
[12] Kenya, Code for Marketing of Breastmilk Substitutes, Standard 05-429, 1983, *revised* 1999, § 8.1.

words, "Mother's milk is best for your baby" as mandated under the law. The difference appears minor but in India, the words "mother's milk" have great emotional appeal and cultural significance. In addition, the phrase when translated into Hindi, the local language, became the equivalent of "udder's milk is best for your baby" with connotations much different from "mother's milk".

Important messages for the consumer

Points (a)-(d) of Article 9.2 of the International Code set forth particular information that must appear on every label of infant formula in a clear and conspicuous manner. The message must be preceded by a phrase such as "Important Notice" and must mention the superiority of breastfeeding, that the product should be used only on advice of a health worker, give preparation instructions and include a warning about the health hazards of inappropriate preparation.

Many countries have found these requirements to be overly general and have opted to require specific warnings and notices to appear on labels of infant formula as well as other products such as follow-up formula, complementary foods, feeding bottles and dummies.[13]

The required notice in some of these countries, rather than simply stating that breastfeeding is superior, describes the protective features of breastfeeding. For example, in Yemen, labels of infant formula must state, "Breastmilk is a complete food containing all the essential elements for infants and it improves the immunity of infants against diseases, especially diarrhoea".[14]

The required message in Brazil for labels of infant and follow-up formula mentions that breastfeeding prevents infections and allergies and strengthens the bond between mother and baby.[15] Brazil also requires a similar statement to appear on the labels of what it calls *follow-up formula for young children*.[16] These labels must also mention that the product should not be used for infants under one year of age and that breastfeeding is recommended for up to two years or more.[17] In Sri Lanka, labels of products within the scope must contain the following statement: "Breastfeeding, in addition to its nutritional qualities, provides protection against many diseases."[18]

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[13] In some countries, *dummies* are referred to as *pacifiers.*

[14] Yemen, Prime Minister Decree N° 18 on Regulation of Breastfeeding Promotion and Protection, 2002, Article 7(1)(a).

[15] Brazil Technical Regulations, Foods for Infant and Young Children, *supra* note 1, ¶ 4.4.

[16] *Ibid.* ¶ 4.7.

[17] *Ibid.*

[18] Sri Lanka Code, *supra* note 5, Article 2.3(b). *See also*, Albania, Law for Promotion and Protection of Breastfeeding, N° 8528, 1999, Articles 7 & 8 ("Breastmilk is the ideal food for healthy growth and development of children"); Pakistan Ordinance, *supra* note 5, § 8(4)(b) ("Mother's milk is best for your baby and helps in preventing diarrhoea and other illnesses"); Uganda Regulations, *supra* note 5, Regulation 19(2)(b), (3)(b), (5)(a) & (6) ("Breastfeeding is best for your baby. It protects against diarrhoea and other illnesses"); Vietnam Decree, *supra* note 5, Articles 10.1.a, 11.1.a & 11.2 ("Mother's milk is best for growth and development of infants and children. It contains anti-infective properties that help protect against diarrhoea and other illnesses"); and Zimbabwe Regulations, *supra* note 3, § 13(3)(c)(viii) & (3)(g) ("Breastmilk is the best food for your baby. It protects against diarrhoea and other illnesses.").

Article 9 requires that labels include preparation instructions. Some countries also require that the label indicate the amount of infant formula that will be consumed over a certain period of time. In Nepal, for example, the quantity required for the child in each month must be stated on the label.[19] The Model Law requires that labels of infant formula and follow-up formula include a feeding chart in the preparation instructions.[20]

Article 9 also requires that labels of infant formula include a warning against the health hazards of inappropriate preparation. Despite the importance of such a warning, a 1998 survey showed that the warning was missing from labels of various brands of infant formula in 20 out of 31 countries.[21] Some countries require a standard warning for product labels, such as that mandated for cigarette packages. In India, for example, in addition to the statement, "Mother's milk is best for your baby" the following warning is required on the label of all infant milk substitutes and infant food:

> Warning/caution - Careful and hygienic preparation of infant food is most essential for health. Do not use fewer scoops than directed, since dilute feeding will not provide adequate nutrients needed by your infant. Do not use more scoops than directed since concentrated feed will not provide the water needed by your infant.[22]

Similarly, Zimbabwe requires that labels of all products within the scope of the regulations include the following statement:

> To avoid illness of your baby, follow the preparation instructions carefully. Do not use more or less of the quantities than indicated. Cup feeding is safer than bottle feeding. If you use a feeding bottle your baby may reject the breast.[23]

In India, in addition to preparation instructions, manufacturers must instruct that any leftover feed be discarded.[24]

International concern about intrinsic contamination of powdered infant formula by pathogens such as *Enterobacter sakazakii* has led to a call for another type of warning on formula labels. The pathogen *E. sakazakii* has been implicated in recent outbreaks of serious illnesses including sepsis, meningitis and necrotizing enterocolitis. In 2004 one outbreak in New Zealand

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[19] Nepal, Breastmilk Substitutes (Marketing Control) Act, N° 39 of 2049, 1992, § 11(6)(e). *See also* Ghana, Breastfeeding Promotion Regulations, 2000, Regulation 10(3)(d)(state amount needed to feed infant for first six months); Uganda Regulations, *supra* note 5, Regulation 19(3)(d)(number of containers needed to feed infant for first six months); Zimbabwe Regulations, *supra* note 3, § 13(3)(f)(vi) (number of containers of infant formula needed to feed infant for first 6 months).

[20] Model Law, § 6(1)(d).

[21] Breaking the Rules, Stretching the Rules 2004, *supra* note 11, p. 41.

[22] India Rules, *supra* note 3, § 7(d)(ii).

[23] Zimbabwe Regulations, *supra* note 3, § 13(3)(f)(v). *See also* Georgia Law, *supra* note 3, Article 21, 2(b) ("Warning: Before deciding to give the child artificial food, seek the advice of a health professional. Follow all preparation instructions carefully.").

[24] India Rules, *supra* note 3, § 7(d)(v).

resulted in the death of a pre-term infant and another in France led to infections of 9 infants causing two deaths and four serious illnesses.[25] Cases of illness due to infant formula contaminated with *Salmonella* have also been reported.[26]

Until recently, it had been believed that hygienic preparation of powdered infant formula with clean water would prevent illnesses. In other words, illnesses resulting from contamination were blamed on poor preparation. It is now recognised that formula is not a sterile product. Low levels of pathogens can contaminate the formula during the production process. This is referred to as "intrinsic contamination". Even low levels of these pathogens can lead to serious illness and death.

International organisations as well as national governments have been seeking ways to mitigate these risks. One way is to require warnings on labels to inform consumers and health workers that infant formula may contain pathogenic microorganisms that can lead to illness and death. The 2005 Resolution WHA58.32 urges Member States to ensure that caregivers are informed about this risk and that "where applicable, this information is conveyed through an explicit warning on packaging".

The Model Law suggests standardised warnings for infant formula, follow-up formula, feeding bottles, teats and pacifiers. For packages of infant and follow-up formulas in powdered form, the Model Law also proposes in accordance wtih Resolution WHA58.32, that the label

> states in preparation instructions for infant or follow-up formula in powdered form that powdered formula may be contaminated with microorganisms during the manufacturing process or may become contaminated during preparation and that it is therefore necessary to discard any unused formula immediately after every feed.[27]

No pictures of infants

Another important protection included in Article 9.2 and that should be repeated in national legislation is the prohibition of pictures of infants on labels of infant formula. Article 9.2 also prohibits "other pictures or text which may idealise the use of infant formula". While it was a common practice prior to adoption of the International Code, very few companies still show infant pictures on labels of infant formula.

Yet rather than leading to simple, non-promotional labels, the ban on infant pictures has led companies to create labels with other kinds of images that can be just as promotional. The baby images have been replaced on labels by an array of cartoon characters ranging from the Abbott-Ross teddy bear with blanket[28] and the Nutricia feeding bottle surrounded by flowers and bears[29]

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[25] International Food Safety Authorities Network, *Enterobacter sakazakii in Powdered Infant Formula* (Information Note N° 1/2005), 13 January 2005.

[26] *See* Chapter 2, p. 31.

[27] Model Law, § 6(1)(c).

[28] The teddy bear with blanket appears on the labels of most infant and follow-up formulas made by the Ross Products Division of Abbott Laboratories.

[29] The feeding bottle surrounded by flowers and bears appears on the labels of some Nutricia (part of Royal Numico) infant formulas such as *Nutrilon.*

to Beatrix Potter's Peter Rabbit (a well-known children's storybook character) being bottle-fed by mother rabbit, which appears on labels of some Mead Johnson products.[30] Following complaints, Mead Johnson removed the feeding bottle from the label in some, but not all countries.

In an effort to stop these promotional images on labels, some countries have gone further than the International Code and prohibit all photographs, pictures or graphics on the label with the exception of graphics necessary for illustrating preparation instructions.[31] The Uganda regulations specify that labels of infant formula may never show a feeding bottle, even in the preparation instructions.[32] In Brazil, Ghana and Pakistan, the prohibition applies to labels of follow-up formula and other breastmilk substitutes as well as to infant formula.[33] In Brazil, labels of follow-up formula for young children may not contain

> Illustrations, photographs or pictures of infants, young children, child characters or any other forms that resemble them, human or not, such as humanised fruits, vegetables, animals and/or flowers, among others, with the purpose of leading to the use of the product for this age bracket.[34]

The Brazil regulations also stipulate that brand or product logos are permitted provided that the logo does not use a picture of an infant, young child or other humanised figure.[35] This regulation was no doubt prompted by the experience in Guatemala with the Gerber Company. In the early 1990s, the government of Guatemala became mired in a dispute with Gerber over Gerber's insistence on using its trademark baby face on the label of its baby foods.[36] Gerber does not use the baby face on labels of baby food products in Brazil although the trademark appears on Gerber baby foods in most other countries.[37] The Model Law prohibits any photograph, drawing or other graphic representation other than those graphics used in the preparation instructions on labels of all products within its scope.[38]

Idealising text

In addition to the pictures, the text on the label is often inappropriate. Article 9.2 requires that labels mention the superiority of breastfeeding and prohibits "text which may idealise the

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[30] Peter Rabbit appears on labels of Mead Johnson's *Enfamil* in many Latin American countries.

[31] *See* Brazil Technical Regulations, Foods for Infant and Young Children, *supra* note 1, ¶ 4.3; Ghana Regulations, *supra* note 19, Regulation 10(3)(a); Pakistan Ordinance, *supra* note 5, § 8(4)(e); and Uganda Regulations, *supra* note 5, Regulation 19(3)(c).

[32] Uganda Regulations, *supra* note 5, Regulation 19(3)(c).

[33] Brazil Technical Regulations, Foods for Infant and Young Children, *supra* note 1, ¶ 4.3.1; Ghana Regulations, *supra* note 19, Regulation 16, definition "designated products"; Pakistan Ordinance, *supra* note 5, §§ 8 & 2(f), definition of "designated products".

[34] Brazil Technical Regulations, Foods for Infant and Young Children, *supra* note 1, ¶ 4.6.1. Brazil's prohibition of *humanised fruits* [and] *vegetables* may have been prompted by Wyeth's use of a carrot as a symbol of the carotene it adds to its formulas. The carrot, often shown wearing a graduation cap, appears on Wyeth's promotional materials in many countries.

[35] *Ibid.* ¶ 4.3.1.

[36] The experience of Guatemala with the Gerber Company is more fully described in Chapter 11, pp. 165-66.

[37] The trademark baby face does not appear on Gerber baby cereals in Bangladesh where pictures of infants on labels of complementary foods are also prohibited. *See* Bangladesh, Breastmilk Substitutes (Regulation of Marketing) Ordinance N° 33, 1984, *amended* 1990, § 5(d).

[38] Model Law, § 5(1).

use of infant formula". Phrases that compare the product with breastmilk are common on labels of infant and follow-up formulas. A Mead Johnson *Enfamil* label declares, "Our closest formula to breastmilk ever"[39] and the label of Wyeth's *SMA Gold* states, "The balance of milk proteins are similar to that found in breastmilk".[40] Although Article 9.2 does not specifically prohibit comparisons to breastmilk, it can be argued that phrases representing a breastmilk substitute to be close or similar to breastmilk serve to *idealise* the product and bottle feeding.

Countries have used more specific language to prevent this kind of promotional text from appearing on labels. A few countries specifically prohibit any comparison between a product and breastmilk. Brazil, for example, prohibits expressions "that may suggest a strong similarity between the product and breastmilk".[41] Under the Bangladesh Ordinance, the label of a breastmilk substitute must state not only that breastmilk is superior, but that nothing is equivalent or can be its substitute.[42]

Companies also idealise infant formula by stating on a label that the formula, or some ingredient therein plays a role in growth or development of the infant. A label of Abbott-Ross *Similac with iron*, for example, prominently displays the phrase, "excellent nutrition clinically shown to support brain development". Such phrases serve, indirectly, to compare the products with breastmilk because only breastmilk has been shown to provide exactly what infants need for brain development.[43]

At least four countries have prohibited *health claims* on products for infants in their food labelling laws.[44] The Codex, which sets worldwide food standards, has been drafting guidelines about the use of health and nutrition claims on food labels.[45] The draft guidelines define a *health claim* as "any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health".[46] Health claims include *nutrient function claims*, which are claims that describe "the physiological role of the nutrient in growth, development and normal functions of the body".[47] Claims that relate the food to a reduced risk of developing a disease or health-related condition are also considered "health claims".[48]

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[39] *Enfamil Lipil*, sold in Puerto Rico and the Dominican Republic in 2002.

[40] *SMA Gold* sold in Tanzania in 2002.

[41] Brazil Technical Regulations, Foods for Infant and Young Children, *supra* note 1, ¶ 4.3.2.

[42] Bangladesh Ordinance, *supra* note 37, § 5(1)(b).

[43] Similar claims, and how they can be considered deceptive in the context of product advertisements and information to health professionals are discussed in Chapter 7, p. 96.

[44] In Canada, health claims must not be directed solely at children less than two years of age; in Brazil, formula for infants and young children must not bear health claims; and in Israel, health and functional claims are prohibited on foods intended for infant consumption. Hawkes, C., *Nutrition Labels and Health Claims: The global regulatory environment,* Geneva: WHO, 2004, p. 49. In the United States, health and nutrition claims, with some minor exceptions, may not appear on labels of foods for infants and children less than two years old. 21 Code of Federal Regulations § 101.13 (b)(3) & 101.14 (e)(5).

[45] Codex Alimentarius Commission, *Draft Guidelines for use of Health and Nutrition Claims* § 1.4. (at step 8), *in* Report of the 32nd Session of the Codex Committee on Food Labelling, ALINORM 04/27/22, Appendix III (2004).

[46] *Ibid*. § 2.2.

[47] *Ibid*. § 2.2.1.

[48] *Ibid*. § 2.2.3.

Codex is considering disallowing such claims for labels of foods for infants and young children, but the most recent draft of the guidelines makes an exception for specific Codex standards or national laws that allow such claims. The 2005 Resolution WHA58.3 is similar in urging Member States to ensure that "nutrition and health claims are not permitted for breastmilk substitutes, except where specifically provided for in national legislation". Because health claims serve to idealise products, drafters should consider prohibiting them. Section 5(3) of the Model Law states:

> A manufacturer or distributor shall not offer for sale or sell a designated product if the container or label affixed thereto contains any representation that states or suggests that a relationship exists between the product or constituent thereof and health, including the physiological role of a nutrient in growth, development or normal functions of the body.

The laws implementing the International Code in Brazil and India have some additional provisions that would prevent promotional language on labels. Some labels use language that subtly undermines a mother's confidence. The Brazil regulations forbid expressions that might cast doubt on the mother's ability to breastfeed such as "when breastfeeding is not possible".[49] In India, labels of infant foods may not use the words "Full protein food, Energy food, Complete food, Health food" or similar expressions.[50] In addition, words implying that the product is recommended or approved by the medical profession may not be used on the label.[51] In 2005, a court in Latvia ruled that a label of Nestlé's *Nan HA* was in violation of the national law on labelling and advertising of breastmilk substitutes because the label says "Recommended by the Latvian Paediatric Association".[52]

Article 9.2 also forbids use of the words *humanised, maternalised* or similar terms on labels of infant formula. Most countries have incorporated this provision into their laws. Nonetheless, companies still use company names or infant formula brand names such as *Humana* (German company) and *Mammamil* (manufactured by Maeil Dairy Industry, Korea). Nestlé's *Lactogen,* takes its name from *placental lactogen,* a prolactin-like substance essential to the body's process of making milk.

The final point in Article 9.2 allows companies to use package inserts to supply additional information about the product's use. The operative word here is *additional;* one company improperly justified the lack of certain required information on its labels by including it only in the package insert.

Articles 9.3 and 9.4

Article 9.3 of the International Code addresses products that are marketed for infant feeding, which do not meet all the requirements of an infant formula, but can be modified to do so. These products must carry a warning that the unmodified product should not be the sole source

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[49] Brazil Technical Regulations, Foods for Infant and Young Children, *supra* note 1, ¶ 4.3.3.
[50] India Rules, *supra* note 3, § 8(d).
[51] *Ibid*., § 8(b).
[52] *Latvian Paediatric Association, et. al, vs. Latvian Breastfeeding Promotion and Protection Association*, City of Riga, Kurzeme District Court, 23 May 2005.

of nutrition of an infant. In addition, labels of sweetened condensed milk should never instruct on how to modify it for infant feeding because this product is not suitable for infant feeding.

Several countries have recognised the importance of warnings on other milk products that are often used to feed infants instead of breastmilk. Brazil requires warnings for skimmed and whole milks.[53] Labels of skimmed or partially skimmed milk must state, "The Ministry of Health says: 'This product should not be used to feed children, except upon prescription from a doctor or a nutritionist. Breastfeeding prevents infections and allergies and is recommended up to two years or more'".[54] Whole milk labels must show a similar warning stating that the product should not be used for children less than one year old.[55] Other countries have general food labelling laws requiring similar warnings.

Finally, Article 9.4 requires labels of food products to include basic information such as the product's ingredients, composition, storage conditions and expiration date. The Model Law makes a few modifications. Labels of infant and follow-up formulas must specify the source of protein.[56] This would serve to identify if the milk comes from an animal other than a cow. In addition, storage conditions both *before* and *after* opening must be specified, taking into account climatic conditions.[57]

Age recommendation

Article 9 of the International Code does not require labels to indicate the age for which a product is recommended nor does it provide guidelines for appropriate age recommendations. Age guidelines are important because supplementing an infant's diet with foods or drinks too soon can interfere with breastfeeding and can pose a danger of infection and diarrhoea. Early introduction of follow-up formula can also pose a health risk to very young infants.[58]

Many infant food products, especially infant teas and juices, are labelled with inappropriate age recommendations. Other labels completely lack an age recommendation. Some companies recommend different ages for the same product depending on the country in which the product is sold. Gerber, Nestlé and some other companies market some of their baby food products as a series of steps or stages, which can be confusing for parents. A Nestlé cereal sold in Honduras, for example, uses a bear that cannot yet sit upright to symbolise Step 1 and a sitting bear for Step 2, yet both are labelled as appropriate to use from the age of six months.

Several countries have addressed this shortcoming in national legislation. Some countries require manufacturers of food products within the scope of the law to include on the label the

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[53] Brazil Technical Regulations, Foods for Infant and Young Children, *supra* note 1, ¶¶ 4.10 & 4.11. *See also* Uganda Regulations, *supra* note 5, Regulation 19(4)(a), (b) & (c) (warnings for skimmed or condensed milk, for low-fat standard milk and for whole cow's milk).

[54] Brazil Technical Regulations, Foods for Infant and Young Children, *supra* note 1, ¶ 4.11.1

[55] *Ibid.*, ¶ 4.11.2

[56] Model Law, § 6(1)(g).

[57] *Ibid.*, § 5(2)(f).

[58] The dangers of introducing foods in addition to breastmilk too early are discussed in Chapter 4, p. 56.

age recommended for feeding the product.[59] In Brazil and Yemen, labels of complementary foods must carry a warning about the hazards of introducing the product prior to the age of six months.[60] Yemen also requires a statement on labels of complementary foods to state that their introduction does not mean the end of breastfeeding and that the product is not equivalent to breastmilk in nutritive value.[61]

Other countries will likely include similar provisions in reaction to Resolution WHA54.2 (2001), which recommends that nations should support exclusive breastfeeding for six months. Nestlé, one of the largest manufacturers of infant cereals and other baby foods, has stated that it has completed changing labels on its complementary foods to reflect the recommendation of exclusive breastfeeding for six months.[62] The company, however, planned to change its complementary food labels only in developing countries.[63]

Codex is in the process of revising the Standard for Processed Cereal-based Foods for Infants and Young Children and has proposed language regarding age.[64] The draft revised standard would require labels for cereal-based infant foods to indicate the age for which the product is intended for use and to state that the product is not recommended for use below 6 months.[65] Codex is also considering requiring on the label a statement

> indicating that the decision when precisely to begin complementary feeding, including any exception to six months of age, should be made in consultation with a health worker, based on the individual infant's specific growth and development needs. . . .[66]

The Codex Standard for Follow-up Formula provides that "follow-up formula should not be introduced before the sixth month of life".[67] The Model Law requires each product label to

[59] *See, e.g.*, Cameroon, Arrêté Interministeriel N° 040 portant sur la réglementation de la commercialisation des substituts du lait maternel, 1993 (Cameroon, Interministerial Decree on the Control of Marketing of Breastmilk Substitutes), Article 13(1). *See also*, Décret N° 000033/PR/MSP portant promotion, protection de l'allaitement maternel et réglementant la qualité, les méthodes de commercialisation ainsi que l'utilisation d'alimentation infantile en République Gabonaise, 2004 (Gabon, Decree on the Promotion and Protection of Breastfeeding and on Regulation of the Quality, Marketing Methods and use of Infant Foods), Article 17; Georgia Law, *supra* note 3, Article 21(1)(c); Niger, Arrêté N° 215 MSP/DSF portant réglementation de la commercialisation des substituts du lait maternel, 1998 (Niger, Decree Regulating the Marketing of Breastmilk Substitutes), Article 14; Zimbabwe Regulations, *supra* note 3,§ 13(3)(c)(vii).

[60] Brazil Technical Regulations, Foods for Infant and Young Children, *supra* note 1, ¶ 4.14; Yemen Decree, *supra* note 14, Article 7(3).

[61] Yemen Decree, *supra* note 14, Article 7(7).

[62] Nestlé, "Nestlé Takes Initiative on 6-month Labelling", *Baby Milk Issue Facts Action Report*, Edition 7, June 2003, http://www.babymilk.nestle.com/Action+Reports/Edition+7/Nestlé+takes+initiative.htm (accessed 25 May 2005).

[63] Nestlé, "New WHO Infant Feeding Recommendations", *Baby Milk Issue Facts News*, 3 July 2001, http://www.babymilk.nestle.com/News/All+Countries/ Other/New+WHO+infant+feeding+recommendations.htm (accessed 25 May 2005). In Australia, Canada, Europe, Hong Kong, Japan, Singapore, South Korea, Taiwan and United States, however, Nestlé has not pledged to change labels but only to support the inclusion of the WHA recommendation in national regulations.

[64] Codex Standard for Processed Cereal-based Foods for Infants and Children, Standard 74-1981 (amended 1985, 1987, 1989, 1991, currently under revision).

[65] Codex Alimentarius Commission, *Proposed Draft Revised Standard for Processed Cereal-based Foods for Infants and Young Children* § 8.6.4. (at step 6), *in* Report of the 26th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses, ALINORM 05/28/26, Appendix V, 2004.

[66] *Ibid.*

[67] Codex Standard for Follow-up Formula, Standard 156-1987 (amended 1989), § 9.9.2.

state the age after which the product is recommended as well as to include a statement regarding the health hazards of introducing the product prior to the recommended age.[68] For complementary foods, the age must not be less than six months.[69]

Malaysia has an additional labelling requirement to address the concern that parents using infant formula may supplement their infant's diet too late. Thus, in Malaysia, labels of infant formula must state, "infant formula is not the only food for infants over six months".[70]

Feeding bottles and teats

The only labelling requirements in Article 9 of the International Code that apply to feeding bottles and teats are those of Article 9.1, which require that the label must provide information about appropriate use of the product and must not discourage breastfeeding. Many national laws and regulations have labelling provisions that relate to feeding bottles and teats and, in some cases, dummies (also known as pacifiers) and feeding cups.[71] Many have improved on Article 9 in this respect. Brazil has specific regulations related to the marketing of feeding bottles, teats, dummies and nipple shields.[72] The regulations devote an entire section to the labelling of these products.

According to the Brazil regulations, every bottle, teat, dummy or nipple shield sold in Brazil must be sold with a label.[73] This is an important regulation because feeding bottles and teats are sold in many countries without any packaging or labels. Pursuant to the Brazil regulations, labels of feeding bottles, teats and dummies must include the following warning:

> The Ministry of Health says:
> A breastfed baby does not need bottles, teats or dummies. The use of bottles, teats or dummies interferes with breastfeeding and prolonged use is harmful to the baby's teething and speech.[74]

The regulations in Zimbabwe require that labels of *feeding articles* and *pacifiers* bear a notice in bold black characters against a white background stating, "The use of a feeding bottle (or feeding cup or pacifier, as appropriate to the particular label) interferes with breastfeeding".[75] Similarly, in Ghana, labels on pacifiers must have a notice stating that the use of a pacifier can interfere with breastfeeding.[76]

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[68] Model Law, § 5(2)(b & c).
[69] *Ibid*. § 5(2)(b).
[70] Malaysia Code, *supra* note 5, § 6.2(xiv).
[71] *See, e.g*., Georgia Law, *supra* note 3, Articles 23 & 24; Ghana Regulations, *supra* note 19, Regulation 11; Nepal Act, *supra* note 19, § 11(11); Pakistan Ordinance, *supra* note 5, § 8; Panama, Ley 50 por la cual se Protege y Fomenta la Lactancia Materna, 1995 (Panama, Law on the Protection and Promotion of Breastfeeding) Article 24; Uganda Regulations, *supra* note 5, Regulation 19(1) & (5); Vietnam Decree, *supra* note 5, Article 11; Zimbabwe Regulations, *supra* note 3, § 13(3)(g).
[72] Brazil Technical Regulations, Dummies, Teats, Bottles and Nipple Shields, *supra* note 1.
[73] *Ibid.,* Article 5.1.1.
[74] *Ibid.*, Article 5.1.4.
[75] Zimbabwe Regulations, *supra* note 3, § 13(3)(g).
[76] Ghana Regulations, *supra* note 19, Regulation 11(2).

In Brazil, labels of bottles, teats, dummies and nipple shields must also include user instructions that include, among other information, the need to boil these items before use; to check dummies and teats for cracks and discard if damaged and not to use a bottle without constant adult supervision.[77]

Brazil also prohibits pictures of children and pictures that resemble infants or young children, whether human or not and whether using bottles, teats or dummies or not, on the labels.[78] Moreover, messages that may raise doubts about a mother's ability to breastfeed her baby or that suggest a similarity of the product with the human breast are not allowed.[79]

Some other warnings already included by some manufacturers concern the danger of tooth decay resulting from prolonged contact with drinks containing sugar such as infant tea. Following several successful lawsuits against Milupa in Germany concerning children whose teeth were severely damaged, Milupa and other manufacturers changed their labelling. Milupa now uses the following warning:

> When bottle feeding, do not allow prolonged or frequent contact of milk feeds with your baby's teeth since this increases the risk of tooth decay. Make sure your baby's teeth are cleaned after the last feed at night.[80]

Another warning to be considered concerns the presence of nitrosamines in rubber teats and the possible choking hazard from cracked or worn out teats.

Model Law

The relevant provisions of the ICDC Model Law are as follows:

Section 5. Prohibitions related to labels of designated products

(1) A manufacturer or distributor shall not offer for sale or sell a designated product if the container or label affixed thereto includes a photograph, drawing or other graphic representation other than for illustrating methods of preparation. [*Optional*: This section shall not apply to complementary foods.]

(2) A manufacturer or distributor shall not offer for sale or sell a designated product, other than a feeding bottle, teat or pacifier unless the container or label affixed thereto indicates in a clear, conspicuous and easily readable manner, in [*insert appropriate language(s)*], the following particulars:

(a) instructions for appropriate preparation and use in words and in easily understood graphics;

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[77] Brazil Technical Regulations, Dummies, Teats, Bottles and Nipple Shields, *supra* note 1, Article 5.2.
[78] *Ibid.,* Article 5.1.5 (a) & (b).
[79] *Ibid.,* Article 5.1.5 (c).
[80] Milupa, "Products: Breastfeeding is Best", *Welcome to Milupa Aptamil,* http://www.milupa-aptimil.co.uk/en/static.asp?mode=bf_notice2& section=12&chli_id=15 (accessed 25 April 2005)

(b) the age after which the product is recommended in numeric figures and in the case of a complementary food, the recommended age shall not be less than six months;

(c) a warning about the health risks of improper preparation and of introducing the product prior to the recommended age;

(d) the ingredients used;

(e) the composition and nutritional analysis;

(f) the required storage conditions both before and after opening, taking into account climatic conditions;

(g) the batch number, date of manufacture and date before which the product is to be consumed, taking into account climatic and storage conditions;

(h) the name and national address of the manufacturer or distributor; and

(i) such other particulars as may be prescribed.

(3) A manufacturer or distributor shall not offer for sale or sell a designated product if the container or label affixed thereto contains any representation that states or suggests that a relationship exists between the product or constituent thereof and health, including the physiological role of a nutrient in growth, development or normal functions of the body.

Section 6. Prohibitions related to labels of infant formula and follow-up formula

(1) A manufacturer or distributor shall not offer for sale or sell infant formula or follow-up formula unless the container or label affixed thereto, in addition to the requirements of Section 5, conforms to the following:

(a) contains the words "IMPORTANT NOTICE" in capital letters and indicated thereunder, the statement "Breastfeeding is best. Breastmilk is the ideal food for the healthy growth and development of infants and young children. It protects against diarrhoea and other illnesses" in characters [*insert particulars relating to character size, placement, appearance, etc. For example, "no less than one-third the size of the characters in the product name, and in no case less than 2mm in height"*];

(b) contains the word "warning" and indicated thereunder, the statement "Before deciding to supplement or replace breastfeeding with this product, seek the advice of a health professional. It is important for your baby's health that you follow all preparation instructions carefully. If you use a feeding bottle, your baby may refuse to feed from the breast. It is more hygienic to feed from a cup" in characters [*insert particulars relating to character size, placement, appearance, etc. For example, "no less than one-third the size of the characters in the product name, and in no case less than 1.5mm in height"*];

(c) states in preparation instructions for infant or follow-up formula in powdered form that powdered formula may be contaminated with microorganisms during the manufacturing process or may become contaminated during preparation and that it is therefore necessary to discard any unused formula immediately after every feed;

(d) includes a feeding chart in the preparation instructions;

(e) does not use the terms "maternalised", "humanised" or terms similar thereto or any comparison with breastmilk;

(f) does not use text that may tend to discourage breastfeeding;

(g) specifies the source of the protein; and

(h) in the case of follow-up formula, states that the product shall not be used for infants less than six months old.

Section 7. Prohibitions related to labels of skimmed or condensed milk

A manufacturer or distributor shall not offer for sale or sell skimmed or condensed milk in powder or liquid form, unless the container or label affixed thereto contains the words "This product should not be used to feed infants" in characters [*insert particulars relating to character size, placement, appearance, etc.*]

Section 8. Prohibitions related to labels of low-fat and standard milk

A manufacturer or distributor shall not offer for sale low-fat or standard milk in powder or liquid form, unless the container or label affixed thereto contains the words "This product should not be used as an infant's sole source of nourishment" in characters [*insert particulars relating to character size, placement, appearance, etc.*]

[Note: *The milks in Sections 7 and 8 do not fall within the scope of this Act unless they are marketed or otherwise represented as suitable for infants. We recommend that these labelling provisions be incorporated into the countries' food labelling laws. In addition, Sections 7 and 8 will require revision according to the types of milk products available in individual countries*.]

Section 9. Prohibitions related to labels of feeding bottles and teats

(1) A manufacturer or distributor shall not offer for sale or sell a feeding bottle or teat unless the package or label affixed thereto, in addition to the requirements of Section 5(1), indicates in a clear, conspicuous and easily readable manner, in [*insert appropriate language(s)*], the following particulars:

(a) the words "IMPORTANT NOTICE" in capital letters and indicated thereunder, the statement "Breastfeeding is best. Breastmilk is the ideal food for the healthy growth and development of infants and young children. It protects against diarrhoea and other illnesses" in characters [*insert particulars relating to character size, placement, appearance, etc. For example, "no less than one-third the size of the characters in the product name, and in no case less than 2mm in height"*];

(b) the statement "Warning: It is important for your baby's health that you follow the cleaning and sterilisation instructions very carefully. If you use a feeding bottle, your baby may no longer want to feed from the breast" in characters [*insert particulars relating to character size, placement, appearance, etc. For example, "no less*

than one-third the size of the characters in the product name, and in no case less than 2mm in height"];

(c) instructions for cleaning and sterilisation in words and graphics;

(d) a statement explaining that feeding with a cup is more hygienic than bottle feeding;

(e) a warning that children should not be left to self-feed for long periods of time because extended contact with sweetened liquids, including infant formula, may cause severe tooth decay; and

(f) the name and national address of the manufacturer or the distributor.

Section 10. Prohibitions related to labels of pacifiers (dummies)

A manufacturer or distributor shall not offer for sale or sell a pacifier unless, in addition to the requirements of Section 5(1), it is labelled with the words "Warning: use of a pacifier can interfere with breastfeeding" in characters [*insert particulars relating to character size, placement, appearance, etc. For example, "no less than one-third the size of the characters in the product name, and in no case less than 1.5mm in height"*] .

CHAPTER 10

Implementing the International Code at the National Level

Relevant provisions of the International Code

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 non-governmental 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 Non-governmental organisations, 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.

The preceding chapters focus on the substance and the legal wording of a national law or other measure. To achieve the aims of the International Code, however, a well-drafted and cogent document is only part of the battle. This chapter examines the various forms of measures that countries have adopted as well as monitoring and enforcement of those measures.

The International Code and relevant WHA resolutions are a set of recommendations from the World Health Assembly. Such recommendations, unlike international treaties or conventions, are not legally binding at the national level, although they do carry moral or political weight.[1] Governments are expected to translate the International Code and the related WHA resolutions into national legislation, regulations or other measures. Article 11.1 of the International Code states that "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".

The World Health Assembly, back in 1981, envisioned the International Code as a starting point for implementation at the national level. The Assembly stressed, "adoption of and adherence to the International Code is a minimum requirement" and urged Member States to implement the Code "in its entirety".[2]

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[1] Shubber, S.,"The International Code of Marketing of Breastmilk Substitutes", *International Digest of Health Legislation,* WHO, 1985, 36: 884. In his later book, Dr. Shubber, a former Senior Legal Officer at WHO who was closely involved in the drafting of the International Code, further examines the question of whether or not the WHA resolutions calling for implementation of the International Code have a binding effect. He concludes that the relevant resolutions "must have been intended to have more than moral effect" and submits that, based on the repeated calls to Member States to implement the Code and the adoption of the resolutions by "huge majorities", they should create an obligation to implement the International Code. Shubber, S., *The International Code of Marketing of Breastmilk Substitutes: An international measure to protect and promote breastfeeding*, The Hague: Kluwer Law International, 1998 (*hereinafter* Shubber), p. 202.

[2] Resolution WHA34.22 (1981).

State of the Code by country

Figure 2 shows nine different categories of steps that have been taken in 192 countries to implement the International Code. Many countries have taken more than one type of action and thus fall within more than one category. However, for purposes of this table, they have been placed in the category for the more significant step they have taken. Any other category that applies to these countries is indicated by a footnote (see explanation below).

It should be noted that countries are classified according to already adopted measures rather than measures still in draft form, unless the country only has a draft. Draft measures are indicated by means of a footnote for countries that also have a voluntary code or a measure that implements only a few of the articles of the International Code.

Figure 2: **The State of the Code in 192 Countries**

Law [30]
Albania
Argentina
Bahrain
Benin
Botswana
Brazil
Burkina Faso
Cameroon
Cape Verde
Costa Rica [1]
Dominican Republic
Gabon
Georgia
Ghana
Guatemala
India
Iran
Lebanon
Madagascar
Nepal
Panama
Peru
Philippines
Saudi Arabia
Sri Lanka
Tanzania
Uganda
Uruguay
Yemen
Zimbabwe

Many provisions law [34]
Austria
Azerbaijan
Bangladesh
Belgium
China
Colombia
Denmark
Djibouti
Finland
France
Germany
Greece
Indonesia
Ireland
Italy
Laos
Latvia
Luxemburg
Mexico
Netherlands
Nicaragua
Niger
Nigeria [1]
Norway
Oman
Pakistan
Papua New Guinea
Portugal
Senegal
Seychelles
Spain
Tunisia
United Kingdom [1]
Vietnam [1]

Voluntary [22]
Australia [4]
Barbados
Bhutan [6]
Bolivia [6]
Chile [4]
Cook Islands
Dominica
Ecuador [4]
Grenada
Guyana
Jamaica
Kenya [6]
Kuwait
Macao, SAR China
Malawi [*]
Malaysia [1,4]
New Zealand
South Africa [6]
Swaziland [2]
Sweden
Tonga
Zambia [6]

Few provisions law [25]
Algeria
Armenia [6]
Canada
Congo, Dem. Rep. of
Cuba
Egypt
Estonia
Ethiopia [6]
Guinea [6]
Guinea Bissau
Hungary
Israel
Libya
Lithuania
Macedonia
Mongolia [*]
Mozambique [6]
Paraguay
Qatar
Sao Tome & Principe [2]
Sudan
Thailand [6]
Trinidad & Tobago [3]
Turkey [6]
United Arab Emirates [6]

Some provisions voluntary [20]
Afghanistan [6]
Bahamas
Brunei
Cambodia [6]
Cyprus

Honduras [6]
Hong Kong, SAR China [4]
Japan [4]
Kiribati [6]
Korea, Republic of
Maldives
Morocco [6]
Samoa
Singapore
St Lucia
St Vincent
Switzerland [4]
Taiwan [4]
Vanuatu
Venezuela [4]

Measure drafted awaiting final approval [23]
Angola
Burundi
Central African Rep.
Congo, People's Rep. of
Cote d'Ivoire
Croatia
Czech Republic
El Salvador
Fiji
Gambia
Haiti
Iraq
Jordan
Lesotho
Mauritius
Micronesia
Namibia
Palau
Poland
Rwanda
Sierra Leone
Timor Leste
Togo

Being studied [21]
Belarus
Belize
Bosnia Herzegovina [3,4]
Bulgaria
Eritrea
Kazakhstan
Kyrgyzstan
Mali
Marshall Islands
Mauritania
Moldova
Myanmar
Palestinian Authority
Romania
Russian Federation
Slovakia
Syria
Tajikistan
Turkmenistan
Ukraine
Uzbekistan

No action [10]
Antigua & Barbuda
Chad
Iceland
Malta
Monaco
Solomon Islands
Somalia
St Kitts & Nevis
Surinam
United States

No information [7]
Equatorial Guinea
Korea, Dem. P. R.
Liberia
Liechtenstein
Serbia & Montenegro
Slovenia
Tuvalu

Notes:

1. Government is revising existing measure.
2. Government is also still studying how to best implement the International Code.
3. Government also has a voluntary code or policy.
4. Government has also adopted some provisions as law.
5. Government has also adopted some provisions as a voluntary measure.
6. Government also has a draft law or other measure.

* In July 2005, news was received that the Mongolian and Malawian Parliaments have adopted laws. Until ICDC has received the full final text, it cannot categorise these laws.

KEY TO CATEGORIES

Law: These countries have enacted legislation or adopted regulations, decrees or other legally binding measures encompassing all or nearly all provisions of the International Code.

Many provisions law: These countries have enacted legislation or adopted regulations, decrees or other legally binding measures encompassing many of the provisions of the International Code.

Voluntary Code or policy measure: In these countries, the government has adopted all or most of the provisions of the International Code through a voluntary code, a government policy, guidelines or other non-binding measure.

Few provisions law: These countries have enacted legislation or adopted regulations, decrees or other legally binding measures encompassing only few of the provisions of the International Code (most frequently those pertaining to quality and/or labelling).

Some provisions voluntary or policy: In these countries, the government has adopted some of the provisions of the International Code through a voluntary code, a government policy, guidelines, or other non-binding measure.

Measure drafted: In these countries, a draft of a law or other measure to implement all or most of the provisions of the International Code exists and awaits final approval.

Being studied: The government in each of these countries is still studying how best to implement the International Code.

No action: These countries have taken no steps to implement the International Code.

No information: No information is available regarding implementation of the International Code in these countries.

Laws, regulations or other measures

The drafters of the International Code envisioned that countries would adopt legislation, regulations or other measures as appropriate to their own social and legal systems. While Article 11.1 of the International Code gives governments the option to implement the Code by "national legislation, regulations or other suitable measures", the term *other suitable measures* is not defined. There is debate as to whether the World Health Assembly meant that other suitable measures can include voluntary agreements or is limited to binding legal instruments.[3] Nonetheless, *Figure 2* shows that countries have adopted a wide variety of measures, binding or voluntary and comprehensive or partial, to implement the International Code. While legally binding measures provide the greatest possibility of being effective because they can be enforced with penalties, in the final count, success will depend on how well any measure is applied.

Implementation by law

There are a variety of legally enforceable measures that countries have taken to implement the International Code running the gamut from legislative acts to regulations, ordinances and executive or ministerial decrees. The process of enacting legislation is worthy in and of itself as it can engender commitment at all levels and educate different sectors about the issue and its importance. On the other hand, the process of enacting a law in the legislature is often long and fraught with opportunity for delay or defeat. In India, it took nearly 10 years for a comprehensive bill to be enacted by Parliament.[4] The infant food industry opposed the measure at every step of the way.[5]

Some countries have found it expedient to adopt regulations pursuant to an existing act on related topics such as food, health or consumer protection. For example, Ghana issued the

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[3] *See* Shubber, *supra* note 1, pp. 210-12. Dr. Shubber interprets the phrase *other suitable measure* to mean legally binding measures. He goes on to say that the International Code can achieve its purpose (to protect and promote breastfeeding) "only by a proper legal instrument enacted at the national level and laying down specific obligations". Shubber, *supra* note 1, p. 210. He refers to one writer commenting on voluntary agreements between governments and tobacco companies, who stated, "voluntary agreements are weak means of controlling tobacco promotion; they are complex and difficult to monitor, and are subject to differences of interpretation which can hinder implementation". *Ibid.* p. 211 (*quoting* Roemer, R., *Legislative Action to Combat the World Tobacco Epidemic,* 1993, p. 15). Roemer further states, "A number of countries that once relied on voluntary agreements with the industry have rejected this arrangement and have replaced it with legislation as a more effective method of control". *Ibid.* p. 213 & note 86 *(quoting* Roemer).

[4] India, Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act N° 41 of 1992, *amended* 2003.

[5] Industry members tried to push the idea of an industry self-regulatory code rather than a law or regulations. A study of Code implementation in India recounts how Nestlé sponsored two members of the government working committee set up to draft a law. Nestlé also offered a large donation to the Indian Academy of Pediatrics, whose president was a member of the working committee. This member then presented a draft to the committee that had been written by the industry. The government ultimately rejected the industry-drafted code and the IAP rejected Nestlé's offer. *See* International Baby Food Action Network, *Using International Tools to Stop Corporate Malpractice-Does it Work?: Checks and balances in the global economy*, Cambridge: Baby Milk Action, 2004, p. 24.

Breastfeeding Promotion Regulations pursuant to the Food and Drugs Law.[6] In Brazil, the International Code is implemented, in part, through regulations of the National Food Safety Monitoring Agency.[7]

Macedonia and Estonia were able to legislate one of the key provisions of the International Code, the prohibition on advertising, by amending existing laws. The government of Macedonia amended restrictions on advertising contained in the Law on Protection of Consumers to forbid the advertising of infant formula, other foods for infants up to six months old as well as feeding bottles, teats and pacifiers.[8] In Estonia, the advertising of infant and follow-up formula is prohibited under the Food Law.[9]

A few countries have followed a different approach and have placed controls on the import or sale of products. Papua New Guinea has legislation, which preceded the International Code, requiring a medical prescription for the purchase of feeding bottles, baby feeding cups, teats and dummies.[10] Quite a number of governments that previously had centrally controlled economies restricted the import, distribution and sale of breastmilk substitutes. In most of these countries, products are now distributed and sold in the free market. A few governments still maintain some central control. In Iran, until recently, three government-owned companies were responsible for importing and distributing the country's supply of infant formula. All manufacturers were obligated to use an identical non-promotional label designed by the government.[11]

In 1991, the Commission of the European Communities (now the European Union) adopted the Directive on Infant Formulae and Follow-on Formulae.[12] At that time, none of the countries of western Europe had enacted a law encompassing all of the provisions of the International Code. Most had limited themselves to incorporating the provisions of the Code on labelling and quality into existing laws.

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[6] Ghana, Breastfeeding Promotion Regulations, 2000 (made under § 47 of the Food and Drugs Law, P.N.D.C.L305B, 1992). *See also* Tanzania, Food (Control of Quality) (Marketing of Breastmilk Substitutes and Designated Products) Regulations, 1994 (made under §§ 16 and 33 of the Food (Control of Quality) Act, 1978); Uganda, Food and Drugs (Marketing of Infant and Young Child Foods) Regulations, 1997 (made under § 42 of the Food and Drugs Act, Cap 271); Zimbabwe, Public Health (Breastmilk Substitutes and Infant Nutrition) Regulations, 1998 (made under § 74 of the Public Health Act).

[7] Brazil, Regulamento Técnico para Promoção Comercial dos Alimentos para Lactentes e Crianças de Primeira Infância, Resolução-RDC N° 222 de 5 de agosto de 2002 (Brazil, Technical Regulation on Commercial Promotion of Foods for Infants and Young Children) and Brazil, Regulamento Técnico Chupetas, Bicos, Mamadeiras e Protetores de Mamilo, Resolução-RDC N° 221 de 5 de agosto de 2002 (Brazil Technical Regulations, Dummies, Teats, Bottles and Nipple Shields).

[8] Macedonia, Law on Protection of Consumers, 2000, Article 14.

[9] Estonia, Food Law, 1999.

[10] Papua New Guinea, Baby Feed Supplies (Control) Act, N° 21 of 1977. In just two years after the legislation was adopted, bottle feeding and malnutrition rates in Papua New Guinea declined dramatically. *See* Palmer, G., *The Politics of Breastfeeding*, 2nd ed., London: Pandora, 1993, p. 262.

[11] *See* Marandi, A., *Review and Assessment of National Action taken in Relation to the International Code of Marketing of Breastmilk Substitutes in the Islamic Republic of Iran, July 1991,* Report to WHO Technical Meeting on Review and Evaluation of Action taken to give Effect to the International Code, The Hague, 30 September - 3 October 1991.

[12] Commission of the European Communities Directive on Infant Formulae and Follow-on Formulae, 91/321/EEC, 1991.

The Directive covers many, but not all of the provisions of the International Code. For those parts it covers, however, the European Union member countries were required to "bring into force the laws, regulations and administrative provisions necessary to comply with this Directive". Those laws were to be effective by 1 June 1994.[13] By the end of 2004, 14 of the 15 European Union countries had passed a law implementing the Directive.[14] The 10 countries that joined the Union in 2004 are expected to align their laws with the EU Directive.[15]

The Directive adopts the International Code's ban on samples and other point-of-sale promotional devices, as well as most of the labelling requirements and the restrictions on information materials. It must be noted that while all of these provisions apply to infant formula, only the provisions on labelling and composition apply to follow-up formula as well. The Directive is weaker than the International Code in two other important aspects.

First, advertising is allowed in publications specialising in baby care and scientific publications.[16] Second, donations of infant formulas are permitted for infants who "have to be fed on infant formulae". Thus, the Directive does not take into account Resolutions WHA39.28 and WHA47.5, which urge countries to prohibit all free supplies. The European Commission is in the process of revising the Directive, mainly with respect to its provisions on composition and labelling.[17]

The Council of the European Communities passed another Directive in 1992 that governs the composition and labelling of infant and follow-up formula that is exported to countries outside the European Union.[18] A complaints procedure that can be utilized by importing countries concerning the marketing practices of Community-based manufacturers was established by a Resolution.[19]

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[13] European Commission Directive, *supra* note 12, Article 10.

[14] Sweden, the remaining country, has implemented the International Code with a combination of a voluntary marketing code, regulations for health staff and regulations that govern quality and labelling.

[15] Those countries are Cyprus, Czech Republic, Estonia, Hungary, Lithuania, Malta, Poland, Slovakia and Slovenia. Latvia, and more recently Lithuania, have already adopted regulations implementing the EU Directive. *See* Latvia, Regulation N° 119, Mandatory Harmlessness Requirements for the Composition of Breastmilk Substitutes and Requirements for Labelling and Advertising thereof, 2001.

[16] Member States may further restrict or prohibit such advertising. European Commission Directive, *supra* note 12, Article 8.

[17] Commission of the European Communities, *Working Document, Draft, Commission Directive on Infant Formulae and Follow-on Formulae* (recast version), SANCO D4/HL/mm/D440180 Rev.2, February 2005.

[18] Council of the European Communities Directive on Infant Formulae and Follow-on Formulae Intended for Export to Third Countries, 92/52/EEC, 1992.

[19] Council of the European Communities, Resolution on the Marketing of Breastmilk Substitutes in Third Countries by Community-based Manufacturers, 92/C 172/01,1992 (EU Resolution). Between 1998 and 2000, citizen groups in Indonesia and Kenya attempted to utilize the complaints procedure established in the EU Resolution, but with little success. The groups in both countries found that relevant officers in both the government and the European Union delegations were not aware of the EU Resolution, that governments did not notify the European delegations about reported violations and when the groups notified the European delegations directly, their complaints were not recognised because they did not come from "competent authorities" within the meaning of the Resolution. WEMOS, *EU Baby Food Export Resolution: Not used or of no use?* (unpublished report of WEMOS Foundation, Amsterdam), November 2002.

Brazil: A case study for implementation of the International Code by law

Whatever its form, the principal attribute of national law is that it can be enforced. Brazil has been successful in adopting the International Code in the form of national regulations. There is much to learn from studying the way that the International Code has been implemented in Brazil.

Decline of Breastfeeding in Brazil

In Brazil, like many countries around the world, breastfeeding rates began to decline at alarming rates towards the middle of the 20th century. Even though Brazil had only one manufacturer of baby milks until the end of the 1980s, advertising in the mass media and promotion to the medical profession was intense. Health services also played a large role in promotion of powdered milk. Maternities routinely separated mothers from their babies after birth, and until the mid-1970s, all mothers received a tin of milk when leaving the maternity. By the 1970s, the average length of breastfeeding in Brazil was less than 3 months and exclusive breastfeeding was nearly non-existent.

Bringing back breastfeeding

Efforts to rediscover and bring back breastfeeding in Brazil began in the 1970s when some health experts became increasingly concerned about the use of artificial milk and the practice of early weaning. In 1974, the State of Pernambuco (one of the poorest states in north-eastern Brazil), banned the distribution of powdered milk and of feeding bottles at health centres in that state. Some Brazilian health professionals participated in the drafting of the International Code in 1980.

In 1981, the Ministry of Health launched the National Breastfeeding Promotion Programme (Programa Nacional de Incentivo ao Aleitamento Materno). The Ministry kicked off the Programme with an intense educational campaign using famous personalities including television actors, singers and football players to transmit the message of the importance of breastfeeding during the first six months of life. The campaign presented breastfeeding messages on television, radio and in newspapers.

Implementing the International Code

As breastfeeding became a priority for national health programmes, interest grew in the International Code. Shortly after the International Code was adopted, a technical group began working on a national law in Brazil. That year, two proposals to prohibit advertising of powdered milk on TV and radio were put forward, but the Ministry of Justice determined that existing legislation was sufficient.

The process leading to the adoption of the International Code had also led to the beginning of IBFAN in Brazil. In 1985, IBFAN Brazil began organising training courses about infant feeding and the marketing of breastmilk substitutes in Brazil and began monitoring compliance with the International Code. IBFAN's activities served to keep breastfeeding and the adverse effects of promotion of breastmilk substitutes in the public eye.

In 1987, the National Programme for the Promotion of Breastfeeding formed a new committee to again look into drafting a national law to implement the International Code in Brazil. A member of IBFAN Brazil coordinated the committee, which also had representatives of several government ministries, various associations of health professionals, other NGOs and the Brazilian Association of Food Industries. Towards the end of 1988, the committee proposed draft Regulations on Marketing of Foods for Infants. The Regulations were finalised and adopted by the National Health Council of the Ministry of Health on 20 December 1988. The Ministry revised the regulations in 1992.

In 2001, the regulations were again reviewed and the Ministry of Health adopted new regulations by decree. Ministry of Health Decree No. 2051 (November 2001) deals with the relationships between manufacturers and the health care system. It also concerns health professionals and educational and 'technical-scientific' materials on infant and young child feeding.[20] In 2002, the National Health and Food Control Agency (ANVISA) also adopted regulations on promotion and marketing of foods for infants and young children.[21] In the same year, ANVISA adopted a separate set of regulations pertaining to the promotion and marketing of feeding bottles, teats, dummies and nipple shields.[22]

Monitoring and enforcement

The Ministry of Health is responsible for implementing and monitoring the regulations. Health inspectors monitor for violations and can impose penalties. Penalties for violations of the regulations are those provided for in the Brazilian Health Law (Law Nº 6437 of 20 August 1977) and include warnings, fines, banning or confiscation of products, suspension of licences to sell or manufacture products, cancellation of product registration, or cancellation of an establishment's licence.

[20] Norma Brasileira de Comercialização de Alimentos para Lactentes e Crianças de Primeira Infância, Bicos, Chupetas e Mamadeiras, Portaria Nº 2051 de 8 de novembro, 2001 (Brazilian Standard for Marketing of Foods for Infants and Young Children, Teats, Dummies and Feeding Bottles)

[21] Brazil, Regulamento Técnico para Promoção Comercial dos Alimentos para Lactentes e Crianças de Primeira Infância, Resolução-RDC N° 222 de 5 de agosto de 2002 (Brazil, Technical Regulation on Commercial Promotion of Foods for Infants and Young Children).

[22] Brazil, Regulamento Técnico Chupetas, Bicos, Mamadeiras e Protetores de Mamilo, Resolução-RDC N° 221 de 5 de agosto de 2002 (Brazil Technical Regulations, Dummies, Teats, Bottles and Nipple Shields)

One of the Ministry's first tasks after the regulations were adopted was to organise, in 1990, regional training courses throughout the country for health inspectors from the National Health and Food Control Agency and other associations and organisations involved in health and nutrition. Since 1985, IBFAN Brazil also continued to regularly train and conduct monitoring throughout the country.

In 1999, the Ministry of Health, with the participation of IBFAN Brazil, carried out a more extensive monitoring survey of marketing practices. The monitoring revealed many violations of the 1992 regulations as well as the existence of new marketing practices that had not been previously considered. It was these findings that had led the Ministry of Health to study and revise the regulations in 2001.

The Regulations

The revised regulations in Brazil are among the most comprehensive in the world. The regulations go far in carrying out one of the main objectives of the WHO/UNICEF *Global Strategy for Infant and Young Child Feeding*. They aim to protect exclusive breastfeeding up to six months and continued breastfeeding with appropriate complementary feeding for up to two years or more.

The scope fulfills this aim by including infant formula as well as follow-up formula for infants and for children from one to three years old. Certain regulations also apply to complementary foods for infants and young children from six months to three years old. Separate regulations apply to the marketing of feeding bottles, teats, dummies and nipple shields.

The regulations include extensive provisions for the labelling of the various products within the scope and require specific notices encouraging exclusive and continued breastfeeding as well as warnings about the health risks of using such products. Illustrations of any type are prohibited from labels of infant formula and follow-up formula. Manufacturers and distributors may not produce education materials on infant and young child feeding. Free supplies are prohibited and samples of formula or complementary foods may only be provided to health professionals when a new product is launched. Samples of feeding bottles, teats, dummies and nipple shields are not allowed.

As a result of the regulations formulas for infants (including follow-up formula for infants) are no longer advertised in Brazil. Moreover, advertisements for feeding bottles and teats, which were common in large-circulation magazines, have diminished since the first revision of the law. Product labels have greatly improved since the adoption of the law and especially after the first revision.

Healthier babies in Brazil

Brazil has seen the exclusive breastfeeding rate during the period following birth and up to four months rise from 3.6 percent in 1986 to 35.6 percent in 1999. The mean duration of breastfeeding in major urban areas has also increased from less than three

months in 1975 to nearly 10 months in 1999.[23] The regulations implementing the International Code are an essential component of Brazil's progress towards a 'breastfeeding culture'. Brazil's success can also be attributed to its integration of efforts to regulate marketing of breastmilk substitutes with other aspects of breastfeeding promotion.

The Ministry of Health, through the National Breastfeeding Promotion Programme works together with members of the IBFAN network as well as the local chapters of the World Alliance for Breastfeeding Action to carry out a number of other activities to promote breastfeeding. These activities include World Breastfeeding Week celebrations; the *Baby Friendly Hospital Initiative,* which has grown to over 300 hospitals since 1990*;* compulsory "rooming-in" of babies with their mothers in all public hospitals; a system of human milk banks and an advanced system of regulations for the Kangaroo Mother Care method of caring for newborn premature and low-birth-weight babies.

This case study was compiled with contributions from Dr. Tereza Toma, Dr. Marina Rea, Rosana de Divitiis, Jean-Pierre Allain, and from the report "IBFAN Case Study: Implementing the International Code and Resolutions in Brazil", April 2002 coordinated by Dr. Sonia de Oliveira Brady with consultants Cristina Passos and Marcia Couto.

[23] Rea, M.F., "Reflexões sobre a amamentação no Brasil: de como passamos a 10 meses de duração" (Reflections on Breastfeeding in Brazil: How we got to 10 month's duration), *Cad. Saúde Pública,* Rio de Janeiro, 19 (Sup. 1): S37-S45, 2003.

Voluntary measures

For some countries, it has been expedient to implement the International Code by way of a voluntary agreement with industry.[24] Voluntary codes have had some effect in controlling some types of inappropriate marketing practices. For example, the compliance panel in Australia asked Wyeth Pharmaceuticals to stop advertising its follow-up formula.[25] It later determined that the label of a Mead Johnson infant formula showing the storybook character *Peter Rabbit* watching his mother bottle-feed a baby rabbit would violate the Agreement and this label was never introduced in Australia.[26]

In the final count, however, success of such codes depends on the will of the industry**.** In all but two of the countries that have voluntary codes, the industry is a formal member of the compliance body.[27] This makes it impossible for monitoring to be carried out in a "transparent, independent manner, free from commercial influence" as urged in Resolution WHA49.15 (1996).

[24] These countries include Australia, Sweden, New Zealand, South Africa, Singapore, Switzerland and Malaysia.
[25] APMAIF, Letter to Greg Perry, 21 January 1993 (stating panel's decision that Wyeth Pharmaceutical's *S-26 Progress*, even though marketed for infants older than six months, falls within the scope of the Australian Agreement).
[26] Minchen, M., *Breastfeeding Matters,* 4th rev. ed., Alfredton, Australia: Alma Publications, 1998, p. 246.
[27] The compliance bodies in Malaysia and Sweden do not have industry members.

In addition, because voluntary agreements are drafted in close cooperation with the industry, the terms are often less comprehensive than the International Code.

The Codes in Switzerland and New Zealand, for example, apply only to infant formula thus allowing promotion for follow-up formula and other products that may discourage breastfeeding.[28] The Singapore Code provides for a Vetting Committee, which may approve direct advertising of products within its scope.[29] More than half of the members of the Committee are industry representatives.[30] Finally, as such codes are voluntary, companies that do not sign on are not bound by their terms.

A number of countries that still implement the International Code through voluntary codes have re-assessed the situation to determine if legal measures could be adopted. South Africa, which adopted a voluntary code in 1986,[31] has gazetted draft regulations that would replace the voluntary code.[32] New Zealand completed a review of its implementation of the International Code in 2004. The New Zealand Ministry of Health decided to maintain a voluntary agreement but plans to revise the complaints process.[33] Australia abandoned efforts to amend its Code because members of the health sector, community groups and industry were unable to agree on changes.[34] Malaysia is in the process of revising the Malaysian Code of Ethics.

Sweden, as a member of the EU was supposed to have a law, regulation or administrative provision in place by 1994 to give effect to the 1991 European Commission Directive on Infant Formulae and Follow-on Formulae. Only some provisions of the International Code have been implemented in Sweden by regulations, including regulations for health staff and regulations that govern quality and labelling. The provisions relating to marketing have been implemented by an agreement between the Swedish Consumer Agency and 17 companies to abide by the voluntary Swedish Code.[35] In 1999, the National Board of Health and Welfare published a revised version of the Swedish Code and the regulations, but the Code remains voluntary.[36]

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[28] Switzerland, Code de Conduite des Fabricants concernant la commercialisation des préparations pour nourrissons, *nouvelle édition* 1994 (Switzerland, Producers' Code of Marketing of Infant Formula), Article 1; New Zealand Infant Formula Marketers' Association Code of Practice for the Marketing of Infant Formula, 1997, Article 2. In its 2004 review of the New Zealand Code, the Ministry of Health noted that guidelines should be developed to ensure that the marketing of follow-up formula does not undermine messages about the importance of breastfeeding for infants up to one year of age. *See* New Zealand Ministry of Health, *Review of the New Zealand Interpretation of the World Health Organization's International Code of Marketing of Breastmilk Substitutes,* 2004, p. 14.

[29] Singapore, Code of Ethics on the Sale of Infant Formula Products, *revised* 2002, Article 8.

[30] Eight of the 14 members of the Singapore Sale of Infant Foods Ethics Committee are industry representatives. *See* Singapore Code, *supra* note 29, Appendix 1.

[31] South Africa, Code of Ethics for the Marketing of Breastmilk Substitutes, 1986.

[32] South Africa, Government Notice, Department of Health, Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972), Regulations relating to Foodstuffs for Infants and Young Children, 26 Sept 2003.

[33] New Zealand Ministry of Health, *Review, supra* note 28, 2004.

[34] Advisory Panel on the Marketing in Australia of Infant Formula, *Annual Report 1999-2000,* p. 5.

[35] Amning och bröstmjölks-ersättningar, *revised* 1999 (Sweden, Code of Marketing of Breastmilk Substitutes).

[36] *See* Brandell, G. and Sjögren, C., *Ligga steget före*, *The International Baby Milk Code: Twenty years of experiences in Sweden 1981-2001*, Göteborg, Sweden: NAFIA, 2001, p. 61.

Some countries have implemented only parts of the International Code with voluntary or policy measures. Voluntary agreements to end advertising among manufacturers are an example. Television and radio station operators as well as publishers of the print media can be involved in such agreements. In South Korea, the three largest producers of breastmilk substitutes entered into an agreement to stop advertising in the mass media. In the United States, which has taken no steps to implement the International Code, a voluntary agreement among the manufacturers was successful until the early 1990s in keeping infant formula advertisements out of the mass media for a number of years. The problem with the voluntary nature of the agreement, however, was evinced when Nestlé, which was not party to the agreement, began to market and advertise infant formula in the United States.

Other countries that have been unwilling or unable to adopt legal measures have adopted the International Code as a matter of policy. For example, in 1996, the Ministry of Health in Guyana published its National Policy on Breastfeeding, but did not adopt it as a legal instrument or as a Code with a functioning administration.

Ministerial or departmental directives are also useful measures for stopping advertising or curbing promotion within the health care system and for making health personnel aware of the requirements of the International Code. For example, two government departments in Taiwan banned advertising of breastmilk substitutes in the media.[37] In Kenya, a series of directives were issued to all health institutions and their employees throughout the country instructing them not to permit company samples, posters, free supplies and other promotional practices.[38] Similarly, in the early 1990s a large number of countries developed policies and issued directives and circulars forbidding health care facilities from accepting free or low-cost supplies of breastmilk substitutes.

Countries sometimes adopt such directives and policies as important interim measures while enforceable measures for implementing the International Code are being developed. For example, the Transitional Government of Afghanistan began developing regulations to implement the International Code in 2003. In the same year, the Ministry of Health issued guidelines to all health officials and health workers in public and private health facilities, which forbid promotion of breastmilk substitutes in the health care system.[39]

Monitoring and enforcement: The procedural elements

While many countries have laws and other measures in place implementing the International Code, they are not always enforced. In 2001, the World Health Assembly called on governments to "strengthen national mechanisms to ensure global compliance with the International Code of Marketing of Breastmilk Substitutes and subsequent relevant World Health Assembly

[37] *See, e.g.*, Taiwan, National Health Department and National Information Bureau, Ban on Advertising of Breastmilk Substitutes in all Media (effective April 1993) *reported in New Straits Times,* Malaysia, 23 February 1993.
[38] *See* Kenya, Circular MIS/17/4/106, 5 November 1986 and Circular MIS/17/4/106 Vol.VII/(114), 15 June 1983.
[39] Islamic Transitional Government of Afghanistan, Ministry of Health, Circular on the Protection, Promotion and Support of Optimal Infant and Young Child Feeding, 26 June 2003.

resolutions".[40] Although laws are likely to be the most effective measures to control inappropriate marketing, form is less important than application. An implementing measure, whether legally-binding or voluntary will only be effective if it has the necessary components to be applied in the country. Thus, the measure must identify the ministry, department or other agency responsible to carry out its provisions; it must confer the necessary powers and must identify what sanctions may be imposed in the case of violations.

Administration

It is important to designate as the responsible agency, the ministry, department or other agency that is best able to carry out the provisions of the law or other measure. Some national laws provide for more than one ministry to be responsible.[41] The Model Law designates the Ministry of Health to be responsible for implementing the Act and gives the Minister the power to promulgate rules and regulations.[42]

Having an active committee responsible to oversee implementation will also increase the likelihood that the law will be applied. Many of the national laws create an interdisciplinary board or committee charged with providing advice to the implementing ministry; arranging for periodic monitoring; reviewing reports of violations; determining which violations should be acted upon and carrying out other functions that are designated by the law.

Such a committee or board is usually made up of representatives from relevant ministries such as health, education, communications and trade as well as representatives from voluntary organisations and experts in designated fields. In some countries manufacturers and distributors of products within the scope of the national law are represented in the Committee. Principles of conflict of interest, however, dictate that companies that are regulated by the law should not sit on a committee that advises the government about administration and enforcement of the law. The role of the regulated companies is to ensure that their own practices are in compliance with the law or regulations. The Model Law sets up an *Advisory Board*, and states, "no person shall be appointed who has any direct or indirect financial interest in any designated product".[43]

Monitoring

As with any law, sanctions can only be applied if violations are discovered and brought to the attention of an authority with power to impose them. Many countries have entrusted enforcement to health or food inspectors. In general, however, such inspectors have no particular training about breastfeeding or about how various marketing techniques affect breastfeeding.

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[40] Resolution WHA54.2 (2001).

[41] Having too many responsible parties can, however, prove to be a liability. In China, six different government ministries and agencies are responsible for enforcing the Rules Governing the Administration of Marketing of Breastmilk Substitutes (1995). The large number of players has made coordination difficult and implementation a challenge.

[42] Model Law, § 16 (1) & 3(a).

[43] Model Law, § 17 (1)(proviso).

It is important that such inspectors receive special training. In Guatemala and Brazil, for example, health inspectors were trained to understand the provisions of the law; the basis for the law, i.e. the need to protect breastfeeding and about the various products and marketing techniques used to sell them.

In Nigeria, the agency that was charged with enforcing compliance with the national law conducted a training workshop to familiarise its staff with the provisions of the law, to develop specific monitoring indicators and to give hands-on experience with monitoring.[44] Similarly, in Albania, the law gives the power to state health inspectors to impose penalties for violations.[45] The Ministry of Health conducted a workshop for supervisors of health inspectors from 10 regions so that the law could be administered. In Vietnam, officials and inspectors from various government departments were trained in monitoring when the 1994 Decree was revised in 2000.[46] The training culminated in a national monitoring exercise and additional amendments to improve the Decree.

Other countries have designated a new agency charged with monitoring and enforcement. Ghana, for example, has established a committee charged with coordinating investigations into alleged complaints, submitting its findings to the implementing agency and following up on actions taken.[47] In Botswana, the Ministry of Health has the power to appoint monitors who have undergone special training regarding the regulations and the International Code. Anyone with a commercial interest in infant feeding is excluded from being appointed as a monitor. The Regulations deem a monitor's report prima facie evidence of the facts in the report for purposes of enforcement proceedings.[48]

Most of the countries with voluntary codes have established boards or panels to monitor compliance. For example, Australia established the Advisory Panel on the Marketing in Australia of Infant Formula (APMAIF) and New Zealand has a compliance panel. The Malaysia Code sets up a Disciplinary Committee, which is charged with coordinating investigations of complaints, assessing and acting on violations and taking disciplinary action.[49]

Again, it is inappropriate for manufacturers or distributors of products within the scope of the Code to be involved in government monitoring (although they should monitor their own practices to ensure compliance). The World Health Assembly made this clear in Resolution 49.15 of 1996, which states that governments are "to ensure that monitoring the application of the International Code and subsequent relevant resolutions is carried out in a transparent manner, free from commercial influence".

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[44] The National Agency for Food and Drug Administration and Control (NAFDAC) is the agency charged with enforcing compliance with the Nigeria Marketing (Breastmilk Substitutes) (Amendment) Decree Nº 22, 1999.

[45] Albania, Law for Promotion and Protection of Breastfeeding, Nº 8528, 1999, Article 12.

[46] Vietnam, Decree on Marketing and use of Breastmilk Substitutes to Protect and Promote Breastfeeding, Nº 74/2000/ND-CP, 2000.

[47] Ghana National Breastfeeding Promotion Regulation Committee.

[48] Botswana, Marketing of Foods for Infants and Young Children Regulations, S. I. Nº 37, 2005, Regulations 4, 5(4) & 5(5).

[49] Malaysia, Code of Ethics for Infant Formula Products, *3rd revision*, 1995, § 7.3(a).

Involving non-governmental organisations

In countries with laws as well as those with voluntary codes, monitoring is rarely ongoing and organisations charged with compliance often handle only incoming complaints. Unless there are active and knowledgeable individuals or organisations that take the time and effort to observe industry practices and submit complaints, the relevant enforcement authorities remain unaware of violations. Ironically, it is often the companies themselves who are most active in submitting complaints about their competitors.

Countries should consider giving non-governmental organisations and individuals an active role in monitoring. In India, the law gives a formal role in enforcement to certain voluntary organisations involved in the field of child welfare and nutrition. Several organisations, including the Association for Consumer Action on Safety and Health and Breastfeeding Promotion Network of India have been gazetted under the India Act as authorised to file a complaint regarding an offence. If the court issues a summons following such a complaint, an assistant public prosecutor must take charge of the case.[50]

Even when NGOs are given a less formal role, their input can be significant in enforcing the law. The authority could make itself receptive to complaints from the public by requesting cooperation, publicising the procedure for submitting complaints, and by responding to them. For example, a conviction of SMA Nutrition (part of Wyeth) in the UK in 2003 began with a mother's complaint to her local Trading Standards Office. The complaint referred to an advertisement that appeared in several parenting magazines, in contravention of the UK Infant Formula and Follow-on Formula Regulations.[51] Wyeth was convicted on six separate breaches of illegal advertising and fined £60,000 (US$94,000) including costs.[52]

Many organisations that focus on consumer protection, or the promotion, protection and support of breastfeeding have developed expertise in this area from years of monitoring compliance with the International Code.[53] The Brazil case study presents a good example of how an NGO can work with the government to ensure that the law is monitored. Monitoring by citizens, however, does not replace the government's obligation to ensure compliance with national measures. At the very least, governments should encourage and enable NGOs to do this work on a regular basis.

Penalties

Most of the countries that have implemented the International Code as a law include criminal sanctions of fines and imprisonment. Administrative remedies can include warnings, confiscation of goods (useful for violations relating to labelling or quality of the product); suspension or revocation of a licence or permit to manufacture, sell or import a product as well as closure of enterprises.

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[50] India Act, *supra* note 4, § 21.

[51] United Kingdom, Infant Formula and Follow-on Formula Regulations, Statutory Instruments N° 77, 1995.

[52] Laurent, C., "Baby Milk Company Fined for Advertising Direct to Consumers", *British Medical Journal*, 2003, 327: 307.

[53] Monitoring by citizen organisations is discussed in Chapter 11.

Often laws provide for both types of remedies. For example, in Guatemala the administrative sanctions available for violations of the Law and Rules are those provided for under the Health Code and include warnings, fines, permit suspensions and closure of enterprises.[54] The Rules also provide that acts or omissions that constitute "crimes against health" shall be prosecuted by the ordinary courts.[55] Similarly, in Cameroon, violations of the marketing law may be punishable by confiscation or destruction of goods, suspension of sales permits or withdrawal of import permits. When a violation is qualified as criminal, the Ministry of Health may submit it to the Attorney General for prosecution.[56]

Countries that have adopted voluntary codes cannot apply penal or administrative sanctions for violations. Remedies for breaches are limited to warnings, requesting corrective action and publicity. The Malaysia Code lists the following penalties for breaches: written warnings; suspension of vetting new materials for two years; notification to WHO, UNICEF and the IFM; press releases and blacklisting such as omitting the company from future tenders for a period of time.[57] The Ministry of Health periodically announces a list of companies that have violated the Code. Similarly in Australia, the Advisory Panel that monitors compliance with the voluntary code puts out an annual report in which it lists any breaches that were found during the year.[58] The panel has no power to impose any penalties.

Sensitisation

Once the law or other measure is in place, it is important that relevant sectors are aware of its provisions. In Guatemala, the Ministry of Health sent copies of the law and regulations to the media, to stores and supermarkets, and to professional organizations. Further, the Ministry conducted meetings with distributors to explain their obligations.

Other countries have conducted workshops to familiarise various groups with the law. For example, the Oman Ministry of Health organised a workshop in 1999, to familiarise officials from various concerned ministries about the provisions of the then newly adopted Ministerial Decree regulating the marketing of breastmilk substitutes in Oman.[59] The workshop was aimed at officials who are responsible for implementing the Decree and sought to familiarise them with its provisions and to guide them regarding implementation and enforcement.

Similarly, shortly after Vietnam issued regulations on the marketing of breastmilk substitutes,[60] the National Breastfeeding Committee of Vietnam organised three workshops to dis-

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[54] Guatemala Health Code, Book III, Article 167.

[55] Guatemala, Reglamento para la Comercialización de los Sucedáneos de la Leche Materna, Acuerdo Gubernativo Nº 841-87, 1987 (Guatemala, Rules for the Marketing of Breastmilk Substitutes), Article 16.

[56] Cameroon, Arrêté Interministeriel Nº 040 portant sur la réglementation de la commercialisation des substituts du lait maternel, 1993 (Cameroon, Interministerial Decree on the Control of Marketing of Breastmilk Substitutes), Article 19.

[57] Malaysia Code, *supra* note 49, § 7.3(d).

[58] *See e.g.,* Advisory Panel on the Marketing in Australia of Infant Formula, *Annual Report,* 2003 (Australian Government, Department of Health and Aging).

[59] Oman, Ministerial Decision Nº 55/98 Regulating the Marketing of Breastmilk Substitutes, 1998.

[60] Vietnam, Decision of the Prime Minister on the Issuance of Regulations on Trading and Use of Breastmilk Substitutes to Promote Breastfeeding, Nº 307/TTG, 1994.

seminate knowledge about the law. The workshops were conducted regionally and each provincial hospital in the region was asked to send three participants at the level of Director or Department Head.

Political will

Laws, regulations, voluntary codes, monitoring, training, vetting bodies and enforcement are all elements of implementing the International Code. Political will, however, must be present at the government level. All but three Member States of the World Health Assembly voted in favour of the International Code in 1981. Since 1981, the WHA has adopted more than 10 resolutions calling on countries to implement the International Code. Yet, many years later, not all countries have acted to give effect to the International Code. Moreover, some countries that have national measures have not succeeded in making them work. The next chapter examines useful tools and arguments to bring breastfeeding and Code implementation onto the national agenda.

CHAPTER 11

Advocacy and Getting on to the National Agenda

National breastfeeding committee

Establishing a national breastfeeding committee is one of the most important ways for beginning the process of implementing the International Code. Most countries already have a multisectoral breastfeeding committee as well as a national breastfeeding coordinator in fulfilment of the targets of the 1990 *Innocenti Declaration*.[1] The impetus to begin implementing the International Code at the national level will often come from such a committee. The committee can develop a plan of action for sensitisation and lobbying the government to enact a law to protect breastfeeding.

Non-governmental organisations

In most countries, there are a variety of NGOs that work to improve infant and young child health. Many of these groups are already lobbying or can be encouraged to lobby for national implementation of the International Code. Community groups concerned with improving infant health have been instrumental in promoting implementation of the Code in countries all over the world. Many began by simply translating and distributing the International Code.

IBFAN is an international network of organisations formed when the International Code was being drafted. IBFAN has over 200 groups in 95 countries that work for better infant nutrition and health through the promotion of breastfeeding and implementation of the International Code. Some of the first countries to implement the International Code at the national level, such as Bangladesh, Brazil and the Philippines did so largely as a result of the activities of groups who were members of IBFAN.

In 1998, the Right Livelihood Award jury awarded IBFAN with the prestigious Right Livelihood Award, commonly known as the 'Alternative Nobel Prize'. The award, presented in the Swedish Parliament, is given annually to groups and individuals for their "vision and work contributing to making life more whole, healing our planet and uplifting humanity". The award jury honoured IBFAN for its over twenty years of campaigning for the rights of mothers to choose to breastfeed free from commercial pressures.

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[1] WHO and UNICEF, *Innocenti Declaration on the Protection, Promotion and Support of Breastfeeding,* Florence, Italy, 1 August 1990. One of the operational targets for all governments to have achieved by the year 1995 was to have "appointed a national breastfeeding coordinator of appropriate authority and established a multi-sectoral national breastfeeding committee composed of representatives from relevant government departments, non-governmental organizations, and health professional associations".

Monitoring

Assessing marketing practices can play an important role in countries where the International Code has not been implemented or where measures are not being applied. Article 11.4 of the International Code gives non-governmental organisations, professional groups, institutions and concerned individuals the responsibility to draw the attention of manufacturers and distributors to "activities that are incompatible with the Code so that appropriate action can be taken".

Community groups, often IBFAN members, have been monitoring the marketing practices of infant food companies on a regular basis since the International Code was adopted. Voluntary monitors visit health care facilities and retail outlets, interview medical personnel, pregnant women, mothers of infants and young children and scrutinise labels, advertisements and written materials, checking for compliance with the International Code and, where they exist, with the provisions of national measures. Other international organisations such as UNICEF and the Interagency Group on Breastfeeding Monitoring have been involved in monitoring as well.

The NGOs publicise information gathered during monitoring so that all parties, including governments and industry are informed. The results of the latest IBFAN monitoring survey were published in 2004.[2] In 1997, the Interagency Group on Breastfeeding Monitoring, a group of key international NGOs and churches, published *Cracking the Code,* which highlights violations of the International Code by various companies in four countries.[3] The UK organization, Baby Milk Action (BMA), carries out the Campaign for Ethical Marketing. BMA produces an action sheet highlighting examples of marketing malpractice by baby food companies. The examples and the companies' responses are posted on BMA's website.[4]

Publication of monitoring results has helped to get the International Code implemented in some countries. In Argentina, results of a monitoring study carried out by a local organisation provided the basis for the Ministry of Health of the Province of Buenos Aires to pass an official resolution adopting the International Code in its territory.[5] Similarly, a voluntary organisation

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[2] International Baby Food Action Network, *State of the Code by Company 2004,* Penang, Malaysia: IBFAN-ICDC 2004. *See also*, International Baby Food Action Network, *Breaking the Rules, Stretching the Rules 2004,* Penang, Malaysia: IBFAN-ICDC, 2004 and International Baby Food Action Network, *Look What They're Doing,* Penang, Malaysia: IBFAN-ICDC, 2004 (series of pamphlets reporting on violations of the International Code in selected countries).

[3] Interagency Group on Breastfeeding Monitoring, *Cracking the Code: Monitoring the International Code of Marketing of Breastmilk Substitutes,* London: IGBM, 1997.

[4] Baby Milk Action, "Action Sheets", *Campaign for Ethical Marketing,* periodic reports, http://www.babymilkaction.org/pages/campaign.html (accessed 25 February 2005).

[5] Argentina Provincial Regulations, Province of Buenos Aires, Decision Nº 024/98 Implementing Ministerial Resolution Nº 4477/97 (on the Implementation of the International Code of Marketing of Breastmilk Substitutes) and Annex, Guidelines for applying Ministerial Resolution Nº 4477/97 in the Health Care System of the Province of Buenos Aires, 8 July 1998 (The preamble to the Decision states: "considering that the results of the first monitoring of the implementation of the International Code of Marketing of Breastmilk Substitutes carried out last year show that manufacturers and/or distributors of breastmilk substitutes still pursue marketing policies that are contrary to the letter and spirit of the Code as well as the principles and aims of the Ministry and that, in so doing, they are using the health care system . . .".).

in Pakistan, The Network, conducted a survey throughout Pakistan in 1997. The results were published in the report *Feeding Fiasco,* which was described by officials in Pakistan as an "eye opener" and as revealing a "disturbing situation".[6] Pakistan adopted the Protection of Breastfeeding and Young Child Nutrition Ordinance in 2002. In 2004, an IBFAN report of Code violations in China[7] influenced the Chinese government to hold a series of meetings to improve implementation of China's Rules Governing the Administration of Marketing of Breastmilk Substitutes.

Role of manufacturers and distributors

Article 11.3 of the International Code states that manufacturers and distributors of products within the scope of the Code have an obligation to monitor their marketing practices according to the Code and to take steps "to ensure that their conduct at every level conforms". This was reiterated in the 2002 WHO/UNICEF *Global Strategy for Infant and Young Child Feeding*, which identified the following two roles of manufacturers and distributors: to ensure that their products meet applicable standards and to monitor their marketing practices for compliance with the International Code, relevant WHA resolutions and relevant national measures.[8]

Thus, companies that market breastmilk substitutes as well as feeding bottles and teats should have internal mechanisms for ensuring that all employees are adhering to the International Code or relevant national measures. Procedures for correcting infractions should also be in place. The IFM does not have a monitoring system, but will accept complaints. According to IFM, complaints it receives concerning non-compliance with the International Code will be forwarded to the relevant company for investigation and if the complaint is found to be justified, the company will take "prompt and appropriate action".[9]

At the 1998 World Health Assembly, the Director of Family and Reproductive Health of WHO stated that the "infant-food industry needs to be proactive and more responsible to monitor its own marketing practices and respond promptly to correct all the violations that are reported". In response to this call for action, Nestlé announced that it had instituted a "new monitoring process with governments around the world to ensure compliance with the *WHO International Code of Marketing of Breastmilk Substitutes"*.[10]

In its 1999 report of this exercise, Nestlé claimed to include "official responses from 54 governments (or designated monitoring bodies) that verify Nestlé compliance with the [International Code] as applied in their countries".[11] The report also states, "At this point in time we

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[6] The Network, *Feeding Fiasco: Pushing commercial infant foods in Pakistan*, Islamabad: The Network, 1998.
[7] International Baby Food Action Network, *Look What They're Doing! Monitoring Code Compliance in China,* Penang, Malaysia: IBFAN-ICDC, 2004.
[8] WHO and UNICEF, *Global Strategy for Infant and Young Child Feeding,* Geneva: WHO, 2003, ¶ 44.
[9] International Association of Infant Food Manufacturers, "Complaints Procedure for Code Violations", 2004, http://www.ifm.net/ issues/complaints.htm (accessed 22 April 2005).
[10] Nestlé, *International (WHO) Code Action Report*, Geneva: Nestlé, October 1999.
[11] Nestlé, *Nestlé Implementation of the WHO Code, Official Response of Governments,* Report to the Director General, World Health Organization, Geneva: Nestlé July 1999, p. E-1.

are aware of only one government which has written to us that we are not in compliance with the WHO Code in their country".[12]

The Nestlé report was met with criticism because of the way the so-called monitoring process was carried out. The company did not investigate systematically or even sporadically its own marketing practices in individual countries. Instead, Nestlé wrote to national health ministries asking relevant health officials to "inform us if, in your judgement (*sic*), Nestlé is in compliance with the [relevant national measure]".[13] Only six of the 54 statements in the report refer to monitoring or something similar conducted by the authority providing the statement.[14]

Human rights

International human rights instruments can also be used as a tool for lobbying governments to implement the International Code. The topic of breastfeeding has become a part of the United Nations' *human rights* approach to food, nutrition and health. The Committee on Economic, Social and Cultural Rights has recognised that breastfeeding is an important component in assuring the right to adequate food.[15] Almost all governments have promised to fulfil the rights contained in international agreements such as the Convention on the Rights of the Child (CRC) and the International Covenant on Economic, Social and Cultural Rights.

Article 24 of the Convention on the Rights of the Child is specifically related to the International Code. Article 24 spells out the right of the child to "the enjoyment of the highest attainable standard of health".[16] Among the appropriate measures that governments are obliged to take to implement that right is "to ensure that all segments of society, in particular parents and children, are informed, have access to education and are supported in the use of basic knowledge of . . . the advantages of breastfeeding".[17]

The Committee on the Rights of the Child, which reviews progress and makes recommendations to governments about implementing the provisions of the CRC, recognises implementation of the International Code as an appropriate measure for the fulfilment of government obligations under the Convention. Because countries that have ratified the CRC are bound to take

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[12] *Ibid.,* p. 5.

[13] *Ibid*., p. 4 (Sample letter to Chairman of Vetting Committee, Ministry of Health Malaysia, 11 November 1998).

[14] For a full analysis of the Nestlé Report, *see* Baby Milk Action, *Don't Judge a Book by its Cover, The truth behind Nestlé's book: Nestlé implementation of the WHO Code–Official responses of governments*, Cambridge: BMA 1999. *See also* International Baby Food Action Network and Geneva Infant Feeding Association, *Nestlé Implementation of the WHO Code (International Code of Marketing of Breastmilk Substitutes): Does the Nestlé Report comply with the International Code? A legal evaluation of the Nestlé Report*, Geneva: IBFAN/GIFA, 2000.

[15] Committee on Economic, Social and Cultural Rights, "The right to adequate food", General Comment N° 12 (1999), ¶ 9, Annex V *to* Report of the 20th and 21st Sessions, Economic and Social Council, Official Record 2000, Supplement N° 2, E/C.12/1999/5.

[16] UN Convention on the Rights of the Child, UN General Assembly Resolution 44/25, 20 November 1989, Article 24.1.

[17] *Ibid.,* Article 24.2(e).

appropriate measures towards its implementation, the CRC committee has, on a number of occasions, recommended that governments enact legislation to implement the International Code or to strengthen and sustain enforcement of existing legislation.[18]

The CRC is an important tool for advocating implementation of the International Code because it is a legally binding convention that has been ratified by 191 countries making it "the most universally embraced human rights instrument in history".[19]

Economic arguments

Presenting the advantages of breastfeeding in economic terms is another powerful argument to convince policy makers to protect and promote breastfeeding by implementing the International Code. Arguments and statistics can be developed about not only the cost of breastmilk substitutes, but also about the economic value of breastmilk to a nation and about the savings in health care costs that result from breastfeeding.

Nations expend large amounts of money on breastmilk substitutes, yet do not assign any economic value to the billions of litres of breastmilk that mothers produce each year. For example, in 2003, retail sales of standard infant formula in Indonesia were 2,679 billion rupiah (US$300 million).[20] In India, it was estimated that in 1998 women produced 400 billion litres of breastmilk. If mother's milk were valued according to the price of tinned milk, the annual value of mother's milk produced in India in that year would have been 6 billion rupees (US$128 million).[21] An analysis in Australia calculated that Australian women produce about 34 million

[18] With regard to Lebanon, for example, the Committee recommended that "the ban of the commercial marketing of infant formula be implemented and that breastfeeding be promoted among mothers in health facilities…". UN Committee on the Convention of the Rights of the Child, *Consideration of Reports Submitted by States Parties under Article 44 of the Convention, Concluding Observations: Lebanon* ¶ 34, 7 June 1996 (*hereinafter* UN Committee *Concluding Observations).* In the case of Hong Kong, the Committee expressed its concern about the apparent insufficiency of measures to encourage breastfeeding. The Committee noted that "powdered milk for babies continues to be freely distributed in hospitals, contrary to international guidelines on this matter". UN Committee *Concluding Observations: Hong Kong (United Kingdom of Great Britain and Northern Ireland)*, ¶ 16, 30 October 1996. In its recommendations to Vietnam in 2003, the Committee suggested that the government "take steps to encourage and educate mothers as well as village health workers and traditional birth attendants on the benefits of exclusive breastfeeding for an infant's first six months and take measures to limit the distribution of infant formulas, for instance, through the formulation of a national marketing code". UN Committee *Concluding Observations*: *Vietnam*, ¶ 40(b), 18 March 2003. The Committee also recommended adopting the International Code in the United Kingdom where it noted the relatively low rate of breastfeeding. UN Committee *Concluding Observations*: *United Kingdom of Great Britain and Northern Ireland* ¶¶ 41-42, 9 October 2002.

[19] UNICEF, *State of the World's Children*, New York: Unicef 1997.

[20] Follow-on formula added an additional retail value of 466 billion rupiah (US$55 million) for 2003. *See* "Baby Food in Indonesia", Euromonitor, September 2003.

[21] "Economic value of breastfeeding in India", *The National Medical Journal of India,* 1999, 12: 3. The cost of tinned milk in 1998 ranged between 15 and 30 rupees. The Breastfeeding Promotion Network of India valued breastmilk produced in 2001 at 148 billion rupees (US$3.1 billion). *See* The Breastfeeding Promotion Network of India, "Breastmilk, a Valuable National and Natural Resource", in *Breastfeeding and Food Security*, Delhi, July 2001.

kilogrammes of breastmilk annually. Basing cost on the value of breastmilk in European milk banks, the annual value was calculated to be A$1.8 billion (US$1.1 billion).[22]

A number of studies have calculated the health care costs that result for a nation when babies are not breastfed.[23] One study compared health care costs for formula-fed babies with health costs for babies exclusively breastfed for at least three months.[24] The author calculated that the additional health costs for the formula-fed babies amounted to between US$331 and $475 per baby during the first year on just three of the most common infant illnesses.[25] The American Academy of Pediatrics states that breastfeeding has the potential to reduce annual health care costs in the United States by US$3.6 billion.[26] Advocates for Code implementation can research and develop economic arguments that apply to their own countries. Such arguments can be used to convince policy-makers that investing in programmes to support and protect breastfeeding can be shown as one of the most cost-effective strategies for child survival.

International trade agreements and Code implementation

The International Code is interdisciplinary. It not only crosses the realms of public health matters and professional ethics but also touches on issues related to commerce. Officials will want to know whether laws that implement the International Code might be successfully challenged as creating trade barriers contrary to international trade agreements.

International trade agreements aim to increase access to markets by removing trade barriers. In general, trade barriers are created when nations impose bans, quotas or restrictions on the import of certain goods. Laws regulating advertising and promotion of breastmilk substitutes and feeding bottles and teats do not impose such bans or restrictions on import of goods. Even if it could be shown that a national law has had the effect of restricting imports, international trade agreements allow for some restrictions under certain circumstances. Free trade in goods is an important goal, but all nations must, above all, protect their citizens and thus, have laws to protect human, animal and plant life.

The relationship between trade and sanitary regulations has been grappled with since the first attempts to create international trade agreements. The concern has been to create a balance between legitimate safety concerns and the potential for countries to use safety regulations to restrict trade. Thus, the various trade agreements have incorporated criteria for determining the types of trade restrictions that are permissible based on the protection of human life, safety and health.

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[22] Smith, J.P., "Human Milk Supply in Australia", *Food Policy*, 1999, 24: 71-91.

[23] *See* Walker, M., *Selling out Mothers and Babies, Marketing of breastmilk substitutes in the* USA, Weston, Massachusetts: National Alliance for Breastfeeding Action, 2001. *See also*, Walker, M., *Economics of not breastfeeding,* bibliography of studies on health costs of not breastfeeding, www.naba-breastfeeding.org/images/Economics.pdf (accessed 10 April 2005).

[24] Ball, T.M. and Wright, A.L.,"Health Care Costs of Formula-feeding in the First Year of Life", *Pediatrics,* 1999, 103: 870-76.

[25] *Ibid.,* p. 870. The study looked at the health care costs of lower respiratory tract illnesses, otitis media and gastrointestinal illnesses. The costs were estimated based on costs for health care providers in a managed health care system in the United States.

[26] American Academy of Pediatrics, Section on Breastfeeding, "Breastfeeding and the use of Human Milk", *Pediatrics*, 2005, 115: 497.

The World Trade Organization (WTO) was established in 1995 to administer the various international trade agreements including the General Agreement on Tariffs and Trade. The main trade agreement relating to food, health and safety is the Agreement on Sanitary and Phytosanitary Measures (SPS). The SPS applies to measures that protect life and health from import of products that might spread disease within a country; from risks of additives, contaminants and toxins in foods, and from the spread of pests.[27]

As a general rule, government measures implementing the International Code would not be considered sanitary or phytosanitary measures and would therefore not be subject to the SPS agreement. It should be noted, however, that a requirement to include a warning on a label concerning the possibility of contamination with micro-organisms could be considered a sanitary measure that would fall within the SPS agreement. For such laws to pass muster under the SPS agreement, they should be based on objective and accurate scientific data, be consistent with international standards and be based on an assessment of the risk.

The Agreement on Technical Barriers to Trade (TBT) is the other trade agreement that could be relevant for national legislation and regulations that implement the International Code. The TBT agreement applies to national technical regulations and standards, which are defined as those governing product characteristics or their related processes and production methods.[28] Technical regulations and standards that deal with "terminology, symbols, packaging, marking or labelling requirements" also fall within the TBT".[29]

Member nations must ensure that national regulations and standards that fall within the TBT are not adopted or applied in order to or with the effect of "creating unnecessary obstacles to international trade".[30] Moreover, such technical regulations and standards "shall not be more trade-restrictive than necessary to fulfil a legitimate objective".[31] Such legitimate objectives may include "the prevention of deceptive practices, protection of human health or safety, . . . or health".[32] Finally, imported products must receive the same treatment as that accorded to like products produced domestically.[33]

Both the TBT and SPS place importance on harmonisation by requiring that Member States base relevant national measures on international standards. The only elements of national measures implementing the International Code that might fall within the reach of either of these trade agreements are those that pertain to product quality, packaging and labelling.

With respect to product quality, Article 10 of the International Code recommends that food products within the scope of the Code should meet applicable Codex standards. Thus, national legislation implementing Article 10 would be based on Codex quality standards. Both the SPS and the TBT have accepted Codex standards as one of the international reference points for

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[27] World Trade Organization, Agreement on the Application of Sanitary and Phytosanitary Measures, Article 1.1.
[28] World Trade Organization, Agreement on Technical Barriers to Trade, Annex 1. The provisions of the TBT do not apply to sanitary and phytosanitary measures. *Ibid.*, Article 1.5.
[29] *Ibid*., Annex 1, definitions of *technical regulation* and *standard.*
[30] *Ibid*., Article 2.2.
[31] *Ibid.*
[32] *Ibid.*
[33] *Ibid.,* Article 2.1.

facilitating international trade and resolving trade disputes in international law. Thus, those parts of the law based on Article 10 of the International Code would pose no obstacle to international trade.[34]

The labelling requirements in national laws implementing the International Code, however, would be in addition to those in Codex because the Codex standards deal only with the name of the food, list of ingredients, declarations of nutritive value, date marking and storage instructions as well as information for utilisation. Were such requirements to be challenged as posing unlawful barriers to trade, they would be judged according to the test in the TBT of whether or not they are "more trade-restrictive than necessary to fulfil a legitimate objective".[35] Such legitimate objectives may include "the prevention of deceptive practices, protection of human health or safety, … or health".[36]

Governments have a strong arsenal of arguments in favour of such legislation. The objective of these labelling requirements is to protect infant life and health. Moreover, the legislation is based on the International Code, a document that had nearly unanimous support of the World Health Assembly. The WHA has, in subsequent resolutions, repeatedly called for Member States to implement the Code. Finally, as the International Code is a minimum requirement,[37] nations are justified in establishing additional labelling requirements in the interests of protecting infant life and health.

Advocates for the International Code need to be aware of these arguments. Governments, or companies via their governments, may use the threat of action under the WTO against weaker countries that want to implement a strong law. In 1992, the Gerber Company lobbied the United States government to pressure Guatemala into amending the labelling provisions of its law by threatening a challenge under international trade agreements. The dispute centred around the provision in the Guatemala regulations that forbids pictures of infants on product labels.[38] Gerber objected to deleting the baby picture from its infant food labels on the grounds that this famous line drawing of a baby face is its company trademark.[39]

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[34] The Food and Agriculture Organization and the WHO created the Codex in 1962. Codex contains more than 200 standards, covering such issues as labelling; additives; methods of analysis and sampling; food import and export inspection and certification; pesticides in foods and contaminants. The Codex contains standards for most products that would fall within a national measure that implements the International Code. *See* Codex Standard for Infant Formula, Standard 72−1981 (amended 1983, 1985, 1987, 1997 and currently under revision); Codex Standard for Follow-up Formula, Standard 156-1987 (amended 1989); Codex Standard for Processed Cereal-based Foods for Infants and Children, Standard 74-1981 (amended 1985, 1987, 1989, 1991 and currently under revision) and Codex Standard for Canned Baby Foods, Standard 73-1981 (amended 1985, 1987 and 1989).

[35] *See* TBT, Article 2.2. The TBT Agreement applies to national technical regulations and standards dealing with goods that are not covered by the SPS. The TBT agreement covers regulations and standards that deal with "terminology, symbols, packaging, marking or labelling requirements". World Trade Organization, Agreement on Technical Barriers to Trade, Annexes 1.1 and 1.2.

[36] TBT, Article 2.2.

[37] Resolution WHA34.22 (1981).

[38] Guatemala, Reglamento para la Comercialización de los Sucedáneos de la Leche Materna, Acuerdo Gubernativo Nº 841-87, 1987 (Guatemala, Rules for the Marketing of Breastmilk Substitutes), Article 12(a).

[39] It is interesting to note that Gerber no longer uses its trademark baby face on labels of its baby food products in Brazil or in Bangladesh.

In the end, Guatemala's Supreme Court of Justice decided in favour of Gerber based solely on a strained interpretation of the definition of *complementary food* in the Guatemala Law.[40] The Court's ruling had nothing to do with trade. Nonetheless, governments need to be aware that laws implementing the International Code, particularly those that are more stringent, may be challenged by larger economic powers who are not in favour of marketing restrictions. They should equally be aware that those challenges are not likely to succeed.

Summing up

A lesson to be learned from country experiences is that no matter what form of measure is eventually decided upon, it is essential to begin with a well-thought-out strategy suited to the country. Too many well-intentioned countries have failed to carry through the process and have been left with a draft law yellowing inside a desk drawer. As shown in *Figure 2* in Chapter 10, many countries still have only a draft measure or have never gotten beyond the stage of studying how best to implement the International Code. In other countries, enabling legislation was passed, but the implementing rules or regulations were never promulgated to assign the task of carrying out the law.

The following check list can be used to ensure that government strategies include all the elements necessary for successful regulation of product promotion that undermines breastfeeding:

- Is there a multi-sectoral committee charged with the promotion of breastfeeding in the country?
- Is there a law or a combination of laws and other measures that together encompass, at a minimum, all of the provisions of the International Code and subsequent relevant WHA Resolutions?
- Is there a responsible agency that has assigned knowledgeable personnel to carry out and enforce its provisions?
- Does the agency have the tools necessary to monitor and enforce the law?
- Are sanctions severe enough to act as a deterrent?
- Have relevant parties been informed of their obligations and the prohibitions of the law?
- Is the regulation of marketing part of an overall plan that includes elements of improved hospital practices, increased knowledge of health workers, the raising of public awareness about the importance of breastfeeding and legislative support for working women?

[40] The Court decided that according to the definition of complementary foods, the Guatemala law applies only to complementary foods that are made locally. Gerber products are imported. The definition of complementary food reads (in Spanish): *todo alimento, manufacturado o preparado localmente como complemento de la leche materna o de las preparaciones para lactantes* . . . . Guatemala, Decreto-Ley Nº 66-83: Ley de Comercialización de Sucedáneos de la Leche Materna, 1983 (Guatemala, Decree–Law on Marketing of Breastmilk Substitutes), Article 2(b). A literal translation of this definition of complementary food could mean either "any food that is manufactured or that is prepared locally" or "any food that is locally manufactured or prepared".

With all of these elements in place, the country will be well on the way to meeting the goal of the *Innocenti Declaration*, reaffirmed by the 2002 *Global Strategy for Infant and Young Child Feeding*, that all governments shall take action to give effect to the International Code of Marketing of Breastmilk Substitutes and subsequent World Health Assembly resolutions in their entirety. The *Innocenti Declaration* aims to have countries return to a "breastfeeding culture" and to defend against incursions of a "bottle-feeding culture". We at ICDC hope that through our Code Implementation Courses and through this Handbook, we have motivated many countries to embark on legislation that will protect breastfeeding.

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MODEL LAW

MODEL LAW

Preface

This Model Law was developed by the International Code Documentation Centre (ICDC) as an instrument to assist governments in translating the International Code into legislation that can be monitored and enforced at the national level. All of the substantive provisions of the International Code as well as the essence of each subsequent, relevant World Health Assembly Resolution adopted between 1983 and 2005 are incorporated in the Model Law; the form has been adapted to conform to the needs of national legislation.

The form of the Model Law will not be appropriate for all countries because of differences among legal systems and drafting conventions. Countries will have to modify the Model Law to fit their own legal systems. ICDC has published under separate cover another Model Law in the form of a principal law and implementing regulations that some countries will find more appropriate to their legal system.

The second caveat in using the Model Law is that it was developed as part of the course materials for the ICDC Training Courses on Implementing the International Code of Marketing of Breastmilk Substitutes. During the courses, participants study, discuss and compare each substantive provision of the Model Law and determine whether it is an appropriate solution for their country. Thus, each country will modify the provisions to fit their own situation. Each participant benefits from the course by fully understanding the reasons and implications for each provision of the Model Law.

This is to say that the Model Law must be used as a tool. It must be studied along with other materials in this Handbook and adapted to meet national situations. With that said, I hope the Model Law eases the daunting task of drafting national legislation and will lead more and more countries to fully implement the International Code.

Ellen J. Sokol June 2005

MODEL LAW

An Act to ensure safe and adequate nutrition for infants and young children by promoting and protecting breastfeeding and by regulating the marketing of certain foods for infants and young children and of feeding bottles, teats and pacifiers.

It is hereby enacted as follows:

CHAPTER I
INTRODUCTORY

Section 1. Short Title and Commencement

(1) This Act may be called the [*Insert short title*].

(2) This Act shall come into effect 60 days after the date of enactment.

(3) It extends to the whole of *[Anyland]*.

Section 2. Definitions

For purposes of this Act—

(1) "Advertise" means to make any representation by any means whatsoever for the purpose of promoting the sale or use of a designated product including but not limited to—

(a) written publication, television, radio, film, electronic transmission including the Internet, video or telephone;

(b) display of signs, billboards, or notices; or

(c) exhibition of pictures or models.

(2) "Advisory Board" means a Board set up under Section 17.

(3) "Brand name" means a name given by the manufacturer to a product or range of products.

(4) "Complementary food" means any food suitable or represented as suitable as an addition to breastmilk, infant formula or follow-up formula for infants from the age of 6 months up to the age of 24 months.

(5) "Container" means any form of packaging of a designated product for sale as a retail unit, including wrappers.

(6) "Designated product" means

(a) infant formula;

(b) any other product marketed or otherwise represented as suitable for feeding infants up to the age of six months;[1]

(c) follow-up formula;

(d) complementary food;

(e) feeding bottles, teats, pacifiers; and

(f) such other product as the Minister of Health may, by Notice in the Official Gazette, declare to be a "designated product" for purposes of this Act.

(7) "Distributor" means a person, corporation or other entity engaged in the business, whether wholesale or retail, of marketing any designated product.

(8) "Follow-up formula" means a milk or milk-like product of animal or vegetable origin formulated industrially in accordance with [*citation to the country's standards for follow-up formula or, in the absence of such standards, citation to the Codex Alimentarius Standard for Follow-up Formula*] and marketed or otherwise represented as suitable for feeding infants and young children older than six months of age.

(9) "Health care facility" means a public or private institution or organisation or private practitioner engaged directly or indirectly in the provision of health care or in health care education. It also includes day-care centres, nurseries or other infant-care facilities.

(10) "Health professional" means a health worker with a professional degree, diploma or licence, such as a medical practitioner, certain registered nurses and midwives or such other person as may be specified by the Minister of Health by a Notice in the Official Gazette.

(11) "Health worker" means a person providing or in training to provide health care services in a health care facility, whether professional or non-professional including voluntary unpaid workers.

(12) "Infant" means a child from birth up to the age of 12 months.

(13) "Infant formula" means a milk or milk-like product of animal or vegetable origin formulated industrially in accordance with [*citation to the country's standard for infant formula or, in the absence of such standard, citation to the Codex Alimentarius Standard for Infant Formula*] and intended to satisfy, by itself, the nutritional requirements of infants from birth and/or during the first six months and includes products that continue to meet part of an infant's

[1] Note that some countries will choose to prohibit promotion of all infant foods including complementary foods for infants up to one year or even for infants and young children up to two years of age. Countries choosing that option must delete "up to the age of six months" in Subsection (6)(b) and specify the upper age limit. They should also delete Subsection (6)(d) "complementary foods", as they would already be included under Subsection (6)(b). *See also* note 2 in Section 4.

nutritional requirements after the first six months. [*Explanatory Note*: *Some brands of infant formula are marketed for infants up to 12 months.]*

(14) "Inspector" means an inspector appointed under Section 21.

(15) "Label" means a tag, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed, attached or otherwise appearing on a container of a designated product.

(16) "Logo" means an emblem, picture or symbol by means of which a company or a product is identified.

(17) "Manufacturer" means a person, corporation or other entity engaged in the business of manufacturing a designated product whether directly, through an agent, or through a person controlled by or under an agreement with it.

(18) "Market" means to promote, distribute, sell, or advertise a designated product and includes product public relations and information services.

(19) "Minister" means Minister of Health of *[Anyland].*

(20) "Pacifier" means an artificial teat for babies to suck, also referred to as a "dummy."

(21) "Prescribed" or "as prescribed" means prescribed or as prescribed by rules or written decision made pursuant to this Act.

(22) "Promote" means to employ any method of directly or indirectly encouraging a person to purchase or use a designated product.

(23) "Sample" means a single or small quantity of a designated product provided without cost.

(24) "Young child" means a child from the age of 12 months up to the age of three years (36 months).

CHAPTER II
PROHIBITIONS

Section 3. Sale of a designated product

(1) A person shall not distribute for sale, sell, stock or exhibit for sale any designated product that—

(a) is not registered according to Section 20 of this Act or is not in accordance with the conditions of its registration; or

(b) has reached its expiration date.

Section 4. Promotion

(1) Except as provided in Subsection 4(2),[2] a manufacturer or distributor shall not him or herself, or by any other person on his or her behalf, promote any designated product. Prohibited promotional practices include but are not limited to—

(a) advertising;

(b) sales devices such as special displays, discount coupons, premiums, rebates, special sales, loss-leaders, tie-in sales, prizes or gifts;

(c) giving of one or more samples of a designated product to any person; and

(d) donation or distribution of information or educational material referring to infant or young child feeding or performance of educational functions related to infant or young child feeding except as provided in Section 14.

(2) A manufacturer or distributor may promote a complementary food provided that—

(a) such promotional practice does not take place in a health care facility; and

(b) any material promoting complementary food encourages exclusive breastfeeding for six months and sustained breastfeeding for up to two years and beyond.

(3) A manufacturer or distributor shall not him or herself, or by any other person on his or her behalf—

(a) donate or provide at lower than the published wholesale price where one exists, and in its absence, lower than 80 percent of the retail price, any quantity of a designated product to a health worker or a health care facility;

(b) donate to or distribute within a health care facility equipment, services or materials such as pens, calendars, posters, notepads, growth charts and toys, which refer to or may promote the use of a designated product;

(c) offer or give any gift, contribution or benefit to a health worker or to associations of health workers engaged in maternal and child health, including but not limited to fellowships, research grants or funding for meetings, seminars, continuing education courses or conferences;

(d) sponsor events, contests, telephone counselling lines or campaigns related to reproductive health, pregnancy, childbirth, infant or young child feeding or related topics; or

(e) include the volume of sales of designated products when calculating employee remuneration or bonuses, nor set quotas for sales of designated products.

(4) A health worker engaged in maternal and child health shall not—

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[2] The exception provided in Subsection 4(2) for complementary foods is only applicable to countries that choose to allow some types of promotion for complementary foods. Countries that choose to prohibit all promotion for complementary foods should delete this exception. *See supra* note 1.

(a) accept any gift, contribution or benefit, financial or otherwise, of whatever value from a manufacturer or distributor or any person on his or her behalf;

(b) accept or give samples of designated products to any person; or

(c) demonstrate the use of infant formula except to individual mothers or members of their families in very special cases of need, and in such cases, shall give a clear explanation of the risks of the use of infant formula as well as the other information required by Chapter IV.

Section 5. Prohibitions related to labels of designated products

(1) A manufacturer or distributor shall not offer for sale or sell a designated product if the container or label affixed thereto includes a photograph, drawing or other graphic representation other than for illustrating methods of preparation. [*Optional: This section shall not apply to complementary foods.*]

(2) A manufacturer or distributor shall not offer for sale or sell a designated product, other than a feeding bottle, teat or pacifier unless the container or label affixed thereto indicates in a clear, conspicuous and easily readable manner, in [*insert appropriate language(s)*], the following particulars:

(a) instructions for appropriate preparation and use in words and in easily understood graphics;

(b) the age after which the product is recommended in numeric figures and in the case of a complementary food, the recommended age shall not be less than six months;

(c) a warning about the health risks of improper preparation and of introducing the product prior to the recommended age;

(d) the ingredients used;

(e) the composition and nutritional analysis;

(f) the required storage conditions both before and after opening, taking into account climatic conditions;

(g) the batch number, date of manufacture and date before which the product is to be consumed, taking into account climatic and storage conditions;

(h) the name and national address of the manufacturer or distributor; and

(i) such other particulars as may be prescribed.

(3) A manufacturer or distributor shall not offer for sale or sell a designated product if the container or label affixed thereto contains any representation that states or suggests that a relationship exists between the product or constituent thereof and health, including the physiological role of a nutrient in growth, development or normal functions of the body.

Section 6. Prohibitions related to labels of infant formula and follow-up formula

(1) A manufacturer or distributor shall not offer for sale or sell infant formula or follow-up formula unless the container or label affixed thereto, in addition to the requirements of Section 5, conforms to the following:

(a) contains the words, "IMPORTANT NOTICE" in capital letters and indicated thereunder, the statement "Breastfeeding is best. Breastmilk is the ideal food for the healthy growth and development of infants and young children. It protects against diarrhoea and other illnesses" in characters [*insert particulars relating to character size, placement, appearance, etc. For example, "no less than one-third the size of the characters in the product name, and in no case less than 2mm in height"*];

(b) contains the word, "warning" and indicated thereunder, the statement, "Before deciding to supplement or replace breastfeeding with this product, seek the advice of a health professional. It is important for your baby's health that you follow all preparation instructions carefully. If you use a feeding bottle, your baby may refuse to feed from the breast. It is more hygienic to feed from a cup" in characters [*insert particulars relating to character size, placement, appearance, etc. For example, "no less than one-third the size of the characters in the product name, and in no case less than 1.5mm in height"*];

(c) states in preparation instructions for infant or follow-up formula in powdered form that powdered formula may be contaminated with micro-organisms during the manufacturing process or may become contaminated during preparation and that it is therefore necessary to discard any unused formula immediately after every feed;

(d) includes a feeding chart in the preparation instructions;

(e) does not use the terms "maternalised", "humanised" or terms similar thereto or any comparison with breastmilk;

(f) does not use text that may tend to discourage breastfeeding;

(g) specifies the source of the protein; and

(h) in the case of follow-up formula, states that the product shall not be used for infants less than six months old.

Section 7. Prohibitions related to labels of skimmed or condensed milk

A manufacturer or distributor shall not offer for sale or sell skimmed or condensed milk in powder or liquid form, unless the container or label affixed thereto contains the words, "This product should not be used to feed infants" in characters [*insert particulars relating to character size, placement, appearance, etc.*]

Section 8. Prohibitions related to labels of low-fat and standard milk

A manufacturer or distributor shall not offer for sale low-fat or standard milk in powder or liquid form, unless the container or label affixed thereto contains the words, "This product should not be used as an infant's sole source of nourishment"

in characters [*insert particulars relating to character size, placement, appearance, etc.*]

[Note: *The milks in Sections 7 and 8 do not fall within the scope of this Act unless they are marketed or otherwise represented as suitable for infants. We recommend that these labelling provisions be incorporated into the countries' food labelling laws. In addition, Sections 7 and 8 will require revision according to the types of milk products available in individual countries*.]

Section 9. Prohibitions related to labels of feeding bottles and teats

(1) A manufacturer or distributor shall not offer for sale or sell a feeding bottle or teat unless the package or label affixed thereto, in addition to the requirements of Section 5(1), indicates in a clear, conspicuous and easily readable manner, in [*insert appropriate language(s)*], the following particulars:

(a) the words, "IMPORTANT NOTICE" in capital letters and indicated thereunder, the statement, "Breastfeeding is best. Breastmilk is the ideal food for the healthy growth and development of infants and young children. It protects against diarrhoea and other illnesses" in characters [*insert particulars relating to character size, placement, appearance, etc. For example, "no less than one-third the size of the characters in the product name, and in no case less than 2mm in height"*];

(b) the statement, "Warning: It is important for your baby's health that you follow the cleaning and sterilisation instructions very carefully. If you use a feeding bottle, your baby may no longer want to feed from the breast" in characters [*insert particulars relating to character size, placement, appearance, etc. For example, "no less than one-third the size of the characters in the product name, and in no case less than 2mm in height"*];

(c) instructions for cleaning and sterilisation in words and graphics;

(d) a statement explaining that feeding with a cup is more hygienic than bottle feeding;

(e) a warning that children should not be left to self-feed for long periods of time because extended contact with sweetened liquids, including infant formula, may cause severe tooth decay; and

(f) the name and national address of the manufacturer or the distributor.

Section 10. Prohibitions related to labels of pacifiers (dummies)

A manufacturer or distributor shall not offer for sale or sell a pacifier unless, in addition to the requirements of Section 5(1), it is labelled with the words, "Warn-

ing: Use of a pacifier can interfere with breastfeeding" in characters [*insert particulars relating to character size, placement, appearance, etc. For example, "no less than one-third the size of the characters in the product name, and in no case less than 1.5mm in height"*] .

CHAPTER III
HEALTH WORKER RESPONSIBILITIES

Section 11. Health worker responsibilities

(1) Heads of health care facilities and national and local health authorities shall take measures to encourage and protect breastfeeding and to promote this Act, and shall give information and advice to health workers regarding their responsibilities and particularly ensure that health workers are familiar with all of the information specified in Chapter IV.

(2) Health workers shall encourage, support and protect breastfeeding. They are expected to know the provisions of this Act, particularly the information specified in Chapter IV.

(3) Health workers shall work to eliminate practices that directly or indirectly retard the initiation and continuation of breastfeeding, such as prelacteal feeds.

(4) Health workers shall make in writing a report to the head of his or her work place, who shall in turn report to the Advisory Board, of any offer he or she receives for a sample or gift or other benefit from a manufacturer or distributor or any other contravention of the provisions of this Act.

CHAPTER IV
INFORMATION AND EDUCATION

Section 12. Information and educational materials about infant feeding

Information or educational materials, whether written, audio or visual, which refer to infant feeding shall—

(1) contain only correct and current information and shall not use any pictures or text that encourage bottle feeding or discourage breastfeeding;

(2) be written in [*insert appropriate language(s)*];

(3) not give an impression or create a belief that a designated product is equivalent to, comparable with or superior to breastmilk or to breastfeeding;

(4) not contain the brand name or logo of any designated product nor of any manufacturer or distributor of a designated product;

provided that this clause shall not be applicable to information about designated products provided to health professionals as authorised by Section 14 of this Act; and

(5) clearly and conspicuously explain each of the following points:

(a) the benefits and superiority of breastfeeding;

(b) the value of exclusive breastfeeding for six months followed by sustained breastfeeding for two years or beyond;

(c) how to initiate and maintain exclusive and sustained breastfeeding;

(d) why it is difficult to reverse a decision not to breastfeed;

(e) the importance of introducing complementary foods from the age of six months;

(f) how and why any introduction of bottle feeding or early introduction of complementary foods negatively affects breastfeeding; and

(g) that complementary foods can easily be prepared at home using local ingredients.

Section 13. Information and educational materials about infant formula, follow-up formula or feeding bottles

If the material referred to in Section 12 includes the topic of bottle feeding, it must also include the following points:

(1) instructions for the proper preparation and use of the product including cleaning and sterilisation of feeding utensils;

(2) how to feed infants with a cup;

(3) the health risks of bottle feeding and improper preparation of the product; and

(4) the approximate financial cost of feeding an infant with such a product in the recommended quantities.

Section 14. Product information for health professionals

Manufacturers and distributors may give materials about designated products to health professionals if such materials—

(1) are restricted to scientific and factual matters regarding the technical aspects and methods of use of the product;

(2) provide references to published studies to support any representation that states or suggests that a relationship exists between the product or constituent thereof and health, growth or development; and

(3) are otherwise in accordance with Sections 12 and 13 of this Act.

Section 15. Submission of materials to Advisory Board

Any person who produces or distributes any materials referred to in this Chapter shall submit copies to the Advisory Board according to procedures as shall be prescribed.

CHAPTER V
ADMINISTRATION

Section 16. Implementation

(1) The Ministry of Health is principally responsible for the implementation of this Act.

(2) The Minister of Health shall, when necessary, call upon other ministries to ensure the implementation of this Act.

(3) For the purpose of implementing this Act, the Minister of Health has the following powers and functions:

(a) to promulgate such rules as are necessary or proper for the implementation of this Act and the accomplishment of its purposes and objectives;

(b) to call for consultations with government agencies and other interested parties to ensure implementation and strict compliance with the provisions of this Act and the rules promulgated hereunder;

(c) to cause the enforcement of this Act; and

(d) to exercise such other powers and functions that may be necessary for or incidental to the attainment of the purposes and objectives of this Act.

Section 17. National Advisory Board for the Promotion and Protection of Breastfeeding

(1) There shall be a National Advisory Board for the Promotion and Protection of Breastfeeding to be composed of the following members:

[*In this section, list the members to be included in this inter-disciplinary committee. Countries usually include representatives of relevant ministries such as Health, Education, Communications and Trade, and repre-*

sentatives of organisations of health professionals, consumers, breastfeeding support groups as well as experts in relevant fields. The proviso excludes manufacturers and distributors of designated products from the committee because it would constitute a conflict of interest for companies who are regulated by the law to take part in a committee that advises the government on enforcement of the law.]

(a) The Minister of Health or his representative who shall be its ex officio Chairman;

(b)

(c)

. . .

(x) Such other persons as the Minister may, by Notice in the Official Gazette, appoint as members of the Advisory Board.

provided that no person shall be appointed who has any direct or indirect financial interest in any designated product.

(2) The Minister shall appoint the members of the Advisory Board within 90 days of the date of enactment.

(3) The members of the Advisory Board shall hold office for a term of 3 years and shall be eligible for renomination.

(4) Any member of the Advisory Board may, at any time, resign his or her office by writing to the Minister or shall vacate his or her office if the Minister so directs. A vacancy shall be filled in the same manner as the original appointment for the balance of the unexpired term.

(5) The Advisory Board may invite national or foreign experts to take part in the meetings as observers and may constitute committees or appoint experts for the purpose of detailed study of any matter set before it.

(6) The Minister may, by Notice published in the Official Gazette, change the size and composition of the Advisory Board.

Section 18. Administration of the Advisory Board

(1) The Minister shall appoint the Secretary of the Advisory Board and such other officers as he or she deems necessary to carry out the purposes of this Act.

(2) The Advisory Board shall hire permanent staff necessary to carry out its functions, subject to the budgetary approval of the Minister.

(3) The Advisory Board shall meet as often as it deems necessary, but not less than once every month at such time and place as the Secretary shall indicate.

(4) The Secretary shall call meetings at the direction of the Chairman; shall maintain minutes of the meetings and shall perform such other duties as may be directed by the Advisory Board.

(5) Two-thirds of the members of the Advisory Board shall constitute a quorum for a meeting.

(6) A majority vote of the members present shall be sufficient to approve any business presented in a meeting of the Advisory Board.

(7) Decisions of the Advisory Board shall be certified by the Secretary.

(8) The Advisory Board may make such other administrative rules as may be required for its proper functioning.

Section 19. Powers and functions of the Advisory Board

(1) The Advisory Board has the following powers and functions:

(a) to advise the [*insert Head of State*] and the Minister on national policy for the promotion and protection of breastfeeding;

(b) to create regional committees to carry out the functions of the Advisory Board at the regional level, as may be prescribed;

(c) to advise the Minister on designing a national strategy for developing communication and public education programmes for the promotion of breastfeeding; information and educational materials on the topics of infant and young child feeding; continuing education for health workers on lactation management and the requirements of this Act; curricula for students in the health professions that include lactation management and to ensure widespread distribution of and publicity concerning this Act, in a method as may be prescribed;

(d) to review reports of violations or other matters concerning this Act;

(e) to issue instructions to inspectors as to actions to be taken, or take such other actions as the case may be, against any person found to be violating the provisions of this Act or the Rules promulgated pursuant thereto;

(f) to scrutinize materials submitted in accordance with Section 14 and recommend appropriate actions to be taken in the case of a violation of Chapter IV; and

(g) such other powers and functions, including the powers of an Inspector, as are conferred on him or her by the provisions of this Act and as may be prescribed.

Section 20. Registration of designated products

(1) The Minister of Health shall cause all designated products to be registered in accordance with such conditions and procedures as may be prescribed.

(2) The Minister of Health shall, by notification in the Official Gazette, fix the date after which no designated product that is not registered may be imported, manufactured or sold.

(3) A person applying for registration of a designated product shall furnish such information and samples as may be prescribed.

(4) Once the registration of a designated product has been approved, a Certificate of Registration shall be issued.

(5) No Certificate of Registration will be granted unless the designated product is in accordance with the [*insert applicable Food Quality Standards*] and has a label which is in accordance with the requirements contained in Chapter II of this Act.

Section 21. Inspectors

The Minister shall appoint such persons as he or she sees fit having the prescribed qualifications to be Inspectors for purposes of this Act within such local limits as he or she may assign to them respectively provided that no person who has any direct or indirect financial interest in any designated product shall be so appointed.

Section 22. Powers of inspectors

(1) An inspector may, within the local limits for which he or she is appointed—

(a) inspect any premises where any designated product is imported, manufactured, sold, stocked, exhibited for sale, advertised or otherwise promoted and all relevant records;

(b) institute prosecution with respect to violations of this Act and the Rules made pursuant thereto; and

(c) exercise such other powers as may be prescribed.

Section 23. Procedure for inspectors

(1) Inspectors shall inspect, not less than the number of times as may be prescribed, the premises as may be prescribed.

(2) After each inspection, the inspector shall submit a report including any finding of a violation of this Act and the Rules made pursuant thereto, to the Advisory Board and seek instructions as to the action to be taken in respect of such contravention.

(3) Institute enforcement, where applicable.

CHAPTER VI
PENALTIES, PROCEDURE

Section 24. Penalties

(1) Any person who him or herself or on behalf of any other person contravenes Sections 3, 4(1), 4(2) or 4(3) shall be punishable with imprisonment for a term which shall not be less than [*time*] or a fine which shall not be less than [*amount*] or both.

(2) Any person having been convicted of an offence under Subsection (1) and who is again convicted of an offence under that Subsection, shall be punishable with imprisonment for a term which shall not be less than [*time*] or with a fine that shall not be less than [*amount*].

(3) Any person who contravenes any other provision of this Act or the Rules made pursuant thereto may be subject to a fine of up to [*amount*] or a period of imprisonment of up to [*time*].

Section 25. Cease and desist orders, etc.

The Minister shall have the power to make cease and desist orders upon receiving a report from an inspector or the Advisory Board of a violation of the provisions of this Act or the Rules promulgated pursuant thereto.

Section 26. Certificate of registration may be suspended or revoked

Where any person has been found to have contravened any of the provisions of this Act, or the Rules pursuant thereto, the Minister, upon written recommendation of the Advisory Board, and after notice and an opportunity to be heard have been given, may suspend or revoke any Certificate of Registration that has been issued to that person pursuant to this Act.

Section 27. Professional licence may be suspended or revoked

Where any health professional has been found to have contravened any provision of this Act, or the Rules pursuant thereto, the Minister may recommend to the relevant authority the suspension or revocation of any licence for the practice of that person's profession.

Section 28. Licence, permit or authority may be suspended or revoked

[Note: *If a licence to manufacture, import or sell is required, give the Minister the power to suspend or revoke that licence.*]

Section 29. Appeal

There shall be a right of appeal to the [*insert higher court*] within 35 days of the judgment.

Section 30. Strict liability for officers, directors, etc.

When the person guilty of an offence under this Act is a corporation, company, partnership, firm or other association, every director, officer, partner, and employee of the corporation, company, partnership, firm or other association, shall also be liable for that offence unless he or she proves that the offence was committed without his or her knowledge or consent.

Section 31. Institution of prosecution

(1) Prosecution under this Act may be instituted only by—

(a) an Inspector appointed pursuant to Section 21;

(b) a member of the Advisory Board; or

(c) a representative of such voluntary organisation engaged in the field of child welfare and development or child nutrition as the Minister, by notification in the Official Gazette, may authorise in this behalf.

Section 32. Public enforcement

(1) Any person has the right to lodge a formal complaint to the Advisory Board, which may recommend that proceedings be instituted against any person relating to a violation of any provision that constitutes an offence under this Act or Rules made pursuant thereto.

(2) Any person has the right to commence an action for damages in [Court of law] against any manufacturer or distributor or other person for any harm suffered as a result of a violation of any provision that constitutes an offence under this Act or Rules made pursuant thereto.

Section 33. Power to make Rules

(1) The Ministry of Health may, by notification in the Official Gazette, make Rules for carrying out the purposes of this Act.

(2) In particular but notwithstanding the generality of the foregoing provision, such Rules may prescribe—

(a) the functions of the Advisory Board;

(b) conditions and procedures for the registration of designated products;

(c) qualifications and powers of and procedures for Inspectors appointed pursuant to the Act; and

(d) procedures for submitting educational or informational materials to the Advisory Board.

Appendix A

Selected National Measures

BOTSWANA

botswana highlights -
wait for ellen

REPUBLIC OF BOTSWANA

FOOD CONTROL ACT

(Cap. 65:05)

MARKETING OF FOODS FOR INFANTS AND YOUNG CHILDREN REGULATIONS, 2005

(Published on 17th June, 2005)

In exercise of the powers conferred on the Minister of Health by section 13 (1) of the Food Control Act, and after consultation with the National Food Control Board, the following Regulations are hereby made

Part I – *Preliminary*

1. These Regulations may be cited as the Marketing of Foods for Infants and Young Children Regulations, 2005 and shall come into operation on publication, with the exception of the parts of regulations 11, 12 and 15 relating to labelling in Setswana, which shall come into operation on the 1st July, 2007.

2. In these regulations, unless the context otherwise requires –

"Codex Alimentarius Commission" means the Joint Food Standards Programme of the Food and Agriculture Organisation of the United Nations and the World Health Organization;
"Codex Standard" means the latest version of the relevant Codex Standard as issued by the Codex Alimentarius Commission;
"complementary food" means any food suitable for use to complement breastmilk or infant formula or follow-up formula;
"container" means any packaging of foods for infants and young children and other designated products for delivery as a single unit and includes wrappers;
"designated products" includes –

(a) infant formula;
(b) formulas for special medial purposes intended for infants;
(c) follow-up formula
(d) complementary foods;
(e) beverages for infants and young children;
(f) any product marketed or otherwise presented as suitable for feeding infants and young children;
(g) feeding bottles;
(h) teats;
(i) pacifiers or dummies;
(j) breast pumps;
(k) cups with spouts or similar receptacles for feeding infants and young children; and
(l) such other products as the Minister may, by notice published in the Gazette, designate.

"distributor" means a person engaged in the business, whether wholesale or retail, of marketing or distribution or sale of foods for infants and young children or any designated products, and includes any person engaged in the business of providing information, or public relations services in relation to foods for infants and young children or designated products;

"foods for infants and young children" means a group of food products distributed, marketed or otherwise represented as suitable for infants and young children including –

(a) infant formula;

(b) formulas for special medical purposes intended for infants;

(c) follow-up formula;

(d) complementary foods;

(e) any other products marketed or otherwise represented as suitable for feeding infants and young children;

"follow-up formula" sometimes referred to as "follow-on formula", means milk or a milk-likw product of animal or vegetable origin industrially formulated in accordance with such regulations as the Minister may make and, in the absence of such regulations, in accordance with the Codex Standard for Follow-up Formula, distributed, marketed or otherwise represented as suitable for infants older than six months of age and young children;

"formula for special medical purposes intended for infants" means infant formula which is specially manufactured to satisfy the nutritional requirements of infants during the first months of life up to the introduction of complementary feeding when medically indicated;

"gift" includes designated products, meals and refreshments, diaries, stationery, calendars, cot tags, stickers, growth charts, prescription pads, tongue depressors or any free item of whatever value;

"health care facility" means any governmental, non-governmental or private institution or organisation engaged, directly or indirectly, in health care for mothers, infants, young children, pregnant women, and includes private practice, nurseries or childcare institutions; but does not include social welfare institutions;

"health worker" means any person working or training to work in a health care facility, whether or not that person is a professional or non-professional and includes voluntary or unpaid workers;

"infant" means a person from birth up to the age of 12 months;

"infant formula" means milk or a milk-like product of animal or vegetable origin formulated industrially in accordance with such regulations as the Minister may make and, in the absence of such regulations, in accordance with the Codex Standard for Infant Formula intended to satisfy the nutritional requirements of infants from birth, and includes formula for special medical purposes;

"manufacturer" means any person, corporation or other entity engaged, directly or indirectly, in the business of manufacturing food for infants and young children and other designated products;

"marketing" means promoting, distributing, selling, or advertising a designated product and includes product public relations and information services, including the use of professional service representatives such as mother craft nurses, or any person acting on behalf of a manufacturer or distributor;

"monitor" means a person appointed by the Permanent Secretary to carry out any exercise necessary to reveal contravention of these Regulations;

"promote" has the meaning assigned to it under regulation 8(1);

"sample" means a single or a small quantity of a food for infants and young children or a designated product provided without cost;

"social welfare institution" means any governmental or non-governmental organisation engaged, directly or indirectly, in providing for the social welfare of infants and young children, but does not include health care facilities;

"tie-in sales" means the sale of any designated product that is linked to a purchase of any other product including a designated product; and

"young child" means a person aged between 12 months and 3 years.

3. These Regulations apply to the marketing, and practices related thereto, of foods for infants and young children and other designated products, when imported into, marketed, distributed, sold or manufactured in, Botswana.

Part II – *Monitoring, Inspection, Stocking, etc.*

4. (1) The Permanent Secretary may designate, as monitors, such number of person he or she considers appropriate, who have undergone training on monitoring of violations of the International Code of Marketing of Breastmilk Substitutes and these Regulations.

(2) The Permanent Secretary shall issue to any person designated as a monitor, a letter of appointment and the monitor shall have such letter in his or her possession when performing any function in terms of these Regulations.

5. (1) A monitor in exercise of his or her duties shall investigate, observe and record information regarding the marketing practices of manufacturers and distributors at any points of sale, health care facilities, border posts and offices, through media, institutions and elsewhere.

(2) A monitor may for the purpose of monitoring violations of these Regulations enter, at any time, any premises which are used for dealing in foods for infants and young children or other designated products and may –

(a) require any person in the premises to furnish any information including documents in his or her possession as the monitor may require;

(b) caution the person on the premises regarding any violations of these Regulations;

(c) seize any goods, or promotional materials or documents where the goods or promotional material or documents in question contravene these Regulations.

(3) A monitor shall, after monitoring under sub-regulation (1), submit a report in writing, in relation to his or her findings to the Board.

(4) In any proceedings under these Regulations, a report signed by a monitor shall be accepted as *prima facie* evidence of the facts stated therein.

(5) No monitor shall have any direct or indirect commercial interest in infant and young child feeding.

(6) A monitor, acting in accordance with these Regulations, shall if required by any person, provide proof of his or her authority.

(7) An owner, occupier or person in charge of any premises entered by a monitor shall give to the monitor all reasonable assistance and shall furnish him or her with such information as the monitor may reasonably require.

(8) No person may obstruct or impede a monitor in the course of performance of his or her duties.

(9) No person may knowingly make any false or misleading statement, either verbally or in writing, to any monitor engaged in carrying out his or her duties.

6. (1) An authorised officer shall implement these Regulations under the powers vested on him or her by the provisions of Section 6 of the Food Control Act.

(2) No authorised officer shall have any direct or indirect commercial interest

7. (1) No person shall stock, distribute, sell or exhibit any foods for infants and young children which have expired or are beyond their shelf life.

(2) No person shall stock, distribute, sell or exhibit any foods for infants and young children or other designated products which are not in their original containers.

(3) A container of foods for infants and young children, for sale or distribution, shall be free from dents or any other form of damage and shall be kept –
(a) in a cool and dry place;
(b) at least 50 cm from the floor; and
(c) in a hygienic manner.

Part III – *Prohibition against Promoting, Advertising, etc*

8. (1) For the purpose of this regulation, "promote" includes –
(a) any direct or indirect method of introducing a designated product or encouraging the buying or use of a designated product;
(b) sale devices such as rebates, special displays to promote sales, tie-in sales, loss leaders, grant of rewards, discount coupons, premiums, special sales, prizes, gifts and giving of samples to mothers;
(c) direct or indirect contact between marketing personnel and member so the public in furtherance of or for the purpose of promoting the business of designated products and indirect contact includes television and radio, telephone or internet help lines, mother and baby clubs and baby competitions;
(d) electronic communication including website, internet and electronic mail;
(e) promotional items such as clothing, stationery or items that refer to a designated product or to a brand name of a designated product;
(f) outdoor advertisements such as billboards;
(g) placard and newspaper or magazine inserts;
(h) practices that create an association between a manufacturer or distributor and breastfeeding.

(2) No person shall –
(a) promote or cause to be promoted, foods for infants and young children or other designated products;
(b) engage in promotional activities of any designated products;
(c) publish or cause to be published any advertisement for any designated product;
(d) advertise or cause to be advertised any designated product.

(3) No manufacturer or distributor shall –

(a) distribute or cause to be distributed any information or educational material relating to infant or young children nutrition or feeding, except in accordance with these regulations;

(b) offer or give or cause to be offered or given, any benefit to a health worker, including, fellowships, study grants, funding for attendance of meetings, seminars, continuing education or conferences;

(c) fund any research, clinical or otherwise, carried out by any health worker on any designated product, except in accordance with a protocol approved by the relevant authority in writing;

(d) directly or indirectly, provide any support, financial or otherwise, to any *(missing text, waiting for reply to fill in this text here)*

(e) employ any persons to provide to health workers in health care facilities, pregnant women, or mothers of infants and young children or any persons with education or instructions regarding the use of a designated product.

(f) sell, donate or distribute or cause to be sold, donated or distributed in a health care facility, any –

(i) equipment, materials or any other services with any reference to any designated products or contain the name or logo of any manufacturer or distributor of any designated product,

(ii) foods for infants and young children or other designated products at a price lower than the published wholesale price or in the absence of such price, lower than 80% of the retail price.

(g) calculate a bonus payment based on the volume of sales of any designated product; or

(h) set a quota for the sale of any designated product as a sales incentive.

(4) Notwithstanding the provisions of sub-regulation (3)(a), manufacturers and distributors may give information about designated products to health professionals if such information is restricted to scientific and factual matters regarding the technical aspects and methods of use of designated products and in accordance with regulations 15 and 16.

(5) Sub-regulation 3(f)(ii) shall not apply where a donation or low price sale is made to an orphanage or other social welfare institution for infants who have to be fed on designated products and shall not prevent the Government from procuring foods for infants and young children, for its feeding programme or for social welfare purposes, at the lowest possible price through bidding procedures.

(6) Donations or low price sales made to orphanages or other social welfare institutions, whether for use in the institutions or for distribution outside them, as provided for under subregulation (5) should be sustained once started and should continue as long the beneficiaries need them.

(7) Manufacturers shall not make donations as referred to in subregulation (5) or set low price sales as sales inducements.

(8) Marketing personnel in their business capacity shall not seek direct or indirect contact of any kind with pregnant women, or with caregivers, or mothers of infants and young children intended to further commercial interests.

9. (1) Health workers shall –
(a) promote and support breastfeeding, unless medically indicated;
(b) keep a records register of contraventions of the provisions of these Regulations by manufacturers or distributors in their respective health care facilities; and
(c) provide the records under subregulation (1) (b) to monitors and authorized officers.

(2) Health workers shall not –
(a) accept from manufacturers or distributors any of the following offers:
(i) gift,
(ii) financial assistance,
(iii) fellowships, study tours, research grants, funding for attendance of conferences,
(iv) samples of foods for infants and young children or other designated products, or
(v) quantities of foods for infants and young children or other designated products at a price lower than the published wholesale price, or in the absence of such price, lower than 80% of the retail price.
(b) display foods for infants and young children or other designated products.

(3) Subregulation (2) shall not apply to –
(a) research activities approved by the health research authority in writing; or
(b) quantities of foods for infants and young children or other designated products for social welfare purposes provided under the Government feeding programmes and in terms of such guidelines as the Board may from time to time approve.

Part IV – *Labelling, Warning, Preparation, etc.*

10. (1) Except to the extent otherwise provided in these Regulations or any other regulations made under the Act, every food for infants and young children shall be labelled in accordance with the Labelling of Pre-packaged Foods Regulations.

(2) Every label on the container of a food for infants or young children shall contain, in written and simple English and Setswana, the following information which shall appear in bold and conspicuous characters in a prominent position on the container –
(a) instructions for the appropriate preparation in words or easily understood graphics;
(b) instructions for the proper sterilisation of equipment and utensils;
(c) a warning about the health hazards of incorrect preparation or use of the product;
(d) the recommended age for use of the product, which in the case of complementary foods should not be before the age of 6 months;
(e) the dangers of introducing the product prior to the recommended age;
(f) the name of the product;
(g) the composition and analysis of the product;
(h) nutritional information of the product;
(i) the batch number of the product;
(j) correct storage instructions of the product;
(k) the country of origin of the product;
(l) the date of manufacture of the product;
(m) the net weight of a solid product;

(n) the net volume of a liquid product;
(o) the name and address of the manufacturer of the product;
(p) the date of expiry of the product, which shall be indented and stated in order of day, month and year; and
(q) the list of ingredients used.

(3) A label on a container for food for infants and young children shall not contain –
(a) pictures of infants, women, animals or toys or any other picture or text or any symbol depicting a health advantage which idealises food for infants and young children or other designated product;
(b) any information comparing breastmilk to foods for infants and young children or other designated products.

(4) No nutrition or health claims shall be made with regard to ingredients or nutrients that are required as a part of the essential composition of a food for infants and young children.

(5) Only infant formula may be marketed or otherwise presented as suitable for infants younger than 6 months of age.

11. (1) No person shall sell infant formula or follow-up formula unless the container or label affixed thereto, contains the following information in written and simple English and Setswana –
(a) in bold and conspicuous characters in a prominent position and in not less than 50% of the size of the largest words on the container or label and not less than 2mm in height –
"IMPORTANT NOTICE: A MOTHER'S BREASTMILK IS BEST FOR HER BABY. CONSULT YOUR HEALTH WORKER BEFORE YOU DECIDE TO USE THIS PRODUCT"; and
(b) stating the dangers of using leftover formula.

(2) The label on any container of infant formula or follow-up formula shall not include words such as "maternalised", "humanised" or terms similar thereto nor any comparison to breastmilk.

12. (1) The label on any container of infant formula or follow-up formula shall contain the following words in bold and conspicuous characters in a prominent position and in not less than 50% of the size of the largest words on the label not less than 1.5mm in height –
"WARNING:
FOLLOW THE INSTRUCTIONS FOR PREPARATION CAREFULLY OR YOUR BABY MAY BECOME ILL. DO NOT USE MORE OR LESS THAN THE QUANTITIES INDICATED. CUP FEEDING IS SAFER THAN FEEDING FROM A BOTTLE".

(2) The label on any container of follow-up formula shall also state that the product shall not be used for infants younger than six months.

(3) The label shall have graphic representations illustrating the method of preparation of the product and methods of feeding using feeding cups and feeding bottles.

13. The label on any container of the following types of milk –

(a) sweetened;
(b) condensed;
(c) evaporated;
(d) dried;
(e) skimmed;
(f) low fat;
(g) imitation milk-like dairy products; or
(h) standardised milk

shall contain the following words in bold and conspicuous characters not less than 2mm in height –

"THIS PRODUCT IS NOT SUITABLE FOR FEEDING BABIES".

14. (1) A label, package or container of a feeding bottle or teat shall include, in simple written English and Setswana –
(a) a statement of the superiority of breastmilk for feeding infants;
(b) a statement that feeding with a cup is safer than bottle feeding;
(c) instruction for proper cleaning and sterilisation of feeding bottle and teat;
(d) a warning of potential health hazards of using feeding bottle especially if it is not properly sterilised;
(e) the need to follow preparation instructions carefully;
(f) the name and address of manufacturer or distributor.

(2) A label, package or container of a feeding bottle or teat shall not contain pictures of infants, women or infant toys nor any other picture or text or any symbol depicting a health advantage which idealises artificial feeding.

(3) A label of a dummy shall include, in simple written English and Setswana –
(a) a notice that the use of such dummy can interfere with breastfeeding;
(b) instructions for proper cleaning and sterilisation of the dummy;
(c) a warning on potential health hazards of using a dummy especially if it is not properly sterilised.

(4) A label of a dummy shall not contain pictures of infants, women, animals or toys nor any other picture or text or any symbol depicting a health advantage which idealises artificial feeding over breastfeeding.

(5) A label of a breast pump shall have written instructions in simple English and Setswana, for proper use, cleaning and sterilisation of the breast pump.

Part V – *Information and Educational Materials*

15. (1) Notwithstanding any other provision of these Regulations, no person shall, directly or indirectly, distribute any educational material or any information relating to infant or young child feeding in Botswana without the approval of the Board.

(2) Any educational material or information, written, audio or visual, electronic or otherwise, relating to infant feeding shall explain –
(a) the importance, benefits and superiority of breastfeeding during the first 2 years of the life of a child;
(b) the value of exclusive breastfeeding for the first six months of life followed by sustained breastfeeding for at least the first 2 years of the life of a child;
(c) the preparation for and the continuance of breastfeeding;

(d) factual and current information and shall not use any pictures or texts discouraging breastfeeding;
(e) how bottle feeding interferes with breastfeeding;
(f) the difficulty in reverting to breastfeeding after a period of formula feeding; and
(g) how the early introduction of complementary foods interferes with breastfeeding.

(3) The educational material or information referred to in subregulation (2) shall not make any reference to the brand name of food for infants and young children or any designated product or the name or logo of any manufacturer or distributor.

16. (1) Where the educational material or information referred to in regulation 15 includes the topic of the feeding of infants with infant formula or follow-up formula, it shall include –
(a) instructions for the proper preparation and use of the product in question including the cleaning and sterilisation of feeding utensils;
(b) the health hazard of bottle feeding and improper preparation of the product;
(c) the importance and proper instructions on cup feeding; and
(d) the approximate financial costs of the product in question if used in recommended quantities for a period of six months.

(2) Where the material referred to in regulation 15 includes the topic of infant feeding with complementary food, it shall explain –
(a) the health hazards of introducing complementary foods too soon or too late; and
(b) that complementary foods can easily be prepared at home using indigenous ingredients.

(3) Feeding with infant formula, follow-up formula or complementary foods whether manufactured or home prepared, shall 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 shall include a clear explanation of the hazards of improper use.

Part VI – *Offences and Penalties*

17. (1) A person who contravenes a provision of these Regulations commits an offence and is liable –
(a) for a first offence, to a fine not exceeding P1 000.00 or to imprisonment for a term not exceeding 3 months, and where the offence is a continuing offence, to an additional fine not exceeding P500.00 or imprisonment for a term not exceeding one month for each day on which the offence continues; and
(b) for a second or subsequent offence, to a fine not exceeding P5 000.00 or to imprisonment for a term not exceeding six months, and where the offence is a continuing offence, to an additional fine not exceeding P2 000.00 or imprisonment for a term not exceeding two months for each day on which the offence continues.

(2) Notwithstanding the provisions of subregulation (1), the Board may recommend to the Minister, any other action to be taken against any manufacturer, distributor, health worker or other person who contravenes the provisions of these Regulations.

(3) On the conviction of any person for an offence under these Regulations, the Minister may cancel, or suspend any licence issued to that person which is relevant to the offence committed.

(4) Where a person has been convicted of an offence under these Regulations, the Minister may order that any article relevant to the offence be forfeited and that it be destroyed or otherwise disposed of, as the Minister considers appropriate.

18. Where an offence under these regulations which has been committed by a body corporate is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, a director, manager, secretary or other similar officer of the body corporate, or any person who was purporting to act in such capacity, he or she as well as the body corporate, shall be guilty of an offence and liable to a fine not exceeding P1000.00 or to imprisonment for a term not exceeding 3 months, or to both.

MADE this 8th day of June, 2005.

SHEILA TLOU,
Minister for Health

L2/7/288 III

BRAZIL

Brazil

Relevant National Measures

1. **Brazilian Standard for Marketing of Foods for Infants and Young Children, Teats, Dummies and Feeding Bottles (Norma Brasileira de Comercialização de Alimentos para Lactentes e Crianças de Primeira Infância, Bicos, Chupetas e Mamadeiras), Decree Nº 2051, 8 November 2001**

2. **Brazil, Technical Regulation on Commercial Promotion of Foods for Infants and Young Children (Regulamento Técnico para Promoção Comercial dos Alimentos para Lactentes e Crianças de primeira Infância), Resolution-RDC N° 222, 5 August 2002**

3. **Brazil Technical Regulations, Dummies, Teats, Bottles and Nipple Shields (Regulamento Técnico Chupetas, Bicos, Mamadeiras e Protetores de Mamilo), Resolution-RDC N° 221, 5 August 2002**

Highlights

Brazil first adopted regulations concerning the marketing of infant foods in 1988. The Ministry of Health revised those regulations in 1992. In 2001, the regulations were again reviewed and the Ministry of Health adopted new regulations by Decree. Ministry of Health Decree No. 2051 (November 2001) deals with the relationships between manufacturers and the health care system and health professionals as well as with educational and 'technical-scientific' materials on infant and young child feeding. In 2002, the National Health and Food Control Agency (ANVISA) also adopted regulations on promotion and marketing of foods for infants and young children. In the same year, ANVISA adopted a separate set of regulations pertaining to the promotion and marketing of feeding bottles, teats, dummies and nipple shields.

The scope of the Decree and Technical Regulations cover a wide range of products including infant formula and follow-up formulas for infants; follow-up formula for young children from one to three years of age; liquid and powdered milks; transitional foods and cereal-based foods for infants and young children; formulas for certain high-risk newborns; feeding bottles, teats, dummies and nipple shields.

Commercial promotion is prohibited for infant formula, follow-up formula for infants and for feeding bottles, teats, dummies and nipple shields. Promotion for follow-up formulas for children from one to three years old is allowed if it includes the following statement:

> *The Ministry of Health says: "Breastfeeding prevents infections and allergies and is recommended up to two years of age or more."*

Commercial promotion for foods for infants and young children is allowed provided that the following statement is included:

> *The Ministry of Health says "After the first six months continue breastfeeding your baby in addition to giving new foods".*

The regulations have extensive provisions on the labelling of the various products within the scope and require specific notices encouraging exclusive and continued breastfeeding as well as warnings about the health risks of using such products. Illustrations of any type are prohibited from labels of infant formula and follow-up formula for infants. Labels for infant foods must state the following:

> *The Ministry of Health says: "This product should not be used for children under six months, except upon prescription from a doctor or a nutritionist. Breastfeeding prevents infections and allergies and is recommended up to two years or more."*

Labels of feeding bottles, teats and dummies must include the following warning on the label:

> *The Ministry of Health says: "A breastfed baby does not need bottles, teats or dummies. The use of bottles, teats or dummies interferes with breastfeeding and prolonged use is harmful to the baby's teething and speech."*

Manufacturers and distributors may not produce or sponsor educational materials on infant and young child feeding. Educational materials dealing with feeding of young children must meet the requirements of the regulations.

Free supplies are prohibited and samples of formula or complementary foods may only be provided to health professionals when a new product is launched. Samples of feeding bottles, teats, dummies and nipple shields are not allowed at all.

Manufacturers and distributors may provide financial support only to scientific research or teaching institutions or to nationally recognized associations of paediatricians or nutritionists. Institutions that receive financial support must ensure that the company does not promote products at a sponsored event and that the financial contribution is disclosed in event materials.

The ban on promotion within health care facilities extends to teaching and research institutions. Institutions that train or educate health workers must include information about these Regulations as well as strategies to implement them in programmes that deal with infant feeding.

Translation from Portuguese

BRAZIL

OFFICIAL JOURNAL No. 215, Section 1
9 November 2001

OFFICE OF THE MINISTER OF HEALTH

DECREE No. 2051 of 8 November 2001

The Minister of State for Health, in the exercise of his attributions, considering:

- The recommendations of the World Health Assembly (WHO) and the United Nations Children's Fund (UNICEF), the UNICEF/WHO Innocenti Declaration, the International Code of Marketing of Breastmilk Substitutes approved by the World Health Assembly in 1981 and the relevant subsequent WHA resolutions;

- The importance of those international standards which were approved as minimum requirements to promote healthy infant feeding practices;

- The provisions of Art. 11.1 of the International Code of Marketing of Breastmilk Substitutes, which calls on governments to adopt their own national legislation to implement the principles and aims of the Code;

- The commitment made by the Government of Brazil at the Children's Summit in New York, in 1990, to promote, protect and support exclusive breastfeeding for the first six months, and continued [breastfeeding] up to two years or more, with introduction of new foods;

- The provisions of Decree Law No 986 of 21 October 1969 (establishing basic food standards), and of Law No 6437 of 20 August 1977 (providing sanctions for violations of federal health legislation), and of Law No 8069 of 31 July 1990 (the Children and Adolescents Statute), and of Law No 8078 of 11 September 1990 (on consumer protection);

- The need to revise and update the Brazilian Standard for Marketing of Infant Foods (NBCAL) established by Resolution No 31 of 12 October 1992;

Hereby resolves:

Art. 1: To establish the new provisions of the **Brazilian Standard for Marketing of Foods for Infants and Young Children, Teats, Dummies and Feeding Bottles**, applicable to the whole national territory and appearing as an ANNEX to this Decree of which it is an integral part.

Art. 2: This Decree shall enter into force on the date of its publication.

BARJAS NEGRI

ANNEX

The **Brazilian Standard for Marketing of Foods for Infants and Young Children, Teats, Dummies and Feeding Bottles** shall be applied in accordance with the following rules:

Art. 1 – The aim of this Standard is to contribute to the appropriate nutrition of infants and young children, by means of:

I – Regulation of the marketing of and instructions for the correct use of foods for infants and young children, as well as the use of feeding bottles, teats and dummies;

II – Protection and promotion of exclusive breastfeeding for the first six months of life;

III – Protection and promotion of continued breastfeeding up to two years, with introduction of new foods into the infants diet.

Art. 2 – This Standard shall apply to the marketing and instructions for correct use of the following products, whether manufactured in the country or imported:

1) Infant formulas for infants and follow-up formulas for infants;

2) Follow-up formulas for young children;

3) Liquid milks, powdered milks, modified milks and milks of plant origin;

4) Transitional foods and cereal-based foods suitable for infants and/or young children, as well as other foods or beverages, milk-based or not, when marketed or otherwise presented as suitable for infants and young children;

5) Nutrient formulas presented as and/or suitable for high-risk newborns;

6) Feeding bottles, teats and dummies.

Art. 3 – For purposes of this Standard, the following definitions shall apply:

1) **Breastmilk substitute**: Any food marketed or otherwise presented as a partial or total replacement of breastmilk and/or human milk*

2) **Transition food for infants and young children**: Any industrialised food for direct consumption or as part of a home-made food, which is used as a complement to breastmilk or to infant formula and is introduced into the diet of infants and young children with the aim of adapting gradually to the common family foods and of providing a balanced diet adapted to her/his needs, according to her/his physiological maturity and neuropsychomotor development. Such a food is also called complementary food (Portaria 34/98 - SVS/MS).

3) **Cereal-based food for infants and young children**: Any cereal-based food suitable for feeding infants after their sixth month and young children, according to their physiological maturity and neuropsychomotor development.

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* *Translator's note*:
The original text in Portuguese speaks of "breastmilk and/or human milk" each time the term is mentioned. Only "breastmilk" is used in the remainder of this English text.

4) **Sample**: A single unit of a product provided free of charge once only.

5) **Special presentation**: Any presentation of a product for purposes of commercial promotion with the aim of inducing to a purchase or sale, such as promotional packaging, decorative packaging, kits with other products not included in the scope of this Standard.

6) **Teat**: An article presented as or suitable for the process of a child's nutritional sucking, with the purpose of administering or providing foods or liquids.

7) **Child**: Any person up to the age of 12 years.

8) **Young child:** Any child from 12 months to 3 years old (Codex Alimentarius Commission).

9) **Dummy**: An artificial teat for the baby to suck on, without the purpose of providing food, medicine or liquids.

10) **Highlighted**: Any manner of showing up a warning, a sentence or text; when written, it shall have a font size at least equal to that of the largest letters used in the information and be in bold, upper case; when audio, it shall be done in a clear and audible manner.

11) **Donation**: Free supply of a product in any quantity larger than a sample.

12) **Distributor**: Any physical or legal person or any other entity, in the public or private sector, directly or indirectly involved in the marketing and/or importation, at wholesale or retail level, of any product within the scope of this Standard.

13) **Kit**: A packet containing one or more products of different brands in varying quantities, shapes or sizes.

14) **Special display**: Any way of exposing a product so as to make it more prominent than others within a sales outlet, such as, but not limited to, display in a shop window, at the top of a show boat, in a product pyramid or island, through shelf talkers or decorations.

15) **Packaging**: The container, box or packet for conservation, transport and handling of a product.

16) **Importer**: Any private or public company or entity that imports a product included in the scope of this Standard.

17) **Manufacturer**: Any private or State company or entity involved in manufacturing a product included in the scope of this Standard.

18) **Infant formula for infants**: A product, in liquid or powder formulation, to feed infants up to the sixth month of life, upon prescription, intended to partially or totally replace breastmilk and to satisfy the nutritional requirements of infants in this age bracket (Portaria N.º 977/98 da SVS/MS).

19) **Infant formula for specific dietary or therapeutic needs**: A formula whose composition has been adapted to suit the specific requirements of infants with temporary or permanent physiological and/or pathological needs and that is not covered by the specific technical regulation on infant formulas.

20) **Follow-up formula for infants**: A liquid or powder product used, when prescribed, to replace breastmilk for infants above six months (Portaria N.º 977/98 da SVS/MS).

21) **Follow-up formula for young children**: A liquid or powder product used to replace breastmilk for young children.

22) **Infant**: A child up to the age of one year (i.e. from zero to 11 months and 29 days).

23) **Modified milk**: A milk that has been classified as such by the Ministry of Agriculture.

24) **Educational material**: Any written or audio-visual material intended for the general public, such as flyers, brochures, books, newspaper articles, cassette tapes, video tapes, Internet [information] or other forms, that purports to give guidance on the appropriate use of products for infants and young children.

25) **Technical-scientific material**: Any material containing proven technical and/or scientific data about products or related to knowledge of nutrition and paediatrics, intended for health professionals and health workers.

26) **Marketing personnel**: Professional staff (sales persons, sales promoters, demonstrators or company representatives) directly or indirectly remunerated by manufacturers and/or importers of products included in this Standard.

27) **Health professional**: A person with higher [university] level, in the health care area.

28) **Health worker**: A staff or worker without a university degree who works in the health care system as technical or nursing staff, attendant or otherwise, including volunteers.

29) **Commercial promotion (or marketing)**: Information and persuasion activities deployed by companies involved in the production and/or handling, distribution and marketing [of products], with the purpose of leading to the purchase or sale of a product, including the dissemination of information by written or audio-visual means, and direct or indirect contact with health professionals. This definition does not include direct or indirect contact with health professionals aimed at providing technical-scientific materials about products.

30) **High-risk newborn**: An infant born with less than 2,500 grammes weight or, an infant who immediately after birth presents [signs of] a pathology requiring intensive care.

31) **Label**: Any inscription, text, picture or any graphic or descriptive material that is written, printed, stamped, engraved, lithographed, sealed or adhered to the packaging of a product.

32) **Health care system**: The ensemble of private and public institutions and entities that provide services for the protection, promotion and recovery of health, including rehabilitation.

33) **Nutrient formula for high-risk newborns**: A composite of nutrients presented and/or prescribed for feeding premature newborns and/or high-risk newborns.

34) **Competent monitoring authority:** An official of the relevant body of the federal, state or municipal government or of the Federal District responsible for Health Inspection or for Consumer Protection.

Art. 4 - Commercial promotion of products referred to in Art. 2, paragraphs 1, 5 and 6 above shall be banned, by any means of communication, including merchandising, dissemination via electronic, written or audio-visual means, promotional strategies aimed at increasing retail sales, such as special displays, discount coupons, below-cost price, prizes, gifts, sales linked to products not covered by this Standard and special presentations.

Art. 5 – The rules for marketing of infant foods covered by Art. 2, paragraphs 2, 3 and 4 and the rules for labelling of products covered by Art. 2 of this ANNEX shall abide by the specific regulations published by the National Health Control Agency.

Art. 6 – Foods for infants and young children, as well as feeding bottles, teats and dummies shall conform to the quality standards set by the relevant national legislation.

Art. 7 – Public health institutions, including health control bodies, teaching and research institutions, professional paediatrics and nutrition associations shall be responsible for ensuring that information on infant and young child feeding provided to families, health professionals and the general public is consistent and objective. Such a responsibility shall include the production, obtaining, dissemination and monitoring of information in the area of human resources training.

Art. 8 – Any educational or technical-scientific material, in any form, that deals with infant feeding, shall comply with the provisions of this Standard and shall include clear information on the following points:

- The benefits and superiority of breastfeeding;
- Guidance on appropriate feeding of pregnant and lactating mothers, with emphasis on the initiation and maintenance of breastfeeding up to two years or more;
- The negative impact of the use of feeding bottles, teats and dummies on natural breastfeeding, and particularly the difficulty of reversing a decision not to breastfeed;
- The economic implications of opting for breastmilk substitutes, in addition to the harmful effects for the infants' health resulting from the use of dummies, teats and feeding bottles when using other foods to replace breastmilk.

§ 1. Educational and technical-scientific materials shall not contain pictures or text, including those of health professionals or health authorities, that recommend the use of dummies, teats and feeding bottles or the use of breastmilk substitutes, or that may lead to their use.

§ 2. Educational materials that deal with infant feeding shall not be produced nor sponsored by manufacturers, importers or distributors of products covered by this Standard.

Art. 9 – Any educational materials, in any form, that deal with feeding young children, shall comply with the provisions of this Standard and shall include clear information on the following points:

- The benefits and superiority of breastfeeding;
- Guidance on appropriate feeding of pregnant and lactating mothers, with emphasis on the initiation and maintenance of breastfeeding up to two years or more;
- The negative impact of the use of feeding bottles, teats and dummies, particularly [the dangers of improper] cleanliness and preparation;
- The economy and the importance of developing [healthy] cultural habits by using the family foods.

Additional paragraph: Such educational materials shall not contain pictures nor text, including those of health professionals or health authorities, that may encourage or lead to the use of dummies, teats and feeding bottles or to the use of breastmilk substitutes.

Art. 10 – Manufacturers, distributors and importers shall be allowed to give samples of products listed under Art. 2, paragraphs 1, 2, 3 and 4, to paediatricians and nutritionists only once, at the time of the launch of said products, in compliance with the specific legislation of the National Health Control Agency.

Additional paragraph: The distribution of samples of nutritional supplements intended for high-risk newborns, as well as samples of feeding bottles, teats and dummies, shall not be permitted.

Art. 11 – Manufacturers, importers and distributors of products covered by this Standard shall be allowed to provide financial and/or material incentives or sponsorship only to scientific research or teaching institutions or to paediatricians or nutritionists associations that are officially registered in the whole country; therefore, any form of incentive to individuals shall be banned.

§ 1. Any institution or entity that receives an incentive or sponsorship shall be responsible for ensuring that the [sponsoring] companies do not make any commercial promotion of their products at the events that they sponsor; they shall [however] be allowed to distribute only technical-scientific materials, in conformity with the provisions of this Standard.

§ 2. Any sponsored events shall include in their information materials the following sentence: “This event has been sponsored by private companies, in conformity with the Brazilian Standard for Marketing of Foods for Infants and Young Children, Teats, Dummies and Feeding Bottles”.

Art. 12 – Donations or below-cost sales of products covered by this Standard for promotional purposes to maternities and other child-care institutions, either for use by the institutions themselves or for distribution to out patients, shall be banned.

§ 1. This ban shall not apply to donations or below-cost sales in situations of exceptional individual or collective need. In such situations, the supply of the products shall be guaranteed for as long as the infants concerned need them. The donated products may bear the name and logo of the donator, but shall not [be used to] advertise the products.

§ 2. Donations [of products] for purposes of research shall be allowed only after approval of a [research] protocol by the Research and Ethics Committee of the institution to which the professional is attached, in conformity with the provisions of Resolution 01/88 of the National Health Council approving the Health Research Standards, and of Resolution 196/

96 of the National Health Council approving guidelines and regulations for research involving human beings.

§ 3. Any products donated for research shall be identified as such on the front panel with the following highlighted sentence: "Donated for research in accordance with existing legislation."

Art. 13 – Marketing personnel shall not be permitted in health care facilities, except for contacts with paediatricians and nutritionists in which they shall restrict [their information] to the technical-scientific aspects [of products] and include the specific information required by Articles 8, 9 and 10.

Additional paragraph: Manufacturers, distributors and importers shall inform their marketing personnel, as well as any advertising agencies that they contract, of the contents of this Standard and their responsibilities in complying with it.

Art. 14 – The bodies of the National Health Care System (Sistema Único de Saúde), under guidance of the Ministry of Health, shall be responsible for the dissemination, implementation and monitoring of this Standard.

Additional paragraph: The Ministry of Health, the State Secretariats of Health and the equivalent municipal authorities shall, whenever necessary, call upon other government agencies to ensure implementation of this Decree.

Art. 15 – Teaching and research institutions, as well as health units of any kind, shall not promote any products under the scope of this Decree.

§ 1. If such institutions or services receive sponsorship [from manufacturers, importers or distributors] they shall include in their information material, highlighted, the requirement of Art. 17 of this Decree and the sentence required by Art. 11, § 2.

§ 2. The institutions or entities that have received any kind of support for research shall, in their publications, name the company that provided support.

§ 3. In any information disseminated prior to an event that has received sponsorship and particularly during the event, the leadership of the teaching or research institutions or the health care institution involved shall be responsible for ensuring that there is no commercial promotion [of products covered by this Standard]. The leadership of said institutions shall also ensure that no marketing personnel [of manufacturers, importers or distributors] is present in creches, maternity wards or other units that provide care for infants, young children, pregnant women or breastfeeding women, nor in the areas adjacent to them.

Art. 16 – Institutions that train or educate health professionals and health workers shall include the dissemination of information about this Standard and strategies for its implementation in the programmes that deal with infant feeding.

Art. 17 – It shall be the responsibility primarily of health professionals and health workers to encourage exclusive breastfeeding for six months and continued breastfeeding up to two years and beyond.

Additional paragraph: Health professionals and health workers, particularly those linked to the National Health Care System (Sistema Único de Saúde) and to [private health care] institutions that have signed an agreement with said System, shall contribute to the dissemination of knowledge about this Decree, to its implementation and its monitoring.

Art. 18 – Only a doctor or a nutritionist shall prescribe feeding with infant formula for infants and with follow-up formula for infants. Other appropriately trained health professionals or health workers may give individual guidance for or a demonstration of the use of such formula.

Art. 19 – Health professionals and health workers shall not give samples of products covered by this Decree to pregnant women or lactating women or to their families.

Art. 20 – Manufacturers, distributors and importers, government agencies and non-governmental organizations, particularly consumer protection associations, private health or social welfare institutions, as well as community associations of health professionals and health workers shall be encouraged to work with the health care system to ensure compliance with this Decree.

Art. 21 – Primary and secondary schools shall inform [pupils] about this Decree.

Art. 22 – Manufacturers shall inform all their marketing staff, including advertising agencies that they contract, about this Decree and their responsibility to comply with it.

Art. 23 – Sanctions for non-compliance with this Decree shall be applied progressively, according to the gravity and frequency of infringements. The penalties provided for in Law No. 6437 of 20 August 1977 shall apply.

Art. 24 – For compliance with this Standard the relevant provisions of the following legislation shall also apply: Consumer Protection Code – Law No. 8078 of 11 September 1990, amended by Law No. 8656 of 21 May 1993; Regulation approved by Decree No 861 of 9 July 1993; Decree-Law No. 986/69; Decree No. 2181/97; Law No. 6437/77 – the Children and Adolescents Statute; Resolution No. 1/88 of the National Health Council; Resolution No. 196/96 of the National Health Council; Decree SVS No. 34/98; Decree SVS No. 36/98; Decree SVS No. 977/98 and Resolution No. 10/99.

Art. 25 – Manufacturers, importers and distributors of foods shall have 180 days from the date of publication of this Decree to make the necessary changes and adaptations to comply with it. During this period, the provisions of Resolution CNS No. 31/92 and other relevant legislation shall continue to apply. At the end of the 180-day period, Resolution CNS No. 31/92 shall be considered revoked.

Translation by JP Allain ©
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Translation from Portuguese

BRAZIL

OFFICIAL JOURNAL – No. 150 – Section 1 – 6 August 2002

NATIONAL FOOD SAFETY MONITORING AGENCY
Board of Management

Resolution RDC No 222, 5 August 2002

The Board of Management of the National Food Safety Monitoring Agency (ANVISA), in exercise of the attributions granted to it by Art. 11, para IV, of the ANVISA Regulations approved by Decree No 3029 of 16 April 1999, c/c of § 1º of Art. 111 of the Rules of Procedure approved by Decree (Portaria) No. 593, of 25 August 2000, reproduced in the Official Journal of 22 December 2000, meeting on 31 July 2002; considering

- the need to constantly improve food safety controls for the benefit of public health;
- the recommendations of the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF); the Innocenti Declaration on Protection, Promotion and Support of Breastfeeding approved by WHO and UNICEF in 1990; the International Code of Marketing of Breastmilk Substitutes adopted by the World Health Assembly in 1981 and the subsequent relevant Resolutions of the WHA;
- the minimum requirements to promote healthy infant and young child feeding practices;
- the commitment made by the Government of Brazil at the Children's Summit in New York, in 1990, to promote, protect and support exclusive breastfeeding during the first six months of life, followed by the introduction of other foods and continuation of breastfeeding up to two years or more;
- the provisions of the Consumer Protection Law No. 8078 of 11 September 1990,

has adopted the following Resolution of the Board of Management and I, Director-President, hereby determine that it shall be published:

Art. 1 - To approve the Technical Regulation on Commercial Promotion of Foods for Infants and Young Children that appears as annex to this Resolution.

Art. 2 - Companies have up to 180 (one hundred and eighty) days from the date of publication of this Regulation to adapt [their behaviour and products to its provisions].

Art. 3 - Non-compliance with the provisions of this Resolution shall constitute infringement of health regulations subject to the provisions of Law No 6437 of 20 August 1977 and to other applicable legislation.

Art. 4 - This Resolution shall enter into force on the date of its publication.

GONZALO VECINA NETO

ANNEX

Technical Regulation on Commercial Promotion of
Foods for Infants and Young Children

1. SCOPE

1.1. **Aim**
To regulate the commercial promotion and instructions for appropriate use of foods for infants and young children.

1.2. **Scope**
This Regulation shall apply to the commercial promotion and instructions for use of the following products, whether manufactured in the country or imported:

1.2.1. Infant formulas and follow-up formulas for infants.

1.2.2. Follow-up formulas for young children.

1.2.3. Liquid milks, powdered milks, modified powdered milks, milks from diverse animal species and similar plant-based products.

1.2.4. Transition foods and cereal-based foods suitable for infants and/or young children, as well as other foods or beverages, whether milk-based or not, if they are marketed or otherwise represented as suitable for infants or young children.

1.2.5. Nutrient formulas presented as suitable and/or intended for high-risk newborns.

2. Definitions[1]

2.1. **Breastmilk substitute**: Any food marketed or otherwise presented as a partial or total replacement of breastmilk and/or human milk[2].

2.2. **Transition food for infants and young children**: Any industrialized food for direct consumption or as part of a home-made food, which is used as a complement to breastmilk or to infant formula and is introduced into the diet of infants and young children with the aim of adapting gradually to the common family foods and of providing a balanced diet adapted to her/his needs, according to her/his physiological maturity and neuropsychomotor development.

2.3. **Cereal-based food for infants and young children**: Any cereal-based food suitable for feeding infants after their sixth month and young children, according to their physiological maturity and neuropsychomotor development.

2.4. **Sample**: A single unit of a product provided free of charge at one time.

2.5. **Special presentation**: Any presentation of a product for purposes of commercial promotion with the aim of inducing to a purchase or sale, such as promotional packaging, decorative packaging, kits with other products not included in the scope of this Regulation.

Translator's notes:

[1] The definitions are listed and numbered in the Portuguese alphabetical order, as in the original.

[2] The original text in Portuguese speaks of "breastmilk and/or human milk" each time the term is mentioned. Only "breastmilk" is used in the remainder of this English text.

2.6. **Competent monitoring authority:** An official of the relevant body of the federal, state or municipal government or of the Federal District responsible for Health Inspection, Consumer Protection and Child Protection.

2.7. **Health authority:** Entity resposible for management of health programs at federal, state or municipal level.

2.8. **Child**: Any person up to the age of 12 years.

2.9. **Young child:** Any child from 12 months to 3 years old.

2.10. **Highlighted**: Any manner of showing up a warning, a sentence or text; when written, it shall have a font size at least equal to that of the largest letters used in the information and be in bold, upper case; when audio, it shall be done in a clear and audible manner.

2.11. **Distributor**: Any physical or legal person or any other entity, in the public or private sector, directly or indirectly involved in the marketing and/or importation, at wholesale or retail level, of any product within the scope of this Regulation.

2.12. **Donation**: Free supply of a product in any quantity larger than a sample.

2.13. **Packaging**: The container, box, packet or sachet for conservation, transport and handling of a product.

2.14. **Special display**: Any way of exposing a product so as to make it more prominent than others within a sales outlet, such as, but not limited to, display in a shop window, at the top of a show boat, in a product pyramid or island, through shelf talkers or decorations.

2.15. **Manufacturer**: The company or public or private entity involved in manufacturing a product included in the scope of this Regulation.

2.16. **Infant formula for infants**: A product, in liquid or powder formulation, to feed infants up to the sixth month of life, upon prescription, intended to partially or totally replace breastmilk and to satisfy the nutritional requirements of infants in this age bracket.

2.17. **Infant formula for specific dietary or therapeutic needs**: A formula whose composition has been adapted to suit the specific requirements of infants with temporary or permanent physiological and/or pathological needs.

2.18. **Follow-up formula for infants**: A liquid or powder product used, when indicated, to replace breastmilk for infants above six months.

2.19. **Follow-up formula for young children**: A liquid or powder product used to replace breastmilk for young children.

2.20. **Nutrient formula for high-risk newborns**: A composite of nutrients presented and/or prescribed for feeding premature newborns and/or high-risk newborns.

2.21. **Importer**: The private or public company or entity that imports a product included in the scope of this Regulation.

2.22. **Kit**: A set of products of different brands, shapes or sizes in a same packaging.

2.23. **Infant**: A child up to the age of one year (i.e. from zero to 11 months and 29 days).

2.24. **Modified powdered milk**: A product made of natural milk or of whole, skimmed or partially skimmed powdered milk, or of a combination of these, according to the rules of the specific Technical Regulation.

2.25. **Educational material**: Any written or audio-visual material intended for the general public, such as flyers, brochures, books, newspaper articles, cassette tapes, video

tapes, Internet [information] or other forms, that purports to give guidance on the appropriate use of products for infants and young children.

2.26. **Technical scientific material**: Any material containing proven technical and/or scientific data, with references, about products or related to knowledge of nutrition and paediatrics, intended for health professionals and health workers.

2.27. **Marketing personnel**: Professional staff (sales persons, sales promoters, demonstrators or company representatives) directly or indirectly remunerated by manufacturers and/or importers of products included in this Regulation.

2.28. **Commercial promotion**: Information and persuasion activities deployed by companies involved in the production and/or handling, distribution and marketing [of products], with the purpose of leading to the purchase or sale of a product, including the dissemination of information by written or audio-visual means, and direct or indirect contact with health professionals or students of health professions. This definition does not include direct or indirect contact with health professionals or students of health professions aimed at providing technical-scientific materials about products.

2.29. **High-risk newborn**: An infant born prematurely (with less than 34 weeks of gestation) or of very low weight at birth (less than 1,500 grammes), including infants who immediately after birth suffer from a pathology that requires intensive care.

2.30. **Label**: Any inscription, text, picture or any graphics or descriptive material that is written, printed, stamped, engraved, lithographed or adhered to the packaging of a product.

2.31. **Health care system**: The ensemble of private and public institutions and entities that provide services for the protection, promotion and recovery of health, including rehabilitation.

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3.16. Sokol, Ellen J., The Code Handbook – A Guide to Implementing the International Code of Marketing of Breastmilk Substitutes, ICDC, Penang, 1997.

3.17. Resolution WHA 39.28 of the World Health Assembly, 1996.

3.18. Resolution WHA 49.15 of the World Health Assembly, 1996.

3.19. Resolution WHA 45.34 of the World Health Assembly, 1992.

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3.22. UNICEF Executive Board Resolution 1991/22, New York, 1991.

4. General Principles

4.1. Commercial promotion of products referred to in paragraphs 1.2.1 and 1.2.5 above shall be banned, by any means of communication, including merchandising, dissemination via electronic, written or audio-visual means, promotional strategies aimed at increasing retail sales, such as special displays, discount coupons, below-cost price, prizes, gifts, sales linked to products not covered by this Regulation and special presentations.

4.2. Commercial promotion of products referred to in paragraphs 1.2.2., 1.2.3. and 1.2.4. shall always include, highlighted, the following visual and/or audio warning, according to the means of dissemination:

4.2.1. For products referred to in 1.2.2. and 1.2.3.: "*The Ministry of Health says* ***'Breastfeeding prevents infections and allergies and is recommended up to two years of age or more.'***"

4.2.2. For products referred to in 1.2.4.: "*The Ministry of Health says* ***'After the first six months continue breastfeeding your baby in addition to giving new foods.'***"

4.3. The container and/or label of infant formula for infants and follow-up formula for infants shall not:

4.3.1. Display photographs, illustrations or other graphic representations, apart from those necessary to show the correct method of preparing and using the product. However, the use of a product brand or logo shall be permitted, provided it does not contain a picture of an infant, young child or other humanized figure.

4.3.2. Use names or expressions such as “humanized milk”, “maternalized milk”, “breastmilk substitute” or similar ones that may suggest a strong similarity between the product and breastmilk.

4.3.3. Use phrases or expressions that may give rise to doubts about the mother’s ability to breastfeed her baby.

4.3.4. Use expressions or names that aim to identify the product as suitable to feed infants, such as the expression “baby” or similar ones.

4.3.5. Provide information that may lead to the use of the product based on a wrong perception of advantage or safety.

4.3.6. Use phrases or expressions suggesting health conditions for which the product could be used.

4.3.7. Promote the product or other products of the same and/or another company.

4.4. In addition to fulfilling the requirements of Chapter III of Decree-Law No 986, of 21 October 1969 and of Resolution 10, of 31 July 1984 of the Interministerial Commission on Industry, Agriculture and Health – CISA, and of the Technical Regulation for Labelling of Packaged Foods, labels of products referred to under paragraph 4.3. shall contain, on the front side, in a conspicuous and legible manner, in contrasting colors and in a font identical to that used for the product designation, the following warning: *“The Ministry of Health says: ‘This product should only be used for children under one year old, upon prescription from a doctor or a nutritionist. Breastfeeding prevents infections and allergies and strengthens the bond between mother and baby.’”*

4.5. Labels of products referred to in paragraph 4.3. shall, furthermore, contain a warning about the risks of incorrect preparation and instructions for the correct preparation of the product, including cleanliness and dilution dosage, where appropriate.

4.6. The packaging and/or labels of follow-up formula for young children shall not:

4.6.1. Contain illustrations, photographs or pictures of infants, young children, child characters or any other forms that resemble them, human or not, such as humanized fruits, vegetables, animals and/or flowers, among others, with the purpose of leading to the use of the product for this age bracket.

4.6.2. Use names or expressions such as “humanized milk”, “maternalized milk”, “breastmilk substitute” or similar ones that may suggest a strong similarity between the product and breastmilk.

4.6.3. Use phrases or expressions that may give rise to doubts about the mother’s ability to breastfeed her baby.

4.6.4. Use expressions or names that aim to identify the product as suitable to feed infants, such as the expression “baby” or similar ones.

4.6.5. Provide information that may lead to the use of the product based on a wrong perception of advantage or safety.

4.6.6. Use the same brands as those used for follow-up formula for infants.

4.6.7. Promote the product or other products of the same and/or another company, covered by the scope of this Regulation.

4.7. In addition to fulfilling the requirements of Chapter III of Decree-Law No 986, of 21 October 1969 and of Resolution 10, of 31 July 1984 of the Interministerial Commission on Industry, Agriculture and Health – CISA, and of the Technical Regulation for Labelling of Packaged Foods, labels of products referred to under paragraph 4.6. shall contain, on the front side, in a conspicuous and legible manner, in contrasting colors and in a font identical to that used for the product designation, the following warning:

"The Ministry of Health says: 'This product should not be used to feed infants under one year of age. Breastfeeding prevents infections and allergies and is recommended up to two years or more.'"

4.8. Labels of products referred to in paragraph 4.6. shall, furthermore, contain a warning about the risks of incorrect preparation and instructions for the correct preparation of the product, including cleanliness and dilution dosage, where appropriate, and shall not use pictures of feeding bottles.

4.9. The packaging and/or labels of infant formulas for specific dietary or therapeutic needs shall contain information on the specific characteristics of the product, without suggesting health conditions for which the product may be used.

4.9.1. The provisions of paragraph 4.3 shall also apply to these products.

4.10. The packaging and/or labels of liquid milk, powdered milk, modified powdered milks, milks from diverse animal species and similar plant-based products shall not:

4.10.1. Contain illustrations, photographs or pictures of infants, young children, child characters or any other forms that resemble them, human or not, such as humanized fruits, vegetables, animals and/or flowers, among others, with the purpose of leading to the use of the product for this age bracket.

4.10.2. Use names or expressions such as "humanized milk", "maternalized milk", "breastmilk substitute" or similar ones that may suggest a strong similarity between the product and breastmilk.

4.10.3. Use phrases or expressions that may give rise to doubts about the mother's ability to breastfeed her baby.

4.10.4. Use expressions or names that aim to identify the product as suitable to feed infants, such as the expression "baby", "first growth" or similar ones.

4.10.5. Provide information that may lead to the use of the product based on a wrong perception of advantage or safety.

4.10.6. Promote the product or other products of the same and/or another company, covered by the scope of this Regulation.

4.11. In addition to fulfilling the requirements of Chapter III of Decree-Law No 986, of 21 October 1969 and of Resolution 10, of 31 July 1984 of the Interministerial Commission on Industry, Agriculture and Health – CISA, and of the Technical Regulation for Labelling of Packaged Foods, labels of products referred to under paragraph 4.10. shall contain, on the front side, in a conspicuous and legible manner, in contrasting colors and in a font identical to that used for the product designation, the following warning:

4.11.1. For skimmed and partially-skimmed milk, with or without added essential nutrients: *"The Ministry of Health says: 'This product should not be used to feed children, except upon prescription from a doctor or a nutritionist. Breastfeeding prevents infections and allergies and is recommended up to two years or more.'"*

4.11.2. For whole milks, milks from diverse animal species and plant-based similar products, with or without added nutrients and for modified powdered milks: *"The Ministry of Health says: 'This product should not be used to feed children, except upon prescription from a doctor or a nutritionist. Breastfeeding prevents infections and allergies and is recommended up to two years or more.'"*

4.12. The packaging and/or labels of transition foods and cereal-based foods suitable for infants and young children, as well as other foods or beverages, whether milk-based or not, if they are marketed or otherwise represented as suitable for infants or young children, shall not:

4.12.1. Use pictures, photographs or illustrations of infants or young children.

4.12.2. Use phrases or expressions that may give rise to doubts about the mother's ability to breastfeed her baby.

4.12.3. Use expressions or names that aim to identify the product as suitable to feed infants, such as the expression "baby" or similar ones.

4.12.4. Provide information that may lead to the use of the product based on a wrong perception of advantage or safety.

4.12.5. Promote any infant formula, milk, milk-based product or cereal-based product that can be fed with a feeding bottle.

4.13. The front side of the label of products referred to in paragraph 4.13. shall indicate the age as of which the product can be given.

4.14. In addition to complying with any specific legislation, labels of products referred to in paragraph 4.12. shall contain, on the front side, in a conspicuous and legible manner, in contrasting colors and in a font identical to that used for the product designation, the following warning: *"The Ministry of Health says: 'This product should not be used for children under six months, except upon prescription from a doctor or a nutritionist. Breastfeeding prevents infections and allergies and is recommended up to two years or more.'"*

4.15. Labels of nutrient formulas for high-risk newborns shall not:

4.15.1. Display photographs, illustrations or other graphic representations, apart from those necessary to show the correct method of preparing and using the product. However, the use of a product brand or logo shall be permitted, provided it does not contain a picture of an infant, young child or other humanized figure.

4.15.2. Use expressions such as "breastmilk fortifier", "breastmilk supplement" or similar ones that may suggest that breastmilk is thin or needs to be supplemented, complemented or enriched.

4.15.3. Use phrases or expressions that may give rise to doubts about the mother's ability to breastfeed her baby.

4.15.4. Use expressions or names that aim to identify the product as suitable to feed infants, such as the expression "baby" or similar ones.

4.15.5. Provide information that may lead to the use of the product based on a wrong perception of advantage or safety.

4.15.6. Promote the product or other products of the same and/or another company.

4.16. Labels of products referred to in paragraph 4.16. shall contain, highlighted, the following sentence: *"This product should only be used for high-risk newborns, upon medical prescription, and only for use in hospital units."*

4.17. In addition to fulfilling the requirements of Chapter III of Decree-Law No 986, of 21 October 1969 and of Resolution 10, of 31 July 1984 of the Interministerial Commission on Industry, Agriculture and Health – CISA, and of the Technical Regulation for Packaged Foods, labels of products referred to under paragraph 4.15. shall contain, on the front side, in a conspicuous and legible manner, in contrasting colours and in a font identical to that used for the product designation, the following warning: *"The*

Ministry of Health says: 'Breastmilk contains the essential nutrients for the baby's growth and development during the first months of life.'"

4.19. Labels of products referred to in paragraph 4.15. shall, furthermore, contain a warning about the risks of incorrect preparation and instructions for the correct preparation of the product, including cleanliness and dilution dosage, where appropriate.

4.20. Products referred to in paragraph 4.15. shall be restricted to hospital use. The sale of such products is therefore not permitted in pharmacies or supermarkets.

4.21. Any educational material or technical-scientific material dealing with the feeding of infants and young children shall comply with the provisions of this Regulation.

5. Samples and Donations

5.1. Labels of samples of products included in the scope of this Regulation shall contain, highlighted, in the front part, the following statement: "Free sample for professional evaluation. Distribution to mothers, pregnant women and families not permitted."

5.2. Manufacturers, distributors and importers may provide samples of products under paragraphs 1.2.1., 1.2.2., 1.2.3. and 1.2.4. to paediatricians and nutritionists, only at the time of the launch of such products, while abiding by the provisions of paragraph 5.1.

5.3. For purposes of this Regulation, a national [product] launch must be completed within a period of 18 months maximum within the national territory.

5.4. The distribution of samples shall not be permitted when a product is re-launched or its brand name is changed.

5.5. No samples of nutrient formulas for high-risk newborns may be distributed.

5.6. A sample of infant formula for infants or of follow-up formula for infants may only be given once, at the time of the launch of the product, upon prior request from the health professional [who receives it].

5.7. Manufacturers, importers and distributors of products covered by this Regulation shall be allowed to make financial and/or material contributions only to associations or scientific entities of paediatricians or nutritionists that are nationally recognized; any kinds of incentives to individuals are thus prohibited.

5.8. Institutions that have received [corporate] sponsorship shall ensure that companies do not promote their products at the sponsored events; only distribution of scientific-technical materials, in conformity with the provisions of this Regulation, shall be permitted.

5.9. Any sponsored event shall include the following sentence in materials that are distributed: *"This event has received sponsorship from private companies, in accordance with the provisions of the Brazilian Regulation on Marketing of Foods for Infants and Young Children [and the regulation] on Teats, Bottles and Dummies."*

5.10. Free or low-priced supplies of products covered by this Regulation for promotional purposes given to maternities and other institutions that provide care to children shall not be permitted, either for use by the institution or for distribution outside the institution.

5.11. The ban established by this article shall not apply to free or low-priced supplies in situations of exceptional individual or collective need. In such situations, supplies must be guaranteed for as long as the infants concerned require them. The supplies may bear the name and logo of the donor, but no advertising for the products shall be permitted.

5.12. Donations [of products] for research purposes shall be allowed only upon approval of a [research] protocol by the Research Ethics Committee of the institution to which the professional [researcher] is attached, in compliance with the provisions of Resolution 01/88 of the National Health Council approving the Standards for Health Research and of Resolution 196/96 of the National Health Council approving the guidelines and standards for research on human beings.

5.13. Any products donated for purposes of research shall be identified by the following sentence highlighted on the main part of the label: "Donation for research, in accordance with legislation."

6. General Provisions

6.1. The institutions of the Health Care System, under the guidance of the Ministry of Health, shall be responsible for the implementation and monitoring of this Regulation.

6.2. The Ministry of Health, the State Secretariats for Health and the corresponding municipal bodies shall, whenever necessary, involve other government agencies for better fulfillment of the provisions of this Regulation.

6.3. Manufacturers, distributors and importers, government agencies and non-governmental organizations, particularly consumer protection agencies, private health care and social services providers, as well as community organizations and health workers' associations, shall be encouraged to cooperate with the public health care system to ensure compliance with this Regulation.

6.4. Manufacturers shall inform all their marketing personnel, including public relations companies that they may contract, about this Regulation and their responsibilities in complying with it.

6.5. Penalties for non-compliance with this Regulation shall be applied in a progressive manner, according to the seriousness and frequency of violations; breaches shall be punished by penalties provided in Law No 6437 of 20 August 1977.

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Translation from Portuguese

BRAZIL

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National Food Safety Monitoring Agency
Board of Management

Resolution RDC No. 221, of 5 August 2002

The Board of Management of the National Food Safety Monitoring Agency (ANVISA), in exercise of the attributions granted to it by Art. 11, para IV, of the ANVISA Regulations approved by Decree No 3029 of 16 April 1999; meeting on 17 July 2002;

- considering the need to adopt safety standards for dummies (pacifiers), teats, [feeding] bottles and nipple shields, as well as to establish health control and prevention measures for these products and their suppliers and distributors, in order to ensure the health of infants;
- whereas the government is committed to aligning its health policies with the recommendations of the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) in the area of infant health, and in particular the UNICEF/WHO Innocenti Declaration; and
- considering the commitment made by the Government of Brazil at the Children's Summit in New York, in 1990, to promote, protect and support exclusive breastfeeding during the first six months of life, followed by the introduction of other foods and continuation of breastfeeding up to two years or more;

has adopted the following Resolution of the Board of Management and I, Director-President, have determined that it shall be published:

Art. 1: Approve the Technical Regulation on dummies, teats, bottles and nipple shields annexed to this Resolution.

Art. 2: Dummies, teats, bottles and nipple shields manufactured 180 (one hundred and eighty) days after the date of publication of this Resolution, shall comply with its provisions.

Art. 3: Non-compliance with the provisions of this Resolution shall constitute a violation of health regulations and violators shall be subject to the sanctions provided by Law No 6437 of 20 August 1977.

Art. 4: This Resolution of the Board of Management shall enter into force on the date of publication, revoking Portaria No 117 of 27 November 1981 of the former National Health Control Secretariat of the Ministry of Health.

GONZALO VECINA NETO

ANNEX

TECHNICAL REGULATION

Dummies, Teats, Bottles and Nipple Shields

Contents:

1. SCOPE

The provisions of this Technical Regulation shall apply to dummies, teats, bottles and nipple shields, to their suppliers and distributors, as defined in Article 2 of this Regulation.

2. DEFINITIONS

2.1. **Sample**: A single unit of a dummy, teat, bottle or nipple shield provided free of charge once only.

2.2. **Special presentation**: Any presentation of a dummy, teat, bottle or nipple shield for purposes of commercial promotion with the aim of inducing to a purchase or sale, such as promotional packaging, decorative packaging, and kits with other products.

2.3. **Health authority:** Entity resposible for management of health programs at federal, state or municipal level.

2.4. **Teat**: The part of the feeding bottle from which the baby sucks the food or liquid; it is made of natural or synthetic rubber, has a hole for the passage of food and may have a hole at the base to allow air flow to equalize the atmospheric pressure with the pressure inside the container during normal use of the bottle, as defined in the Brazilian Technical Standard NBR 12793 – Safety of Feeding Bottles.

2.5. **Dummy**: An object which allows the baby to suck, without the purpose of providing food, medicine or liquids, composed of a teat or bulb, a shield, a pin or a button and a ring, as defined in the Brazilian Technical Standard NBR 10334 – Safety of Dummies.

2.6. **Child**: A person up to the age of 12 years.

2.7. **Young child:** A child from 12 months to 3 years old.

2.8. **Highlighted**: Any manner of showing up a warning, a sentence or text; when written, it shall have a font size at least equal to that of the largest letters used in the information, with the exception of the brand, and be in bold, upper case; when audio, it shall be done in a clear and audible manner.

2.9. **Distributor**: An individual or company, or any other entity, in the private or the public sector, directly or indirectly involved in the marketing and/or importation, at retail or wholesale level, of dummies, teats, bottles or nipple shields.

2.10. **Donation**: Free supply of dummies, teats, bottles or nipple shields any quantity larger than a sample.

2.11. **Packaging**: The sealed container or wrapping of a dummy, teat, bottle or nipple shield, meant to ensure conservation, and to facilitate transport and handling of the product.

2.12. **Special display**: Any way of exposing a dummy, teat, bottle or nipple shield so as to make it more prominent than others within a sales outlet, such as, but not limited to, display in a shop window, at the top of a show boat, in a product pyramid or island, through shelf talkers or decorations.

2.13. **Supplier**: A company that manufactures in Brazil or imports dummies, teats, bottles or nipple shields.

2.14. **Instructions for use**: A leaflet accompanying the product, with information on the correct, safe and recommended use of the dummy, teat, bottle or nipple shield.

2.15. **Kit**: A packet containing one [or more] of the products covered by this Regulation in varying quantities, shapes or sizes, or a set of bottles and teats in one single packet.

2.16. **Infant**: A child up to the age of one year (i.e. from zero to 11 months and 29 days).

2.17. **Feeding bottle**: An object used to feed liquids to infants, composed of a teat and a container to hold the food; it may have a ring to attach the teat to the container, as defined in the Brazilian Technical Standard NBR 13793 – Safety of Bottles.

2.18. **Educational material**: Any written or audio-visual material intended for the general public, such as flyers, brochures, books, newspaper articles, cassette tapes, video tapes, Internet [information] or other forms, that purports to give guidance on the appropriate use of products for infants and young children.

2.19. **Technical-scientific material**: Any material containing validated and referenced technical and/or scientific data about dummies, teats, bottles or nipple shields, intended for health professionals and health workers.

2.20. **Health professional**: A person with higher [educational] level, in the health care area.

2.21. **Commercial promotion**: Information and persuasion activities carried out by a supplier or distributor of dummies, teats, bottles or nipple shields, by any means of dissemination, with the purpose of leading to the purchase or sale of such products.

2.22. **Nipple shield:** An object used to cover the nipple [breast] during breastfeeding, for babies to suck the mother's milk.

2.23. **Label**: Any inscription, text, picture or any graphics that is written, printed, stamped, engraved, lithographed, glued, stuck or adhered to the container and/or packaging of a dummy, teat, bottle or nipple shield.

3. SAFETY REQUIREMENTS

3.1 Dummies shall comply with the physical and toxicological requirements of Brazilian Technical Standard NBR 10334.

3.2 Teats, bottles and nipple shields shall comply with the physical and toxicological requirements of Brazilian Technical Standard NBR 13793.

3.3 Dummies, teats, bottles and nipple shields shall not contain more than 10 (ten) parts per billion (ppb) of N-nitrosamines. Furthermore, the total N-nitrosamines in one single product shall not exceed 20 (twenty) parts per billion (ppb).

4. HEALTH CONTROL

4.1. When there is an indication of non-compliance with a provision of this Technical Regulation, or when the health of a user of a dummy, teat, bottle or nipple shield has been harmed, the [competent] authority of the National Health Control System – SNVS, shall be empowered to ban immediately the sale and use of the implicated product, according to the provisions of Law No. 6437/77, to allow for checking and verification.

4.2. Suppliers or distributors of dummies, teats, bottles or nipple shields shall not be required to have any authorization to operate from ANVISA nor need they register their products with that agency, but they shall be subject to the health controls of the national system for all other aspects provided for in national health legislation.

4.3. The importation of dummies, teats, bottles and nipple shields shall be subject to an import licence granted by the Integrated Foreign Trade System – SISCOMEX. The health authority of ANVISA at the place of disembarcation of the products shall be responsible for granting the shipment authorization, as well as for the physical inspection [of products] to verify compliance with the provisions of this Regulation, for approval and health release.

4.4. When a product covered by this Regulation has been forbidden by a health authority, ANVISA shall immediately be informed and shall be responsible to check and verify that the product did not comply with a requirement of this Regulation, and if appropriate, shall determine the health measures to be applied to the supplier of the product within the whole national territory.

4.5. The verification of compliance with the requirements of this Technical Regulation shall be carried out by the health authority, using results of tests carried out by the laboratories of the Brazilian Network of Analytic Laboratories – REBLAS and an assessment of the conformity of the product with the requirements of Article 3 of this Regulation shall be done according to the Brazilian Certification System – SBAC, if [the product] is regulated by the National Institute of Industrial Metrology, Standardization and Certification – INMETRO.

5. LABELLING AND INSTRUCTIONS FOR USE

5.1 Labelling

5.1.1 The packaging of dummies, teats, bottles and nipple shields shall bear a label that shall contain at least the following information, in Portuguese, in letters of no less than 1 (one) millimetre:

(a) the name of the manufacturer, importer or distributor, as the case may be;

(b) an identification of the manufacturing batch;

(c) a presentation of the product, as required by Article 31 of Law N° 8078/90;

(d) sufficient and necessary instructions for the correct, safe and adequate use of the product, including the following:

I) before each use, place the dummy, teat, bottle or nipple shield in boiling water for at least 5 (five) minutes;

II) do not use a ribbon or string to attach the dummy to the neck, to avoid risk of strangulation;

III) before each use, check the dummy or teat for any cracks or perforation and discard if damaged;

IV) the teat hole is already large enough; it should not be increased, to avoid risk of asphyxiation;

V) do not dip the dummy or teat in sweet substances, to avoid caries;

VI) do not use a bottle without constant supervision from an adult.

VII) keep the packaging and/or label, to consult instructions again.

5.1.2 If the instructions required by Article 5.1.1 (d) do not fit on the label, for lack of space, the label should state "see instructions for use".

5.1.3 The label of glass bottles shall contain, highlighted, on its front side, the warning "Glass Bottle".

5.1.4 In addition to complying with the specific legislation, labels of bottles, teats and dummies shall contain, on the front side or on other sides, in a conspicuous and legible manner, in contrasting colours and in a font identical to that used for the product designation, the following framed warning: *"The Ministry of Health says:*
- *A breastfed baby does not need bottles, teats or dummies.*
- *The use of bottles, teats or dummies interferes with breastfeeding and prolonged use is harmful to the baby's teething and speech."*

5.1.5 In addition to the content indicated in Article 5.1.1, labels of dummies, teats, bottles or nipple shields may contain other information, but shall not include:

(a) illustrations, photos or pictures of children;

(b) any children's pictures, illustrations or characters that resemble infants or young children, human or not, using bottles, teats or dummies or not;

(c) sentences or expressions that may raise doubts about the mother's ability to breastfeed her baby or that suggest similarity of the product with the human breast or teat;

(d) expressions or names that aim to identify the product as suitable to feed infants, such as the expression "baby" or similar ones, except if these are used as the registered trade mark of the product or company;

(e) information that may lead to the use of the product based on a wrong perception of advantage or safety;

(f) advertising for the product or for other products covered by this Regulation, belonging to the supplier or to other suppliers.

5.2 Instructions for use

5.2.1 Instructions for use need not accompany the product, if the information about the product required by Article 5.1.1. is printed on the label.

5.2.2 When necessary, the instructions for use shall contain at least the information described in Articles 5.1.1. and 5.1.3., except that provided for in Article 5.1.1.(b) and in accordance with Article 5.1.5.

6. MARKETING, DISTRIBUTION, PROMOTION AND ADVERTISING

6.1. The distribution of samples shall not be permitted in any quantity.

6.2 Commercial promotion of dummies, teats, bottles and nipple shields shall be banned, by any means of communication, including merchandising, dissemination via electronic, written or audio-visual means, promotional strategies aimed at increasing retail sales, such as special displays, discount coupons, reduced price, prizes, gifts, linked sales and special presentations.

N.B.: This ban shall not apply to the provision of technical-scientific material to health professionals.

6.3 Donations or low-priced supplies of dummies, teats, bottles and nipple shields shall not be permitted to individuals or legal entities, including maternities and other institutions that provide care to children, either for use by the institution or for distribution outside the institution. This ban shall not apply to donations of such products in situations of exceptional individual or collective need, as defined by the health authority. [In such cases, however,] no advertising of the products shall be permitted.

6.4 Any educational or technical-scientific material about dummies, teats, bottles or nipple shields, in addition to complying with the provisions of Article 5.1.5 of this Regulation, shall contain information highlighting:

(a) the benefits and superiority of breastfeeding;

(b) the detrimental effects of the use of bottles, teats, dummies and nipple shields on breastfeeding and possible health risks to the infant, in particular risks of cranio-oral-facial growth, development difficulties and impairment of oral functions.

6.5 Educational and technical-scientific materials shall not contain pictures, text, illustrations or images that recommend the use of bottles, teats, dummies or nipple shields or that may lead to said use.

6.6 Educational materials dealing with bottles, teats, dummies or nipple shields shall not be produced nor sponsored by suppliers or distributors of said products.

6.7 Suppliers and distributors of dummies, teats and bottles shall be allowed to make financial and/or material contributions to scientific bodies. Suppliers and distributors of nipple shields shall not provide financial sponsorship to any body.

6.8 Institutions that have received a contribution under Article 6.7 shall ensure that [donating] companies do not promote their products at the sponsored events; only distribution of scientific-technical materials, in conformity with the provisions of this Regulation, shall be permitted.

6.9 Any sponsored events shall include in any distributed material the following statement: “This event has received sponsorship from private companies, in accordance with the provisions of the Brazilian Regulation on Marketing of Foods for Infants and Young Children, Dummies, Teats, bottles and nipple shields.”

7. General Provisions

7.1. Suppliers and distributors shall inform all their marketing personnel, including public relations companies that they may contract, about this Regulation and their responsibilities in complying with it.

7.2. Suppliers, distributors, government agencies and non-governmental organizations, particularly consumer protection agencies, private health care and social services providers, as well as community organizations and health workers' associations, shall be encouraged to cooperate with the public health care system to ensure compliance with this Regulation.

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EUROPEAN UNION

EUROPEAN UNION

Relevant Regional Measure

1. **Commission Directive on Infant Formulae and Follow-on Formulae,[1] 91/321/EEC, 14 May 1991.**

2. **Council Directive on Infant Formulae and Follow-on Formulae Intended for Export to Third Countries, 92/52/EEC, 18 June 1992.**

3. **Council Resolution on the Marketing of Breastmilk Substitutes in Third Countries by Community-based Manufacturers 92/C 172/01, 18 June 1992.**

Highlights

The Commission of the European Communities (now European Union) adopted the Commission Directive on Infant Formulae and Follow-on Formulae in May 1991. The Directive lays down compositional and labelling requirements for infant formulae and follow-on formulae. It also provides for Member States of the European Community to give effect to the International Code of Marketing of Breastmilk Substitutes.

The only products within the scope of the Directive are infant formulae and follow-up formulae. *Infant formulae* is defined as "foodstuffs intended for particular nutritional use by infants during the first four to six months of life and satisfying by themselves the nutritional requirements [of these infants]". *Follow-up formulae* is defined to mean "foodstuffs intended for particular nutritional use by infants aged over four months and constituting the principal liquid element in a progressively diversified diet".

The EU Directive was adopted years before the WHA adopted Resolution 54.2 (2001), which recommends exclusive breastfeeding for a full six months. The EU is revising this Directive and will be changing the definitions of *infant formulae* and *follow-on formulae* to reflect current global health recommendations.

Many of the labelling requirements originate from the International Code. The Directive diverges from the Code, however, with respect to the "Important Notice" statement. Whereas the Code requires a warning that the products should not be used without the advice of a *health worker*, the Directive requires a statement, or its equivalent recommending that the "product be used only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care".

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[1] *Editor's note*: The EU employs *formulae* as the plural form of formula. Except in direct quotes from the EU Directives, ICDC uses *formulas* as the plural form.

Consumer groups in EU countries are concerned about encouraging consumers to consult pharmacists for advice on infant nutrition. Pharmacists have a conflict of interest when it comes to recommending a profitable product like infant formula. Countries within the EU were urged to modify this provision in national legislation.

While the provisions in the Directive relating to product labelling and composition apply to both infant and follow-up formula, the provisions relating to advertising and promotion pertain only to infant formula. The advertising provision of the Directive differs from the International Code in that it allows for advertising of infant formula in publications specialising in baby care and in scientific publications. The Directive provides, however, that Member States may further restrict or prohibit such advertising. Advertisements are subject to the conditions set fourth for product labels.

The requirements for information and educational materials on infant and young child feeding are similar to those of Article 4 of the International Code. Donations or low-price sales of infant formula are not prohibited as recommended in WHA Resolutions 39.28 (1986) and 47.5 (1994). The Directive states only that Member States should ensure that such donations and low-price sales "shall only be used by or distributed for infants who have to be fed on infant formulae and only for so long as required by such infants".

Member States were to bring into force the laws, regulations and administrative provisions necessary to comply wtih the Directive, to be effective by June 1994. In June 1992, the European Commission passed Directive 92/52/EEC governing the composition and labelling of infant and follow-on formula intended for export to countries outside of the EU. It also adopted Council Resolution 92/C172/01 outlining a complaints procedure that can be utilized by importing countries concerning the marketing practices of EU-based manufacturers.

By the end of 2004, 14 of the 15 Member States of the EU had passed a law implementing the Directive. The remaining Member, Sweden, has implemented the Directive by a combination of regulations and a voluntary marketing code. The 10 countries that joined the EU in 2004 are expected to align their laws with the EU Directive. At least one, Latvia, has already done so.

In 1999, the European Commission adopted Directive 1999/21/EC on Dietary Foods for Special Medical Purposes. Foods intended for feeding infants "with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary foodstuffs", would fall under this Directive rather than the 1992 Directives.

EUROPEAN UNION

Commission Directive

of 14 May 1991

on infant formulae and follow-on formulae

(91/321/EEC)

COMMISSION DIRECTIVE of 14 May 1991 on infant formulae and follow-on formulae (91/321/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs for particular nutritional uses (1), and in particular Article 4 thereof,

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

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

Whereas this Directive reflects current knowledge about these products; whereas any modification, to allow innovation based on scientific and technical progress, will be decided by the procedure laid down in Article 13 of Directive 89/398/EEC;

Whereas because of the persons for which these products are intended it will be necessary to lay down microbiological criteria and maximum levels for contaminants; whereas given the complexity of the subject these will have to be adopted at a later stage;

Whereas infant formula is the only processed foodstuff which wholly satisfies the nutritional requirements of infants during the first four to six months of life; whereas in order to safeguard the health of such infants it is necessary to ensure that the only products marketed as suitable for such use during the period would be infant formulae;

Whereas pursuant to Article 7 (1) of Directive 89/398/EEC the products covered by this Directive are subject to the general rules laid down by Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer (2), as last amended by Directive 89/395/EEC (3); whereas this Directive adopts and expands upon the additions and exceptions to those general rules, where it is appropriate, in order to promote and protect breast-feeding;

Whereas, in particular, the nature and destination of the products covered by this Directive require nutritional labelling for the energy value and principal nutrients they contain; whereas, on the other hand, the method of use must be specified in conformity with Article 3 (1) (8) and Article 10 (2) of Directive 79/112/EEC, in order to prevent inappropriate uses likely to be detrimental to the health of infants;

Whereas, pursuant to Article 2 (2) of Directive 79/112/EEC, and in order to supply objective and scientifically verified information, it is necessary to define the conditions under which claims about the particular composition of an infant formula are authorized;

Whereas, in an effort to provide better protection for the health of infants, the rules of composition, labelling and advertising laid down in this Directive should be in conformity with the principles and the aims of the International Code of Marketing of Breast-Milk Substitutes adopted by the 34th World Health Assembly, bearing in mind the particular legal and factual situations existing in the Community;

Whereas given the important role which information on infant feeding plays in choosing, by pregnant women and mothers of infants, the type of nourishment provided to their children, it is necessary for Member States to take appropriate measures in order that this information ensures an adequate use of the products in question and is not counter to the promotion of breast-feeding;

Whereas this Directive does not concern the conditions of sale of publications specializing in baby care and of scientific publications;

Whereas the Scientific Committee for Food, in accordance with Article 4 of Directive 89/398/EEC, has been consulted on the provisions liable to affect public health;

Whereas issues relating to products intended for export to third countries should be dealt with in a coherent and homogeneous manner in a separate measure;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive is a specific Directive within the meaning of Article 4 of Directive 89/398/EEC and lays down compositional and labelling requirements for infant formulae and follow-on formulae intended for use by infants in good health in the Community. It also provides for Member States to give effect to principles and aims of the International Code of Marketing of Breast-Milk Substitutes dealing with marketing, information and responsibilities of health authorities.

2. For the purposes of this Directive,

   (a) 'infants' means children under the age of 12 months;

   (b) 'young children' means children aged between one and three years;

   (c) 'infant formulae' means foodstuffs intended for particular nutritional use by infants during the first four to six months of life and satisfying by themselves the nutritional requirements of this category of persons;

   (d) 'follow-on formulae' means foodstuffs intended for particular nutritional use by infants aged over four months and constituting the principal liquid element in a progressively diversified diet of this category of persons.

Article 2

Member States shall ensure that the products referred to in Article 1 (2) (c) and (d) may be marketed within the Community only if they conform to the definitions and rules laid down

in this Directive. No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first four to six months of life.

Article 3

1. Infant formulae shall be manufactured from protein sources defined in the Annexes and other food ingredients, as the case may be, whose suitability for particular nutritional use by infants from birth has been established by generally accepted scientific data.

2. Follow-on formulae shall be manufactured from protein sources defined in the Annexes and other food ingredients as the case may be whose suitability for particular nutritional use by infants aged over four months has been established by generally accepted scientific data.

3. The prohibitions and limitations on the use of food ingredients laid down in Annexes I and II shall be observed.

Article 4

1. Infant formulae must comply with the compositional criteria specified in Annex I.

2. Follow-on formulae must comply with the compositional criteria specified in Annex II.

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

Article 5

1. Only the substances listed in Annex III may be used in the manufacture of infant formulae and follow-on formulae in order to satisfy the requirements on:

   - mineral substances,

   - vitamins,

   - amino acids and other nitrogen compounds,

   - other substances having a particular nutritional purpose.

   The purity criteria for these substances shall be stipulated at a later stage.

2. The provisions relating to the use of additives in the manufacture of infant formulae and follow-on formulae shall be laid down in a Council directive.

Article 6

1. Infant formulae and follow-on formulae shall not contain any substance in such quantity as to endanger the health of infants. Where necessary the maximum levels of any such substance shall be stipulated at a later date.

2. Microbiological criteria shall be established at a later date.

Article 7

1. The name under which the products covered by Article 1 (2) are sold shall be, respectively:

- in English:

  'infant formula' and 'follow-on formula',

- in Danish:

  'Modermaelkserstatning' and 'Tilskudsblanding',

- in German:

  'Saeuglingsanfangsnahrung' and 'Folgenahrung',

- in Greek:

  'Παρασκευασμα για δρεφη' and 'Παρασκευασμα δευτερης δρεφικης ηλικιας',

- in Spanish:

  'Preparado para lactentes' and 'Preparado de continuación',

- in French:

  'Préparation pour nourrissons' and 'Préparation de suite',

- in Italian:

  'Alimento per lattanti' and 'Alimento di proseguimento',

- in Dutch:

  'Volledige zuigelingenvoeding' and 'Opvolgzuigelingenvoeding',

- in Portuguese:

  'Fórmula para lactentes' and 'Fórmula de transiçao'.

However, the name of products manufactured entirely from cows' milk proteins, shall be respectively:

- in English:

  'Infant milk' and 'follow-on milk',

- in Danish:

  'Modermaelkserstatning udelukkende baseret paa maelk' and 'Tilskudsblanding udelukkende baseret paa maelk',

- in German:

  'Saeuglingsmilchnahrung' and 'Folgemilch',

- in Greek:

  'Γαλα για δρεφη' and 'Γαλα δευτερης δρεφικης ηλικιας',

- in Spanish:

'Leche para lactentes' and 'Leche de continuación',

- in French:

'Lait pour nourrissons' and 'Lait de suite',

- in Italian:

'Latte per lattanti' and 'Latte di proseguimento',

- in Dutch:

'Volledige zuigelingenvoeding op basis van melk' or 'Zuigelingenmelk' and 'Opvolgmelk',

- in Portuguese:

'Leite para lactentes' and 'Leite de transiçao'.

2. The labelling shall bear, in addition to those provided for in Article 3 of Directive 79/112/EEC, the following mandatory particulars:

(a) in the case of infant formulae, a statement to the effect that the product is suitable for particular nutritional use by infants from birth when they are not breast-fed;

(b) in the case of infant formulae that do not contain added iron, a statement to the effect that, when the product is given to infants over the age of four months, their total iron requirements must be met from other additional sources;

(c) in the case of follow-on formulae, a statement to the effect that the product is suitable only for particular nutritional use by infants over the age of four months, that it should form only part of a diversified diet and that it is not to be used as a substitute for breast milk during the first four months of life;

(d) in the case of infant formulae and follow-on formulae, the available energy value, expressed in kJ and kcal, and the content of proteins, lipids and carbohydrates per 100 ml of the product ready for use;

(e) in the case of infant formulae and follow-on formulae, the average quantity of each mineral substance and of each vitamin mentioned in Annexes I and II respectively, and where applicable of choline, inositol and carnitine, per 100 ml of the product ready for use;

(f) in the case of infant formulae and follow-on formulae, instructions for appropriate preparation of the product and a warning against the health hazards of inappropriate preparation.

3. The labelling of infant formulae and follow-on formulae shall be designed to provide the necessary information about the appropriate use of the products so as not to discourage breast-feeding. The use of the terms 'humanized', 'maternalized', or similar terms shall be prohibited. The term 'adapted' may only be used in conformity with paragraph 6 and Annex IV, point 1.

4. The labelling of infant formulae shall in addition bear the following mandatory particulars, preceded by the words 'Important Notice' or their equivalent:

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

(b) a statement recommending that the product be used only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care;

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

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

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

(a) the presentation of the products concerned, in particular their shape, appearance or packaging, the packaging materials used, the way in which they are arranged and the setting in which they are displayed;

(b) advertising.

Article 8

1. Advertising of infant formulae shall be restricted to publications specializing in baby care and scientific publications. Member States may further restrict or prohibit such advertising. Such advertisements for infant formulae shall be subject to the conditions laid down in Article 7 (3), (4), (5), (6) and (7) (b) and contain only information of a scientific and factual nature. Such information shall not imply or create a belief that bottle-feeding is equivalent or superior to breast-feeding.

2. There shall be no point-of-sale advertising, giving of samples or any other promotional device to induce sales of infant formula directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales.

3. Manufacturers and distributors of infant formulae shall not provide, to the general public or to pregnant women, mothers or members of their families, free or low-priced products, samples or any other promotional gifts, either directly or indirectly via the health care system or health workers.

Article 9

1. Member States shall ensure that objective and consistent information is provided on infant and young child feeding for use by families and those involved in the field of infant and young child nutrition covering the planning, provision, design and dissemination of information and their control.

2. Member States shall ensure that informational and educational materials, whether written or audiovisual, dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children, shall include clear information on all the following points:

(a) the benefits and superiority of breast-feeding;

(b) maternal nutrition and the preparation for and maintenance of breast-feeding;

(c) the possible negative effect on breast-feeding of introducing partial bottle-feeding;

(d) the difficulty of reversing the decision not to breast-feed;

(e) where needed, the proper use of infant formulae, whether manufactured industrially or home-prepared.

When such materials contain information about the use of infant formulae, they shall include the social and financial implications of its use; the health hazards of inappropriate foods or feeding methods, and, in particular, the health hazards of improper use of infant formulae. Such material shall not use any pictures which may idealize the use of infant formulae.

3. Member States shall ensure that donations of informational or educational equipment or materials by manufacturers or distributors shall be made only on request and with the written approval of the appropriate national authority or within guidelines given by that authority for this purpose. Such equipment or materials may bear the donating company's name or logo, but shall not refer to a proprietary brand of infant formulae and shall be distributed only through the health care system.

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

Article 10

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive. They shall immediately inform the Commission thereof. Those provisions shall be applied in such a way as to:

- permit trade in products complying with this Directive, by 1 December 1992,

- prohibit trade in products which do not comply with this Directive, with effect from 1 June 1994.

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Article 11

This Directive is addressed to the Member States. Done at Brussels, 14 May 1991.

For the Commission

Martin BANGEMANN

Vice-President

Council Resolution

of 18 June 1992

on the marketing of breastmilk substitutes in third countries

by Community-based manufacturers

(92/C 172/01)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Whereas Council Directive 92/52/EEC of 18 June 1992 on infant formulae and follow-on formulae intended for export to third countries [1] renders applicable to such products a certain number of Community provisions relating to the composition and the labelling of infant formulae and follow-on formulae;

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

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

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

Whereas the Community cannot legislate for these countries; whereas it is nevertheless necessary to encourage compliance with the International Code of Marketing of Breastmilk Substitutes when these products are placed on sale in export markets, in so far as this does not conflict with the provisions in force in the countries concerned;

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

HAS ADOPTED THE FOLLOWING RESOLUTION:

1. The Community will contribute to the application of appropriate marketing practices for breastmilk substitutes in third countries.

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

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

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

5. The Commission will forward to the European Parliament and to the Council every two years a report on the results of the application of this resolution.

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[1] OJ No L 179, 1.7. 1992.

Council Directive

of 18 June 1992

on infant formulae and follow-on formulae intended

for export to third countries

(92/52/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 113 thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the European Parliament [2],

Having regard to the opinion of the Economic and Social Committee [3],

Whereas Community rules concerning infant formulae and follow-on formulae are laid down by Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs for particular nutritional uses [4] in Commission Directive 91/321/EEC [5];

Whereas given the nature of the products in question it is desirable that Community rules or international standards relating to their composition are made applicable to such products intended for export to third countries;

Whereas in order to prevent inappropriate use of these products which could prejudice the health of infants it is also desirable to extend the application of the Community rules on labelling of infant formulae and follow-on formuale to those products intended for export to third countries;

Whereas the products complying with Directive 91/321/EEC may be marketed in the Community as from 1 December 1992; whereas no legislation prohibits the export of such products to third countries,

HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive concerns infant formulae and follow-on formulae, as defined by Article 1 (2) (c) and (d) of Directive 91/321/EEC, intended for export to third countries.

Article 2

Member States shall ensure that the products referred to in Article 1 may be exported from the Community only if they comply with this Directive.

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[1] OJ No C 124, 16. 5. 1992, p. 14 and OJ No C 155, 20. 6. 1992, p. 18.
[2] OJ No C 125, 18. 5. 1992.
[3] OJ No C 106, 27. 4. 1992, p. 4.
[4] OJ No L 186, 30. 6. 1989, p. 27.
[5] OJ No L 175, 4. 7. 1991, p. 35.

Article 3

1. No product other than infant formulae may be represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first four to six months of life.

2. In addition the products referred to in Article 1 must comply:

   (a) with Articles 3, 4, 5 and 6 of Directive 91/321/EEC or with relevant applicable world standards established by Codex Alimentarius;

   (b) with Article 7 (2) to (6) of Directive 91/321/EEC;

   (c) with the provisions of Council Directive 89/396/EEC of 14 June 1989 on indications or marks identifying the lot to which a foodstuff belongs [6],

   unless otherwise requested or stipulated by provisions established by the importing country.

3. These products shall be labelled in an appropriate language and in such a way as to avoid any risk of confusion between infant formulae and follow-on formulae.

4. The stipulations, prohibitions and restrictions laid down in Article 7 (2) to (6) of Directive 91/321/EEC shall also apply to the presentation of the products concerned and in particular their form, aspect or packaging and the packaging materials used.

Article 4

Member States shall take the necessary measures to comply with this Directive. They shall forthwith inform the Commission thereof. Those measures shall be applied in such a way as to prohibit exports of products which do not comply with this Directive, with effect from 1 June 1994.

When Member States adopt these provisions, they shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The methods of making such a reference shall be laid down by the Member States.

Article 5

This Directive is addressed to the Member States.

Done at Luxembourg, 18 June 1992.

For the Council

The President

Vitor MARTINS

[6] OJ No L 186, 30. 6. 1989, p. 21. As last amended by Directive 91/238/EEC (OJ No L 107, 27. 4. 1991, p. 50).

GHANA

GHANA

Relevant National Measures

Ghana, Breastfeeding Promotion Regulations, 2000

Highlights

The Regulations in Ghana were made pursuant to the Ghana Food and Drugs Law, 1992 and came into effect on 9 May 2000.

The scope of the Regulations is defined by the term *designated products*, thus avoiding the ambiguity of the term *breastmilk substitutes. Designated product* is defined to included "infant formula, any other product marketed or represented as suitable for feeding infants up to six months of age, follow-up formula, feeding bottles, teats and pacifiers, and gives the Minister of Health the power to designate other products.

The Regulations prohibit the sale of designated products in any health care facility. Prior to the adoption of the Regulations, feeding bottles and infant foods had been common items sold in hospital shops and clinics. Advertising and other types of promotion of designated products are not permitted in any health care facility or in any public place.

Manufacturers and distributors of products within the scope of the Regulations may not produce or distribute educational materials related to the feeding of infants or young children unless the material is first approved by the Food and Drugs Board. Ghana has closed a loophole in the International Code by prohibiting any reference in such materials not only to designated products, but also to the name or logo of a manufacturer or distributor (except in indicating a copyright). Manufacturers and distributors may, however, provide product information for health personnel if the information is "restricted to scientific and factual matters that relate to the technical aspects and method for the use of the product".

No person is permitted to distribute free supplies or samples of any designated product to health personnel or health care facilities. The Regulations also forbid manufacturers and distributors of designated products from providing fellowships or other kinds of financial assistance to health personnel or to sponsor their attendance at a conference or related professional meeting.

The labelling provisions of the Regulations, unlike those of the International Code, apply to all designated products. Moreover, the Regulations prohibit any photograph, drawing or graphic on labels except for illustrating preparation instructions. The Regulations also improve on the International Code by providing detailed requirements for the labels of feeding bottles and teats.

The Ghana National Breastfeeding Promotion Regulation Committee has been set up in Ghana and is charged with coordinating investigations concerning allegations of violations of the Regulations, submitting its findings to the Ministry of Health and following-up on actions taken pursuant to those allegations.

GHANA

Breastfeeding Promotion Regulations, 2000

In exercise of the powers conferred on the Minister responsible for Health by section 47 of the Food and Drugs Law, 1992 (P.N.D.C.L.305B), and after consultation with the Food and Drugs Board these regulations are made this 19th day of January, 2000.

Prohibition of sale and promotion of designated products

1. (1) No person shall
   (a) sell, advertise, promote or assist in the sale, advertisement or promotion of a designated product in any health care facility; or
   (b) undertake or participate in any promotional practice in respect of a designated product in any public place.
   (2) For the purpose of paragraph (b) of subregulation (1) promotional practice includes
   (a) sale devices such as rebates, special display to promote sales, tie-in sales, grant of rewards, discount coupons, prizes and gifts;
   (b) the distribution without charge of one or more samples of a designated product to any person;
   (c) direct or indirect contact between marketing personnel of a designated product and members of the public in furtherance of or for the purpose of promoting the business of the marketing personnel; and
   (d) the distribution of any information or educational material on feeding of infants and young children except in accordance with regulations 7 and 8 of these Regulations.
   (3) The Minister may, by legislative instrument, specify a product as a designated product for purposes of these regulations.

Exhibition of manufacture and expiry dates

2. (1) No person shall sell, distribute for sale, exhibit for sale or stock for sale any designated product
   (a) which does not have the dates of manufacture and expiry on the label; and
   (b) which is not in its original container
   (2) No person shall sell, distribute for sale or exhibit for sale any designated product the expiry date for which has expired.

Distribution of free and low cost designated products

3. (1) No person shall distribute free or at low cost, supplies or samples of any designated product to
   (a) a health personnel;
   (b) a health care facility; or
   (c) a person known to that other person as an employee of a health care facility on the premises of the facility.
   (2) No health personnel shall accept or give to any other person a sample of a designated product.
   (3) No person shall without the prior written approval of the Minister, carry out professional evaluation, research or activities of any other description at a health care facility in respect of a designated product.

Prohibition of display of printed material or designated products in a health care facility

4. No person shall display or permit to be displayed in a health care facility or in any public place printed material that bears the name, logo or trademark of any other description of a designated product.

Prohibition of donation of equipment and material

5. (1) No manufacturer of distributor of a designated product shall directly or indirectly donate any equipment or material to a health care facility unless it is with the prior approval in writing of the Minister given after consultation with the Board.

(2) No person shall donate or distribute within a health care facility equipment or material that bears the name, logo, graphic, trademark or any other description of a designated product.

Provision of fellowship and sponsorship prohibited

6. (1) No manufacturer or distributor of a designated product shall directly or indirectly

(a) provide a fellowship, research grant or any other financial assistance to a health personnel; or

(b) sponsor the attendance of a health personnel at a conference, seminar or any health related professional meeting without the approval of the Minister given after consultation with the Board.

(2) No manufacturer or distributor of a designated product shall for the purpose of promoting his business, directly or indirectly offer a gift in cash or in kind to a health personnel of a health care facility.

(3) No health personnel shall accept a gift in cash or in kind from a manufacturer or distributor of a designated product for the purpose of promoting the use of the designated product.

Distribution of information and other material

7. (1) Subject to the other provisions of this regulation and regulation 8, no person shall directly or indirectly produce educational material, any other material or distribute information that relates to feeding of infants or young children.

(2) Subregulation (1) does not apply where a manufacturer or distributor provides information about a designated product to a health personnel where the information is restricted to scientific and factual matters that relate to the technical aspects and methods for the use of the designated product.

(3) Any manufacturer or distributor who produces any educational material or who intends to distribute any information referred to in subregulation 7(1) shall submit copies of the material or information to the Board in such form and at such time as the Board may direct.

(4) The Minister may in writing authorise a person specified in the authorisation to produce educational material, any material or information relating to feeding of infants and young persons.

Information and educational material

8. Any information, educational material or other material whether written, audio or visual on infant feeding made available in the country by any person shall

(a) clearly explain

(i) the benefits and superiority of breastfeeding;

(ii) how to initiate and maintain breastfeeding including maternal nutrition;

(iii) a recommended duration of six months exclusive breastfeeding from birth and sustained breastfeeding after the six month period until the child is two years or more;

(iv) how and why the introduction of bottle feeding or early introduction of complementary foods interferes with breastfeeding;

(v) why it is difficult to return to breastfeeding after a period of bottle feeding even if limited to a few bottles per day;

(b) contain correct and current information and shall not use any pictures or texts that encourage bottle feeding or discourage breastfeeding;

(c) be written in English; and

(d) not make any reference to any designated product or contain the name or logo of any manufacturer or distributor of a designated product except by way of indicating a copyright.

Explanatory material

9. (1) Where material or information referred to in regulation 7(2) and (4) includes the subject of feeding infants with breastmilk substitutes through feeding bottle the material or information shall clearly and conspicuously state

(a) the proper preparation and use of the product;

(b) the approximate financial cost of feeding an infant with the product for a period of six months;

(c) the health hazards of bottle feeding and improper preparation of the product; and

(d) how to feed infants with a cup.

(2) Where the material referred to in regulation 7(2) and (4) includes the subject of feeding infants with complementary food the material shall explain

(a) the health hazards of introducing food complement before the infant is six months old;

(b) that food complement can easily be prepared at home using local ingredients; and

(c) the benefit and value of sustaining breastfeeding after the child is six months until the child is two years or more.

Labelling of designated products

10. (1) A manufacturer or distributor shall not offer for sale or sell a designated product if the container or label affixed to it does not

(a) have a clear, conspicuous and easily readable message that breastmilk is the best food for infants and prevents diarrhoea and other illnesses;

(b) provide instructions for the proper preparation and use of the designated product;

(c) include a warning preceded by the words “Important notice” against the health hazards of improper preparation and use of the designated product; and

(d) indicate the health hazards of introducing the product prior to the recommended age.

(2) A manufacturer or distributor shall not offer for sale or sell a designated product if the container or label affixed to the container includes as a means of expression the terms “maternalised” or similar expression.

(3) In addition to any other requirement in respect of designated products provided in these Regulations the label of a designated product shall

(a) not show any photograph, drawing or other graphic representation other than for illustrating the method for preparation of the designated product;

(b) be written in English;

(c) contain

(i) the name and address of the manufacturer and where applicable the distributor;

(ii) the dates of manufacture and expiry;

(iii) the composition and contents of the product;

(iv) the batch number;

(v) the required storage conditions for the product; and

(d) indicate the quantity of the food in the containers necessary to feed an infant during the first six months of its life.

(4) Where a designated product does not satisfy all the nutritional requirements of an infant but can be modified to do so, its label shall include a warning that the unmodified product should not be the sole source of the infant's nourishment and that the designated product should not be used to feed an infant except under the guidance of health personnel.

(5) Where modification is required under subregulation (4) the manufacturer shall indicate how the modification should be made on the label.

Labels on feeding bottles and teats

11. (1) A label on a feeding bottle or package or container of a feeding bottle or teat shall include

(a) a statement on the superiority of breastmilk for feeding infants;

(b) a statement that feeding with a cup is safer that bottle feeding;

(c) instructions for proper cleaning and sterilization of feeding bottles and teats;

(d) a warning on the potential health hazards of using a feeding bottle especially if it is not properly sterilized;

(e) a warning on the negative impact of bottle feeding and the need to follow preparation instructions carefully to ensure that an infant does not fall ill; and

(f) the name and address of the manufacturer or distributor of the product or the local agent.

(2) The label on a pacifier shall have a notice that use of a pacifier can interfere with breastfeeding.

Labels on condensed milk

12. A label on a container of condensed milk shall have a clear and conspicuous warning that it shall not be used for infant feeding.

Authorised officer

13. Pursuant to section 36(1) of the Food and Drugs Law, 1992 (P.N.D.C.L.305B), a person appointed and designated as an authorised officer of the Board shall carry out such functions as may be necessary to give full effect to the provisions of these Regulations.

Health personnel to support breastfeeding

14. Health personnel in any health facility shall support, protect and encourage breastfeeding.

Offences and penalties

15. Any person who

(a) advertises, sells or promotes any designated product contrary to regulation 1;

(b) distributes, exhibits or stocks for sale any designated product which does not indicate the manufacture and expiry dates or that the expiry date has passed contrary to regulation 2;

(c) distributes free of charge or offers for sale any designated product contrary to regulation 3;

(d) displays or permits to be displayed printed material contrary to regulation 4;

(e) donates equipment or material contrary to regulation 5;

(f) provides a fellowship or sponsorship or gives any gift contrary to regulation 6;

(g) distributes information on infant feeding that contravenes regulation 7 or 8;

(h) labels a designated product, a container, or a condensed milk product contrary to regulation 10, 11 or 12; or

(i) fails to indicate a modification required under regulation 10(5);

(j) contravenes any other provision of these Regulations, commits an offence and is liable on summary conviction to a fine not exceeding five million cedis or to imprisonment for a term not exceeding twelve months or to both.

Interpretation

16. In these Regulations unless the context otherwise requires

"advertise" includes to make any representation by any means for promoting directly or indirectly the sale or disposal of a designated product and is not limited to

(a) a written publication;

(b) television, radio, film, video or telephone;

(c) a display of signs, hoarding, notices or goods; or

(d) an exhibition of pictures or models;

"authorised officer" has the same meaning as provided in the Law;

"Board" means the Food and Drugs Board established under section 27 of the Food and Drugs Law, 1992 (P.N.D.C.L.305B);

"breastmilk substitutes" means any food that is marketed or otherwise represented as a partial or total replacement for breast milk whether suitable for that purpose or not;

"complementary food" or "food complement" means any food substitute or alternative to breast milk suitable as a complement to breastmilk or to infant formula, when either becomes insufficient to satisfy the nutritional requirements of the infant;

"container" means any form of packaging products for sale including wrappers;

"designated product" includes infant formula, any other product marketed or otherwise represented as suitable for feeding infants up to six months of age, follow-up formula, feeding bottles, teats and pacifiers and a product so designated by the Minister;

"distributor" includes means a person engaged in the business, whether wholesale or retail of marketing any designated product and includes any person engaged in the

business of providing information or public relations services in relation to any designated product;

"follow-up formula" means an animal or vegetable based product intended for infants older than six months and young children and formulated industrially in accordance with the standards of the Ghana Standards Board or in the absence of such standards in accordance with the International Codex Alimentarius Standards;

"health care facility" includes a public or private health care institution, organisation or practice engaged directly or indirectly in the provision of health care or health care education, and day-care centres, nurseries or other infant-care facilities;

"health personnel" includes a person working in a health care facility whether professional or non professional including a person providing voluntary service;

"infant" means a child from birth up to the age of twelve months;

"infant formula" means an animal or vegetable based product formulated industrially in accordance with the standards of Ghana Standards Board or in the absence of such standards in accordance with the International Codex Alimentarius Standards to satisfy some or all of the nutritional requirements of infants up to the age of six months and adapted to their physiological characteristics for use as food or drink;

"label" includes any tag, brand mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, impressed or attached to a container of a designated product;

"Law" means the Food and Drugs Law, 1992 (P.N.D.C.L305B);

"manufacturer means a person engaged in the business of manufacturing a designated product whether directly or through an agent;

"marketing personnel" means a person who promotes the sale of a designated product;

"maternalised" means infant formula processed in a manner that makes it similar to breast milk;

"Minister" means the Minister responsible for Health;

"pacifier" means a rubber teat not attached to a bottle;

"promote" means any direct or indirect method of introducing or encouraging any person to purchase a designated product;

"public place" means a place to which, the public have or are permitted to have access whether on payment or otherwise;

"sample" means a single or small quantity of a designated product provided without cost;

"sell" has the same meaning as provided in the Law;

"tie-in-sales" means the sale of any designated product that is linked to the purchase of any other product including a designated product.

ALHAJI MAHAMA IDDRISU
Ag. Minister responsible for Health

Date of Gazette notification: 28th January, 2000
Entry into force: 9th May 2000

INDIA

INDIA

Relevant National Measures

1. **The Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, Nº 41 of 1992, *amended* 2003.**

2. **The Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Rules 1993, *amended* 2003.**

Highlights

The Indian Act (Act) was passed by Parliament and received the assent of the President on 29 December 1992. The Act went into force on 1 August 1993. The Rules made pursuant to the Act were passed in July 1993 and also came into force on 1 August 1993. Both the Act and the Rules were amended in 2003.

The provisions of the Act, as amended, apply to *infant milk substitutes* defined as, "any food being marketed or otherwise represented as a partial or total replacement for mother's milk, for infants [and young children] up to the age of two years" and to feeding bottles and teats. The provisions of the Act also apply to *infant food* defined as, "any food (by whatever name called) being marketed or otherwise represented as a complement to mother's milk to meet the growing nutritional needs of the infant after the age of six months and up to the age of two years".

Infant milk substitutes, infant foods and feeding bottles may not be advertised. In addition, no person is permitted to supply or distribute samples or contact pregnant women or mothers of infants, or offer inducements of any kind for the purpose of promoting the use or sale of any of these products.

No person is permitted to donate infant milk substitutes, infant foods or feeding bottles to any person other than an orphanage. Health care institutions, however, may distribute infant milk substitutes or feeding bottles to a mother who is unable to breastfeed and who cannot afford to purchase infant milk substitutes.

Information and educational materials or equipment relating to products within the scope of the Act may only be donated through the health care system and must contain details required by the Rules. Moreover, they may be donated only if it is found necesary for the health and growth of the infant by a medical practitioner.

Producers and distributors of products within the scope of the Act may not offer or give financial inducements or gifts to health workers or members of their families for the purpose of promoting the use of such products. In addition, the Act prohibits producers and distributors from giving any contribution to health workers and their associations for meetings, conferences, fellowships and the like.

The Indian Act and Rules add many details to the labelling provisions of Article 9 of the International Code. For example, the size of the lettering for all product labels is specified. The Rules also state that the colour of the text must be different from the colour of the background and that the warning must be conspicuous and placed on the central panel of the label. The required warning is more detailed than that in the International Code.

Written complaints of offences under the Act may be made by authorised officers, who must have medical training, or by an authorised representative of a voluntary organisation engaged in the field of child welfare and development and child nutrition. The Act provides sanctions including fines and imprisonment for violations. Goods may also be confiscated if not in compliance with the Act and Rules.

INDIA

The Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992 *as amended* by Act Nº 38 of 2003

An Act to amend the Infant Milk Substitutes, Feeding Bottles and Infants Foods (Regulation of Production, Supply and Distribution) Act, 1992. It provides for the regulation of production, supply and distribution of infant milk substitutes, feeding bottles and infant foods with a view to the protection and promotion of breastfeeding and ensuring the proper use of infant foods and for matters connected therewith or incidental thereto.

Be it enacted by Parliament in the Fifty-fourth Year of the Republic of India as follows:

1. (1) This Act may be called the Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act 1992, *as amended* in 2003.

(2) It extends to the whole of India.

(3) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint.

2. (1) In this Act, unless the context otherwise requires:

(a) "advertisement" includes any notice, circular, label, wrapper or any other document or visible representation or announcement made by means of any light, sound, smoke or gas or by means of electronic transmission or by audio or visual transmission;
(b) "container" means a box, bottle, casket, tin, can, barrel, case, tube, receptacle, sack, wrapper or other thing in which any infant milk substitute, feeding bottle or infant food is placed or packed for sale or distribution;
(c) "feeding bottle" means ant bottle or receptacle used for the purpose of feeding infant milk substitutes, and includes a teat and a valve attached or capable of being attached to such bottle or receptacle;
(d) "health care system" means an institution or organisation engaged, either directly or indirectly, in health care for mothers, infants or pregnant women, and includes a health workers in private practice, a pharmacy, drug store and any association of health workers;
(e) "health worker" means a person engaged in health care for mothers, infants or pregnant women;
(f) "infant food" means any food (by whatever name called) being marketed or otherwise represented as a complement to mother's milk to meet the growing nutritional needs of the infant after the age of six months and up to the age of two years;
(g) "infant milk substitute" means any food being marketed or otherwise represented as a partial or total replacement for mother's milk, for infants up to the age of two years
(h) "label" means a display of written, marked, stamped, printed or graphed matter affixed to, or appearing upon, any container;
(i) "prescribed" means prescribed by rules made under this Act.
(j) "promotion" means to employ directly or indirectly any method of encouraging any person to purchase or use infant milk substitute, feeding bottle or infant food.

(2) Any reference in this Act to any other enactment or any provision thereof, shall, in relation to an area in which such enactment or such provision is not in force, be

construed as a reference to the corresponding law or the relevant provision of the corresponding law, if any, in force in that area.

3. No person shall:

(a) advertise, or take part in the publication of any advertisement, for the distribution, sale or supply of infant milk substitutes feeding bottles or infant foods; or
(b) give an impression or create a belief in any manner that feeding of infant milk substitutes and infant foods are equivalent to, or better than, mother's milk; or
(c) take part in the promotion of infant milk substitutes, feeding bottles or infant foods.

4. No person shall:

(a) supply or distribute samples of infant milk substitutes or feeding bottles or infant foods gifts of utensils or other articles; or
(b) contact any pregnant woman or the mother of an infant; or
(c) offer inducement of any other kind,

for the purpose of promoting the use or sale of infant milk substitutes or feeding bottles or infant foods.

5. Subject to the provisions of sub-section (4) of section 8, no person shall donate or distribute –

(a) infant milk substitutes or feeding bottles or infant foods to any other person except to an orphanage;
(b) any informational or educational equipment or material relating to infant milk substitutes or feeding bottles or infant foods;

Provided that nothing in this clause shall apply to the donation or distribution, subject to such conditions and restrictions as may be prescribed, of such equipment or material through the health care system.

6. (1) Without prejudice to the provisions of the Prevention of Food Adulteration Act, 1954 and the rules made thereunder, no person shall produce, supply or distribute any infant milk substitute or infant food unless every container thereof or any label affixed thereto indicates in a clear, conspicuous and in an easily readable and understandable manner, the words "important notice" in capital letters in such language as may be prescribed and indicating thereunder the following particulars in the same language, namely:

(a) a statement "mother's milk is best for your baby" in capital letters;
(b) a statement that infant milk substitute or infant food should be used only on the advice of a health worker as to the need for its use and the proper method of its use;
(c) a warning that infant milk substitute or infant food is not the sole source of nourishment of an infant;
(d) the instructions for its appropriate preparation and a warning against the health hazards of its inappropriate preparation;
(e) the ingredients used;
(f) the composition or analysis;
(g) the storage conditions required;
(h) the batch number, date of its manufacture and the date before which it is to be consumed, taking into account the climatic and storage conditions of the country;

(i) such other particulars as may be prescribed.

(2) No container or label referred to in sub-section (1) relating to infant milk substitute or infant food shall:

(a) have pictures of an infant or a woman or both; or
(b) have pictures or other graphic material or phrases designed to increase the saleability of infant milk substitutes or infant food; or
(c) use on it the word "humanised" or "maternalised" or any other similar word; or
(d) bear on it such other particulars as may be prescribed.

7. (1) Every educational or other material including advertisements or material relating to promotion of infant milk substitues, feeding bottles and infant foods whether audio or visual, dealing with pre-natal or post-natal care or with the feeding of an infant and intended to reach pregnant women or mothers of infants shall include clear information relating to:

(a) the benefits and superiority of breastfeeding;
(b) the preparation for, and the continuance of, breastfeeding;
(c) the harmful effects on breast-feeding due to the partial adoption of bottle feeding;
(d) the difficulties in reverting to breastfeeding of infants after a period of feeding by infant milk substitute;
(e) the financial and social implications in making use of infant milk substitutes and feeding bottles;
(f) the health hazards of improper use of infant milk substitutes and feeding bottles;
(g) the date of printing and publication of such material and the name of the printer and publisher;
(h) such other matters as may be prescribed.

(2) No material referred to in sub-section (1) shall be utilised to promote the use or sale of infant milk substitutes or feeding bottles or infant foods.

8. (1) No person shall use any health care system for the display of placards or posters relating to, or for the distribution of, materials for the purpose of promoting the use or sale of infant milk substitutes or feeding bottles or infant foods:

Provided that the provisions of this sub-section shall not apply to:

(a) the donation or distribution of informational or educational equipment or material made in accordance with the proviso to clause (b) of section 5; and
(b) the dissemination of information to a health worker about the scientific and factual matters relating to the use of infant milk substitutes or feeding bottles or infant foods along with the information specified in sub-section (1) of section 7.

(2) No person who produces, supplies, distributes or sells infant milk substitutes or feeding bottles or infant foods shall make any payment to any person who works in the health care system for the purpose of promoting the use or sale of such substitutes or bottles or foods.

(3) No person, other than a health worker, shall demonstrate feeding with infant milk substitutes or infant foods to a mother of an infant or to any member of her family and such health worker shall also clearly explain to such mother or such other member the hazards of improper use of infant milk substitutes or feeding bottles or infant foods.

(4) No person, other than an institution or organisation, engaged in health care for mothers, infants or pregnant women, shall distribute infant milk substitutes or feeding bottles to a mother who cannot resort to breastfeeding and who cannot afford to purchase infant milk substitutes or feeding bottles.

(5) An orphanage may purchase infant milk substitutes or feeding bottles at a price lower than their sale price for the purpose of utilising them in the said orphanage.

Explanation - For the purposes of this sub-section, such purchases shall not amount to an inducement for promoting the use or sale of infant milk substitutes or feeding bottles.

9. (1) No person who produces, supplies, distributes or sells infant milk substitutes or feeding bottles or infant foods shall offer or give, directly or indirectly, any financial inducements or gifts to a health worker or to any member of his family for the purpose of promoting the use of such substitutes or bottles or foods.

(2) No producer, supplier or distributor referred to in sub-section (1), shall offer or give any contribution or pecuniary benefit to a health worker or any association of health workers, including funding of seminar, meeting, conferences, educational course, contest, fellowship, research work or sponsorship.

10. (1) No person who produces, supplies, distributes or sells infant milk substitutes or feeding bottles or infant foods shall fix the remuneration of any of his employees or give any commission to such employees on the basis of the volume of sale of such substitutes or bottles or foods made by such employees.

(2) The employees of such person shall not perform any function which relates to educating a pregnant woman or mother of an infant on pre-natal or post-natal care of the infant.

11. (1) No person shall sell or otherwise distribute any infant milk substitute or infant food unless it conforms to the standards, specified for such substitute or food under the Prevention of Food Adulteration Act, 1954, and the rules made thereunder and the container thereof has the relevant Standard Mark specified by the Bureau of India Standards established under section 3 of the Bureau of Indian Standards Act, 1986 to indicate that the infant milk substitute or infant food conforms to such standards:

Provided that where no standards have been specified for any infant milk substitute or infant food under the Prevention of Food Adulteration Act, 1954, no person shall sell or otherwise distribute such substitute or food unless he has obtained the approval of the Central Government in relation to such substitute or food and the label affixed to the container thereof under the rules made under that Act.

(2) No person shall sell or otherwise distribute any feeding bottle unless it conforms to the Standard Mark specified by the Bureau of Indian Standards referred to in sub-section (1) for feeding bottles and such mark is affixed on its container.

12. (1) Any food inspector appointed under section 9 of the Prevention of Food Adulteration Act 1954 (hereinafter referred to as the food inspector) or any officer not below the rank of a Class I officer authorised in this behalf by the State Government (hereinafter referred to as the authorised officer) may, if he has any reason to believe that any provision of section 6 or section 11 has been or is being contravened, enter and search at any reasonable time any factory, building, business premises or any other place where any trade or commerce in infant milk substitutes or feeding bottles or

infant foods is carried on or such substitutes or bottles or foods are produced, supplied or distributed.

(2) The provisions of the Code of Criminal Procedure, 1973, relating to searches and seizures shall, so far as may be, apply to every search or seizure made under this Act.

13. (1) If any food inspector or authorised officer has reason to believe that in respect of any infant milk substitute or feeding bottle or infant food or container thereof, the provisions of this Act have been or are being contravened, he may seize such substitute or bottle or food or container.

(2) No such substitute or food or bottle or container shall be retained by any food inspector or authorised officer for a period exceeding ninety days from the date of its seizure unless the approval of the District Judge, within the local limits of whose jurisdiction such seizure has been made, has been obtained for such retention.

14. Any infant milk substitute or feeding bottle or infant food or container thereof, in respect of which any provision of this Act has been or is being contravened, shall be liable to confiscation:

Provided that where it is established to the satisfaction of the court adjudging the confiscation that the person in whose possession, power or control any such substitute or bottle or food or container is found is not responsible for the contravention of the provisions of this Act, the court may, instead of making an order for the confiscation of such substitute or bottle or food or container, make such other order authorised by this Act against the person guilty of the breach of the provisions of this Act as it may think fit.

15. (1) Whenever any confiscation is authorised by this Act the court adjudging it may, subject to such conditions as may be specified in the order adjudging the confiscation, give to the owner thereof an option to pay in lieu of confiscation such cost not exceeding the value of the infant milk substitute or feeding bottle or infant food or container thereof in respect of which the confiscation is authorised as the court thinks fit.

(2) On payment of the cost ordered by the court the seized infant milk substitute or feeding bottle or infant food or container shall be returned to the person from whom it was seized on the condition that such person shall, before making any distribution, sale or supply of such substitute or bottle or food or container, give effect to the provisions of this Act.

16. No confiscation made or cost ordered to be paid under this Act shall prevent the infliction of any punishment to which the person affected thereby is liable under the provisions of this Act or under any other law.

17. Any confiscation may be adjudged or costs may be ordered to be paid,

(a) without any limit, by the principal civil court of original jurisdiction within the local limits of whose jurisdiction such confiscation has been made or costs have been ordered to be paid, as the case may be;
(b) subject to such limits as may be specified by the Central Government in this behalf, by such other court, not below a civil court having pecuniary jurisdiction

exceeding five thousand rupees, as the Central Government may, by notification in the Official Gazette, authorise in this behalf.

18. (1) No order adjudicating confiscation or directing payment of costs shall be made unless the owner of the infant milk substitute or feeding bottle or infant food or container thereof has been given a notice in writing informing him of the grounds on which it is proposed to confiscate such substitute or bottle or food or container and giving him a reasonable opportunity of making a representation in writing, within such reasonable time as may be specified in the notice, against the confiscation and if he so desires, of being heard in the matter:

Provided that where no such notice is given within a period of ninety days from the date of the seizure of the infant milk substitute or feeding bottle or infant food or container thereof, such substitute or bottle or food or container shall be returned after the expiry of that period to the person from whose possession it was seized.

(2) Save as otherwise provided in sub-section (1), the provisions of the Code of Civil Procedure, 1908, shall, so far as may be, apply to every proceeding referred to in sub-section (1).

19. (1) Any person aggrieved by any decision of the court adjudicating a confiscation or ordering the payment of costs may prefer an appeal to the court to which an appeal lies from the decision of such court.

(2) The appellate court may, after giving the appellant an opportunity of being heard, pass such order as it thinks fit confirming, modifying or revising the decision or order appealed against or may send back the case with such directions as it may think fit for a fresh decision or adjudication, as the case may be, after taking additional evidence if necessary:

Provided that an order enhancing any fine in lieu of confiscation or for confiscating goods of greater value shall not be made under this section unless the appellant has had an opportunity of making a representation and if he so desires of being heard in his defence.

(3) No further appeal shall lie against the order of the court made under sub-sector (2).

20. (1) Any person who contravenes the provisions of section 3,4,5,7,8,9,10 or sub-section (2) of section 11 and the rules made under section 26 of the Act shall be punishable with imprisonment for a term which may extend to three years, or with fine which may extend to five thousand rupees, or with both.

(2) Any person who contravenes the provisions of section 6 or sub-sector (1) of section 11 and the rules made under section 26 of the Act shall be punishable with imprisonment for a term which shall not be less than six months but which may extend to three years and with fine which shall not be less than two thousand rupees.

Provided that the court may, for any adequate and special reasons to be mentioned in the judgement, impose a sentence of imprisonment for 44 Law – 2, a term which shall not be less than three months but which may extend to two years and with fine which shall not be less than one thousand rupees.

21. (1) Save as otherwise provided in section 173 of the Code of Criminal Procedure, 1973, no court shall take cognizance of any offence punishable under this Act except upon a complaint in writing made by:

(a) a person authorised in this behalf under sub-section (1) of section 20 of the Prevention of Food Adulteration Act, 1954; or
(b) an officer not below the rank of a Class I officer authorised in this behalf, by general or special order, by the Government; or
(c) a representative of such voluntary organisation engaged in the field of child welfare and development and child nutrition as the Government may, by notification in the Official Gazette, authorise in this behalf.

(2) Where a complaint has been made by a representative of the voluntary organisation authorised under clause (c) of sub-section (1) and the court has issued a summons or, as the case may be, a warrant under sub-section (1) of section 204 of the Code of Criminal Procedure, 1973, the Assistant Public Prosecutor for that court shall take charge of the case and conduct the prosecution.

22. (1) Where an offence under this Act has been committed by a company, every person who, at the time the offence was committed, was in charge of, and was responsible to, the company for the conduct of the business of the company, as well as the company, shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this sub-section shall render any such person liable to any punishment, if he proves that the offence was committed without his knowledge or that he had exercised all due diligence to prevent the commission of such offence.

(2) Notwithstanding anything contained in sub-section (1), where any offence under this Act has been committed by a company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Explanation – For the purposes of this section,

(a) "company" means any body corporate and includes a firm or other association of individuals; and
(b) "director", in relation to a firm, means a partner in the firm.

23. Notwithstanding anything contained in the Code of Criminal Procedure, 1973, an offence punishable under this Act shall be –

(a) bailable;
(b) cognizable.

24. No suit, prosecution or other legal proceeding shall lie against the Central Government or any State Government or any officer of the Central Government or a representative of such voluntary organisation which is notified under clause (c) of sub-section (1) of section 21 for anything which is in good faith done or intended to be done under this Act.

25. The provisions of this Act, or the rules made thereunder shall be in addition to, and not in derogation of, the Prevention of Food Adulteration Act, 1954, or the rules made thereunder.

26. (1) The Central Government may, by notification in the Official Gazette, make rules to carry out the provisions of this Act.

(2) In particular, and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely:

(a) the conditions and restrictions subject to which educational equipment and other material may be donated or distributed under the provision to clause (b) of section 5;
(b) the language in which the notice and other particulars shall be indicated under sub-section (1) of section 6;
(c) the particulars which are to be indicated under clause (i) of sub-section (1) of section 6;
(d) the particulars which a container or label shall not bear under clause (d) of sub-section (2) of section 6;
(e) the matters to be included in the information which reaches pregnant women or mothers of infants under clause (g) of sub-section (1) of section 7;
(f) any other matter which is required to be, or may be, prescribed.

(3) Every rule made under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in section, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.

Subhash C. Jain,
Secy. To the Govt of India

INDIA

Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Rules, 1993, as Amended in 2003

In exercise of the powers conferred by section 26 of the Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992 (41 of 1992), the Central Government hereby makes the following rules further to amend the Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Rules, 1993, namely:-

1. Short title and commencement

   (1) These rules may be called the Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Rules 1993, as amended in 2003.

   (2) They shall come into force on the 1st Day of January, 2004.

2. Definitions

   (1) In these rules, unless the context otherwise requires

      (a) "Act" means the Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Amendment Act, 1992, as amended in 2003;

      (b) "authorised officer" means an officer not below the rank of a Class I (Group A or whatever name called) officer of the Government duly authorised by the State Government under section 12;

      (c) "Food inspector" means a person appointed by the Government as such under sector 9 of the Prevention of Food Adulteration Act, 1954 (37 of 1954);

      (d) "Section" means a section of the Act.

   (2) Words and expressions used in these rules and not defined but defined in the Act shall have the respective meanings assigned to them in the Act.

3. Local limits of jurisdiction of food inspectors. The local limits of jurisdiction of food inspectors shall be the same as are assigned to them under the Prevention of Food Adulteration Act, 1954 (37 of 1954).

4. Authorised officers

   (1) No officer of the Government shall be authorised by the State Government under section 12 unless he is:

      (a) a medical officer in charge of health administration of a local area; or

      (b) a graduate in medicine and has received at least one month's training in food inspection under the Prevention of Food Adulteration Act, 1954 (37 of 1954) by the Central Government or a State Government.

   (2) The State Government may, by notification in the Official Gazette, define the local limits of jurisdiction of authorised officers.

5. Conditions and restrictions for donations and distribution of infant milk substitutes or infant foods or feeding bottles or equipments and materials relating to them through health care system. No institution, organisation or health worker in private practice, pharmacy, drug store or any association of health workers, engaged in health care for mothers, infants or pregnant woman, shall donate or distribute any educational or other informational or communication aids relating to infant milk substitutes or infant food or feeding bottles without complying with the following conditions and restrictions, namely:

    (a) the donee should be informed in writing on:

        (i) the need for promoting breastfeeding;

        (ii) the nutritional superiority of mother's milk;

        (iii) the benefits of breastmilk, that is to say that breastmilk is:

            (A) the best natural food for infants;

            (B) always clean;

            (C) protects the infant from infection and diseases;

            (D) available always;

            (E) requires no special preparation;

        (iv) that breastfeeding helps parents to space their children.

        (v) the danger of microbial contaminations involved in bottle feeding.

    (b) informational or educational equipment or material relating to infant milk substitutes or feeding bottles should be donated or distributed only in case it is found necessary for healthy growth of the infant by a medical practitioner.

6. Language of the notice and other particulars of declaration.

    (1) No person shall produce, supply or distribute any infant milk substitute or infant food unless the container thereof or any label affixed thereto indicates in a clear, conspicuous and in an easily readable and understandable manner the words "IMPORTANT NOTICE", in capital letters in English and its equivalent in Hindi in Devnagri script.
    Provided that nothing herein contained shall prevent the use of any local language in addition to the language required to be used under this sub-rule.

    (2) The particulars of declaration to be specified on the label under the Prevention of Food Adulteration Act, 1954 (37 of 1954) and the rules made thereunder shall be in English or in Hindi in Devnagri script.
    Provided that nothing herein contained shall prevent the use of any language in addition to the language required to be used under this sub-rule.

7. Particulars of labelling of infant milk substitutes and infant foods. In addition to the requirements specified by or under the Prevention of Food Adulteration Act, 1954 and under section 6 of the Act, the label or the container of every infant milk substitute or infant food shall conform to the following, namely:

(a) the types of letters used shall not be less than 5 millimetres in size.

(b) the colour of the text printed or used shall be different from that of the background of the label, container, as the case may be.

(c) the text of the particulars shall be prominent and conspicuous in the central panel of the label, container.

(d) it shall indicate:

(i) that an infant milk substitute or an infant food should be prepared appropriately and hygienically besides taking adequate care in cleaning of utensils, bottles and teats.

(ii) a warning against health hazards of inappropriate preparation as under:

"Infant milk substitutes / Infant foods"

"Warning / caution Careful and hygienic preparation of infant food is most essential for health. Do not use fewer scoops than directed, since diluted feeding will not provide adequate nutrients needed by your infant. Do not use more scoops than directed since concentrated feed will not provide the water needed by your infant."

(iii) the approximate composition of nutrients per 100 grams of product including its energy value in calories.

(iv) the storage conditions specifically stating "Store in cool and dry place in an air-tight container" or the like.

(v) the feeding chart and direction for use and instruction for discarding left over feed, the batch number and date of manufacture.

(vi) instructions for use of measuring scoop (level or heaped) and the quantity per scoop.

(vii) the prescribed period by which the infant milk substitutes or the infant foods, as the case may be is to be consumed.

(viii) the Protein Efficiency Ratio (PER) which shall be minimum of 2.5 if the product other than the infant milk substitutes and infant foods is claimed to have high quality protein.

8. Particulars which a label or container should not contain.
Without prejudice to the requirements under the Prevention of Food Adulteration Act, 1954 (37 of 1954) and the rules made thereunder, the following restrictions on use of words in any language on the label or container, as the case may be, shall be applicable:

(a) the label or container shall not contain any reference to the Act or these rules or any comment on, or reference to, or explanation of any particulars or declaration required by the Act or any of these rules to be included in the label which directly or by implication, contradicts, qualifies or modifies such particulars or declaration.

(b) no words implying "recommended by the medical profession" or any words which imply or suggest that the food is recommended, prescribed or approved by medical practitioners shall be used in a label or container.

(c) the label or container shall not contain the terms "Humanised" or "Maternalised" or any other similar expressions in any language.

(d) no label or container of infant food shall exhibit the words "Full Protein Food", "Energy Food", "Complete Food" or "Health Food" or any other similar expressions in any language.

9. Details of information intended to reach pregnant women or mothers of infants through education or other material.

(1) Every educational or other material, whether audio or visual, dealing with pre-natal or post-natal care or with the feeding of an infant and intended to reach pregnant women and mothers of infants shall, besides the information specified in clauses (a) to (f) of sub-section (1) of section 7 shall include:

(a) the following details of advantages, as also nutritional superiority of breastfeeding:

(i) Immediately after delivery, breastmilk is yellowish and sticky. This milk is called colostrum, which is secreted during the first week of delivery. Colostrum is more nutritious than mature milk because it contains more protein, more anti-ineffective properties which are of great importance for the infant's defence against dangerous neonatal infections. It also contains higher levels of Vitamin 'A'.

(ii) breastmilk:

(A) is a complete and balanced food and provides all the nutrients needed by the infant in the first six months of life;

(B) has anti-infective properties that protect the infants from infection in the early months;

(C) is always available;

(D) needs no utensils or water (which might carry germs) or fuel for its preparation;

(iii) breastfeeding is much cheaper than feeding infant milk substitutes as the cost of the extra food needed by the mother is negligible compared to the cost of feeding infant milk substitutes;

(iv) mothers who breastfeed usually have longer periods of infertility after child birth than non-lactators.

(b) details of management of breastfeeding as under:

(i) breastfeeding:

(A) immediately after delivery enables the contraction of the womb and helps the mother to regain her figure quickly;

(B) is successful when the infant suckles frequently and the mother wanting to breastfeed is confident in her ability to do so.

(ii) in order to promote and support breastfeeding the mother's natural desire to breastfeed should always be encouraged by giving, where needed, practical advice and making sure that she has the support of her relatives.

(iii) adequate care for the breast and nipples should be taken during pregnancy.

(iv) it is also necessary to put the infant to the breast as soon as possible after delivery.

(v) let the mother and the infant stay together after the delivery, the mother and her infant should be allowed to stay together (in hospital, this is called "rooming-in").

(vi) give the infant colostrum as it is rich in many nutrients and anti-ineffective factors protecting the infants from infections during the few days of its birth.

(vii) the practice of discarding colostrum and giving sugar water, honey water, butter or other concoctions instead of colostrum should be very strongly discouraged.

(viii) let the infants suckle on demand.

(ix) every effort should be made to breastfeed the infants whenever they cry.

(x) mother should keep her body and clothes and that of the infant always neat and clean.

MALAYSIA

MALAYSIA

Relevant National Measure

Code of Ethics for Infant Formula Products, *3rd revision*, 7 August 1995.

Highlights

The Malaysian Code of Ethics was first formulated in 1979, before the adoption of the International Code of Marketing of Breastmilk Substitutes. The Ministry of Health initiated the process, but worked in close cooperation with the infant food companies operating in Malaysia at the time. The Code was then revised in 1983 and again in 1985, yet it still closely resembled the weak *Code of Ethics* published in 1975 by the International Council of Infant Food Industries. In 1995, the Ministry of Health made substantial improvements to the Code and in 2005 was preparing another revision. The Code remains voluntary.

The provisions of the Code apply to *infant formula products* including feeding bottles and teats. *Infant formula* products are defined to include infant formula, follow-up formula, special formula, ready-to-feed formula and any other infant formula promoted for use by infants (a child up to 12 months). *Follow-up formula* is defined to include infant formula marketed for babies from six months up to the age of three years. *Special formula* means formula marketed for premature or low-birth-weight infants or for infants with cow's milk hypersensitivity, carbohydrate intolerance and other metabolic disorders. Thus, the Code closes several loopholes associated with the scope of the International Code.

Advertising is prohibited in the health care system, retail outlets and through the media. Moreover, products may not be marketed in a way that "challenges the supremacy of breastmilk or that competes in any way with breastmilk".

Free supplies are prohibited in the health care system. Free product samples may be given only to health professionals, but only for new products for evaluation after approval by the Medical Research Ethical Committee.

The industry is not permitted to participate in baby shows for babies and children up to three years old. In addition, companies may not perform educational functions for parents related to infant feeding, nor display products at conferences, exhibits or other functions.

Educational materials regarding products may be distributed only to specific health professionals and only after approval by the Vetting Committee, established pursuant to the Code. The approval is valid for three years.

Products must comply with numerous labelling requirements. For one, labels must include the statement in the Malay language, "Breastmilk is the best food for infants" in bold lettering no less than 10 point in size for a 500g tin. The letter size

must increase proportionally with the size of the tin. The label may not be used as a vehicle for advertising another product.

Labels of infant formula products must also comply with Malaysia's general food laws, which include provisions related to labels of infant formula. Skimmed and full cream milk powders must include specific warnings regarding their use for feeding infants.

The Code is to be implemented by a National Disciplinary Committee and by a Committee in each State. The penalties for Code violations include written warnings, suspension of vetting of new materials for up to two years, notification to WHO, UNICEF and to the International Association of Infant Formula Manufacturers, press releases and black-listing of companies from future tenders.

MALAYSIA

Code of Ethics for Infant Formula Products in Malaysia

Preface

As Malaysia moves ahead towards becoming a developed and industrialised country by the year 2020, its commitment to human resource development would remain the mainstay of its thrust. Within this framework, Malaysia has expressed that due priority will be given to development of the poor, the disadvantaged and to the vulnerable groups including women, infants and children. In this respect, infants and children that make up more than one-third of the country's population will continue to be the focus of the government in terms of provision of health care, education and other basic services to enable them to attain optimal growth and development potential.

While the survival and health of the infant are dependent on factors during pregnancy, mainly on the health and nutritional status of the pregnant mother, care and feeding of the newborn play a vital role in ensuring its survival and future development. With the fostering of a caring culture and society, it is implicit that all Malaysians would want to promote practices and habits to show that we MALAYSIANS CARE. There is no better way of demonstrating this caring culture than to begin putting a baby to the mother's breast immediately after birth. This practice of nature not only shows that a mother cares, but sets the foundation for the child's life and development.

BREAST MILK IS THE BEST FOOD AND NUTRITION FOR THE BABY and protects the infant from diseases such as diarrhoeal and respiratory infections which could have serious effects on the child's health and growth. In addition, breastfeeding is an act of love and affection to the child, fosters bonding and nurtures a warm mother-child relationship that is important for the social, emotional and psychological development of the child. It is also through breastfeeding that family relationships can continue to be strengthened with support from the husband and family members. In this way, the care of the child would be a shared responsibility of all family members, thereby creating a happy and harmonious family and a conducive environment in which the child will grow and receive its fair share of affection and security.

Breastfeeding is a natural way of feeding infants and this practice transcends all religious, societal and cultural boundaries. This practice is regarded as a noble one in Islam and one that is advocated to all women both for the health of the child as well as the mother.

It is within the spirit of fostering a happy family and a caring society, as Malaysia moves towards Vision 2020, that this Code of Ethics for Infant Formula Products (1995) is put forward for adoption and implementation by **ALL** to demonstrate that we MALAYSIANS are committed to the protection, promotion and support of breastfeeding for the health and welfare of our children.

1. AIM OF THE CODE

The overall aim of this Code is to uphold the supremacy of breast milk; to assist in the safe and adequate nutrition of infants by the protection, promotion and support of breastfeeding; and to ensure proper use of Infant Formula Products when required.

2. SCOPE OF THE CODE[1]

This Code covers the basic principles of marketing and product information for **all Infant Formula Products (including feeding bottles and teats) in Malaysia**. It also provides guidelines on ethical practices for the Infant Formula Industry and the medical and health professional/personnel in the health care system.

3. DEFINITION

3.1 **ADVERTISEMENT** means any representation by any means whatsoever (written, audio or visual) for the purpose of promoting, directly or indirectly, the sale or disposal of any Infant Formula Product. It includes any notice, press release, circular, report, commentary, pamphlet, ball-point pen, poster, label, wrapper, sticker, book marker, stationery, shelf-talker, catalogue, magazine, toy, can-insert, pad (writing, note, prescription), card and letter (announcement, immunisation, congratulation, introduction, telephone), calendar, clock, diary, badge, banner, lapel pin, tie-pin, dummy tin, shop signboard, notice on vehicle, billboard, corporate souvenir and **any other means**.

3.2 **APPROPRIATE DESIGNATION** means a name or description, being specific and not a generic name or description, which shall indicate to the prospective purchaser the true nature of the food to which it is applied.

3.3 **COMPANY PERSONNEL** means any professional, demonstrator, medical representative, sales representative, nutritional representative and **other employee** working for the Infant Formula Industry or any other agent marketing the company's brand of Infant Formula Products.

3.4 **FOLLOW-UP FORMULA** means Infant Formula marketed for older babies from six months onwards up to the age of three years.

3.5 **HEALTH CARE SYSTEM** means all hospitals, clinics, mothercraft services, and maternity homes **both in the government and in the private sector** engaged, directly or indirectly, in the health care of infants and mothers especially pregnant and lactating women.

3.6 **INFANT** means a child up to twelve (12) months of age.

3.7 **INFANT FORMULA** means any food described or sold as an alternative for human milk for the feeding of infants. It is a product prepared from milk of cow or other animal or plant suitable for infant feeding.

3.8 **INFANT FORMULA INDUSTRY** means all companies marketing Infant Formula Products in Malaysia.

3.9 **INFANT FORMULA PRODUCTS** include Infant Formula, Follow-Up Formula, Special Formula, Ready-To-Feed Formula and **any other Infant Formula promoted** for use by infants.[2]

3.10 **LABEL** means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, painted, embossed or impressed on, or attached to or included in, belonging to, or accompanying any Infant Formula Product.

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[1] *Editor's note*: The Malaysian Code is being revised. The scope is expected to be broadened to include any infant food marketed for infants up to the age of six months.

[2] *See* Editor's note.

3.11 **MARKETING** means selling, distribution, promotion, advertising, product public relation and product information services.

3.12 **MEDICAL AND HEALTH PROFESSIONAL/PERSONNEL** means any hospital administrator, medical doctor, nutritionist, food technologist, dietician, pharmacist, matron, nurse, hospital assistant and midwife working in the health care system except those working for the Infant Formula Industry.

3.13 **PACK SHOT** means any representation of the Infant Formula Products either by photo or graphic or by line drawing.

3.14 **PROMOTION** means direct or indirect forms of inducing sales. It includes cheap sale, offer, free supply, donation, redemption scheme, free gift related or unrelated to purchase, free utensil or article, prizes, carrier-bag with pack shot or product logo, discount coupon, special display at retail outlets and **other giveaways**.

3.15 **READY-TO-FEED FORMULA** means Infant Formula Products **in liquid form** in disposable bottle, tetrapack and other packaging.

3.16 **RETAIL OUTLET** means any pharmacy, shop, supermarket, medical hall and other premises (distributor, agent, importer).

3.17 **SAMPLE** means any Infant Formula Products provided free.

3.18 **SPECIAL FORMULA** means Infant Formula marketed for premature or low birthweight infants or for infants with cow's milk hypersensitivity, carbohydrate intolerance and other metablic disorders.

4. ETHICAL PRACTICES FOR THE INFANT FORMULA INDUSTRY

The Infant Formula Industry should:

4.1 subscribe to and abide by the Code and observe professional and marketing ethics and established rules of conduct in all contacts within the health care system, retail outlets and the community.

4.2 ensure that their respective company personnel involved in sales and marketing of Infant Formula Products are familiar with the Code.

4.3 not market, promote, or advertise their Infant Formula Products in such a way as to

(a) challenge the supremacy of breast milk or

(b) complete in any way with breast milk.

4.4 not provide samples of Infant Formula Product to

(a) the health care system for use within it or for subsequent redistribution to pregnant and lactating women, parents of infants and children and members of their families and

(b) the retail outlets for subsequent redistribution to the community.

Samples of new Infant Formula Products may, however, be provided to Medical and Health Professionals for evaluation upon approval by the Medical Research Ethical Committee.

4.5 not promote or advertise their Infant Formula Products within the health care system, the retail outlets and the mass media. However, vetted scientific and educational materials may be distributed to hospital administrators, medical doctors, nutritionists, food technologists, dieticians, pharmacists and matrons.

4.6 not provide bottled water, feeding bottles, teats (pacifiers) and other related formula feeding equipment to the medical and health professional/personnel for use within the health care system or subsequent redistribution to the public.

4.7 not be involved in any manner with baby shows (0-36 months).

4.8 ensure that the remuneration of company personnel be on a fixed and regulated basis, and not related in any way with sales of Infant Formula Products.

4.9 not give, directly or indirectly, incentives in cash or in kind to the medical and health professional/personnel or retail outlets as an inducement for promoting Infant Formula Products.

4.10 not obtain, directly or indirectly, the names and addresses of pregnant and lactating mothers for the purpose of promoting Infant Formula Products.

4.11 not permit company personnel to have direct or indirect contacts with pregnant and lactating women, parents of infants and children, and members of their families and child-care providers for the purpose of promotion of Infant Formula Products and to perform educational functions related to infant formula feeding. However, they may be permitted to investigate specific complaints related to their products.

4.12 not allow company personnel to wear uniform which is similar to that of the government medical and health personnel.

4.13 not display Infant Formula Products in conferences, exhibitions or any other similar forum.

4.14 not provide mothercraft services, either directly or indirectly.

5. ETHICAL PRACTICES FOR MEDICAL AND HEALTH PROFESSIONAL/PERSONNEL

All Medical and Health Professional / Personnel should:

5.1 encourage all mothers to breastfeed their babies for as long as possible but for at least the first four to six months. Management of breastfeeding should start during pregnancy and continue after delivery.

5.2 not accept any Infant Formula Product, sponsorship or any incentive in cash or in kind from the Infant Formula Industry. Acceptance of new Infant Formula Products for evaluation by Medical and Health Professionals as provided for under article 4.4 is, however, permitted.

5.3 not allow marketing of Infant Formula Products to the public in the health care system. However, hospital administrators, medical doctors, nutritionists, food

technologists, dieticians, pharmacists and matrons may accept vetted scientific and educational materials.

5.4 ensure that company personnel do not have direct or indirect contact with pregnant and lactating women, parents of infants and children and members of their families in the health care system for the purpose of promoting Infant Formula Products.

5.5 ensure that company personnel do not copy the names and addresses of mothers from the Admission Register, Birth Register and any other source in the health care system.

5.6 not request nor receive samples for themselves or for redistribution to pregnant and lactating women, parents of infants and children and members of their families.

5.7 ensure that all Infant Formula Products are kept away from the view of mothers.

5.8 not have preferences over any individual company except for Special Formula on medical grounds.

5.9 give all the necessary instructions for the safe use of the Infant Formula Products to the very small number of mothers who are not able to breastfeed their babies. Such advice should be given individually and should include a clear explanation of the financial implications and consequences of the inappropriate use of Infant Formula Products that supplement or replace breastmilk.

5.10 not be involved in any manner with baby shows.

Any breach of this Code in hospitals, clinics, maternity homes and retail outlets is to be reported to the Disciplinary Committee on the Code of Ethics for Infant Formula Products.

6. GUIDELINES FOR PRODUCING AND VETTING OF INFORMATIONAL AND EDUCATIONAL MATERIALS

6.1 General Principles

(a) All information related to Infant Formula Products must be submitted to the Vetting Committee for approval.
(b) Can-insert approved by the Vetting Committee is permitted.
(c) The correct translation of the approved materials into Bahasa Malaysia and other languages is the responsibility of the Infant Formula Industry.
(d) The approval Code given by the Vetting Committee is based strictly on the scope of the Code.

6.2 Product Labelling

All product labelling must:

(i) comply with the Food Act 1983, the Food Regulations 1985 and the Trade Description Act 1972;

(ii) be in Bahasa Malaysia and may include translation thereof in any other language;

(iii) not display any claim of superiority of the product to breastmilk;

(iv) have a statement that the product shall be used only on medical advice;

(v) have instructions for correct preparation, and a warning against the health hazards of incorrect preparation;

(vi) not use the term "humanised" or "maternalised" or **similar terms**;

(vii) not be used as a vehicle for advertising another product;

(viii) have names and addresses of the importer and exporter;

(ix) have an expiry date;

(x) have instructions on proper storage of the Infant Formula Product;

(xi) provide the appropriate designation of major ingredients used in the Infant Formula Product in descending order of proportion by weight;

(xii) not bear the words "Infant Formula with Iron" unless the product contains no less than 1mg of iron (Fe) per 100 available calories;

(xiii) have the name of the animal or plant from which the major ingredients are derived written on the Ingredient List in bold characters;

(xiv) have the following mandatory statements in the **principal display panel** on the label:

- the Approval Code from the Vetting Committee.
- **"SUSU IBU ADALAH MAKANAN TERBAIK UNTUK BAYI"**. These words shall be in bold lettering and not less than 10 points in size for 500g tin. The size of the lettering shall increase proportionately with the size of the tin.
- The appropriate designation eg. **INFANT FORMULA, FOLLOW-UP FORMULA, SPECIAL FORMULA,** etc. These words shall be more prominent in visual emphasis and position and not less than half the height when compared with the brand name of the Infant Formula Product.
- **"RUMUSAN BAYI BUKANLAH MAKANAN TUNGGAL UNTUK BAYI LEBIH DARI ENAM BULAN"**. These words shall be in bold lettering and not less than 4 points in size for 500g tin.

(xv) no label of an infant formula shall display any picture or graphic of infants or babies or parts of infants or babies, mothers, feeding bottles or teats. For the purpose of illustrating methods of preparation, graphics may be used.

6.3 Materials Directed at Medical and Health Professionals (hospital administrator, medical doctor, nutritionist, food technologist, dietician, pharmacist and matron)

(a) The aim is to provide accurate information on maternal and infant nutrition.

(b) All materials on Infant Formula Products must devote at least **one quarter** of its content or space to positive statements on breastfeeding including:

(i) the importance of early initiation of breastfeeding within one hour of delivery;

(ii) the benefits of breastfeeding and superiority of breast milk;

(iii) maternal nutrition and management of breastfeeding;

(iv) the negative effects on breastfeeding of introducing partial bottle feeding;

(v) the difficulty of reversing the decision not to breastfeed;

(vi) advice and support of breastfeeding for working mothers;

(vii) the source of the Infant Formula Product eg. cow, goat, soya-bean.

(c) Such materials should not use any picture of infant which may idealise bottle feeding.

(d) When such materials contain information about the use of an Infant Formula Product, such materials should contain information about:

(i) the proper use of the Infant Formula Product;

(ii) the social and financial implications of its use;

(iii) the health hazards of unnecessary or improper use of the Infant Formula Product.

(e) Product claims will reflect scientific integrity without implicating that any product is superior or equal to breast milk.

(f) Presentation of a product's benefits without reference to breast milk is permitted.

(g) Balanced and factual information of any Infant Formula Product in textual form is allowed so long as it does not challenge the supremacy of breast milk. Illustrations (table, graph, chart, diagram) comparing breast milk with Infant Formula Products are not permitted.

(h) Scientific literature which contains factual information on topics related to infant nutrition is permitted.

(i) The featuring of pack shot in informational and educational materials may be permitted upon approval by the Vetting Committee.

6.4 Materials for Vetting

The procedure for submission of materials for vetting is as follows:

(a) The purpose and target population must be clearly stated in the submission.

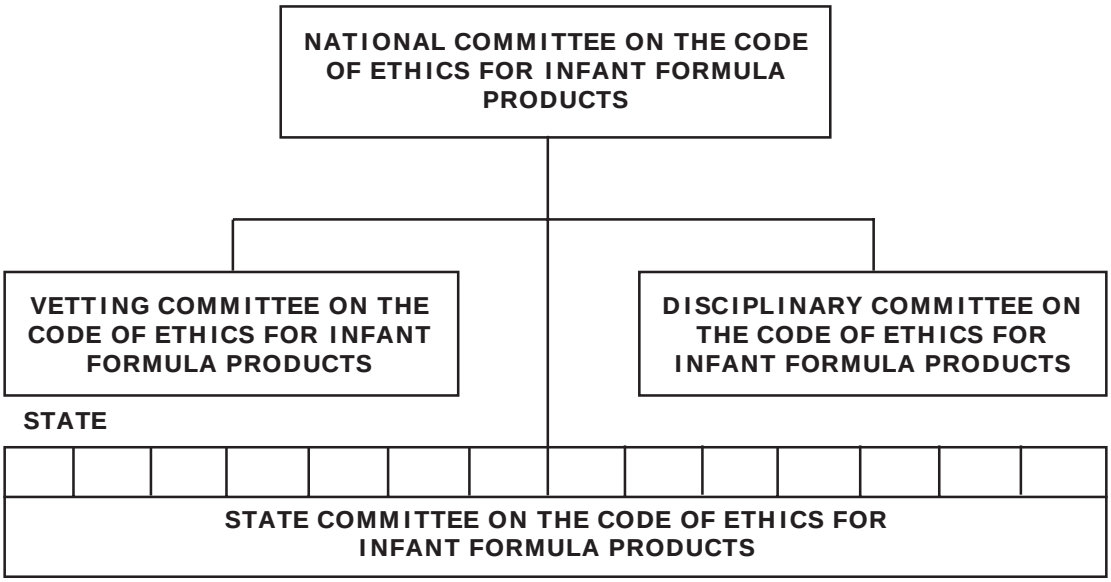
(b) Every request must be accompanied by **ten (10)** copies of the vetting materials.

(c) All vetting materials must be "**in the final draf**t" before submission to the Vetting Committee.

(d) All approved materials must be printed in exactly the same format, lettering, design, wording, style, display and proportionate size as approved by the Vetting Committee.

7. ORGANISATION

NATIONAL



ORGANISATION CHART

(e) Each vetted material is approved on its own merits and no two or more approved materials can be combined together without the approval of the Vetting Committee.

(f) A copy of the **final** printed product must be sent to the Vetting Committee for record purposes.

(g) The approved materials with the exception of product labels will be valid only for a period of **three (3) years** from the date of approval. A request for extension is obligatory after the expiry period.

7.1 NATIONAL COMMITTEE ON THE CODE OF ETHICS FOR INFANT FORMULA PRODUCTS

(a) Terms of Reference:

(i) To uphold the supremacy of breastmilk, consistent with the spirit and objective of the Code.

(ii) To provide a forum for discussion on issues related to the Code.

(iii) To formulate policies on the promotion, protection support of breastfeeding.

(b) Members:

Chairman:	Deputy Director-General of Health (Public Health)
Secretary:	Assistant Director (Nutrition)
Members:	Deputy Director-General of Health (Medical)
	Director of Family Health Development
	Director of Food Quality Control
	Senior Paediatrician
	Senior Obstetrician and Gynaecologist
	Principal Assistant Director (Family Health)
	Assistant Director (Nutrition)
	Principal Matron, Nursing Division
	Other co-opted members

This National Committee is assisted by the Vetting Committee on the Code of Ethics for Infant Formula Products and the Disciplinary Committee on the Code of Ethics for Infant Formula Products at the National Level.

7.2 VETTING COMMITTEE ON THE CODE OF ETHICS FOR INFANT FORMULA PRODUCTS

(a) Terms of Reference:

(i) To vet all materials including product labelling related to Infant Formula Products.

(ii) To review and revise the Code of Ethics for Infant Formula Products whenever necessary.

(iii) Responsible for making recommendations on amendments pertaining to the Infant Formula Products, in the Food Act 1983 and the Food Regulations 1985.

(iv) Responsible for monitoring and implementing the Code.

(b) Members:

Chairman:	Director of Family Health Development
Secretary:	Assistant Director (Nutrition)
Members:	Director of Food Quality Control
	Senior Paediatrician
	Senior Obstetrician and Gynaecologist
	Obstetrician and Gynaecologist from a local university
	Paediatrician from a local university
	Principal Assistant Director (Family Health)
	Assistant Director (Nutrition)
	Other co-opted members

7.3 DISCIPLINARY COMMITTEE ON THE CODE OF ETHICS FOR INFANT FORMULA PRODUCTS

(a) Terms of Reference:

(i) To coordinate investigations on specific complaints on alleged violations of the Code.

(ii) To assess the seriousness of the violations of the Code.

(iii) To act on findings of the alleged violations of the Code.

(iv) To take appropriate disciplinary actions after considering all appeals (written and in person).

(b) Members:

Chairman:	Deputy Director-General of Health (Public Health)
Secretary:	Assistant Director (Nutrition)
Members:	Deputy Director-General of Health (Medical)
	Director of Family Health Development
	Senior Paediatrician
	Senior Obstetrician and Gynaecologist
	Principal Matron
	Representative from Ministry of Domestic Trade and Consumer Affairs

(c) Appeal:

All appeals should be submitted within a period of one month from the date of notification to the Chairman of the Disciplinary Committee whose decision shall be final.

(d) Penalty:

Any one or a combination of the following penalties will be imposed depending on the seriousness and frequency of the violations of the Code:

(i) Written warning with copies to the parent company of the Infant Formula Product and Chairman of the State Committee on the Code of Ethics for Infant Formula Products

(ii) Suspension of vetting of all new materials for one to two years

(iii) Notification to the World Health Organization and UNICEF

(iv) Notification to the International Association of Infant Food Manufacturers

(v) Press release

(vi) Black-listing such as omission of the relevant company from future tenders for a period of time.

For non-compliance by medical doctors, the Chairman of the Disciplinary Committee may request compliance in writing with copies to the Malaysian Medical Council and Malaysian Medical Association.

7.4 STATE COMMITTEE ON THE CODE OF ETHICS FOR INFANT FORMULA PRODUCTS

This Committee assists the National Committee on the Code of Ethics for Infant Formula Products in the implementation of the Code at state and district level.

(a) Terms of Reference:

(i) To monitor the implementation of the Code at state and district level.

(ii) To investigate all alleged complaints.

(iii) To submit findings to the Disciplinary Committee for appropriate action.

(iv) To implement appropriate actions recommended by the Disciplinary Committee.

(v) To meet at least once in six months or whenever necessary.

(b) Members

Chairman:	State Director of Health
Secretary:	Nutrition Officer
Members:	State Deputy Director of Health (Public Health)
	State Deputy Director of Health (Medical)
	State Deputy Director of Health (Pharmacy)
	Paediatrician
	Obstetrician and Gynaecologist
	Maternal and Child Health Officer
	State Matron
	Other co-opted members

YEMEN

highlights for yemen
wait for ellen

REPUBLIC OF YEMEN

In the name of God the Compassionate the Merciful

Republic of Yemen

Ministry of Legal Affairs

Prime Minister Decree # 18/ 2002 on Breastfeeding Promotion and Protection

The Prime Minister, after reviewing:

The Constitution of the Republic of Yemen,

The Republican Decree # (17) for 1994 General Provisions on Contraventions,

The Republican Decree # (1) for 1999 Ministry of Public Health Regulations,

The Republican Decree # (46) for 2001 Government Constitution and designation of its Members;

According to:

The proposal presented by the Minister of Public Health and Population and following the approval of the Cabinet,

Decided on the following Decree.

Chapter One
Title, definitions, objectives and scope of application
Section I
Title and definitions

Article (1) The title of these Regulations is "Breastfeeding Promotion and Protection Regulations"

Article (2) For the purpose of implementing these Regulations, terms used below should have the meaning stated alongside of each, unless context shows otherwise.

Republic:	Republic of Yemen.
Minister:	Minister of Public Health and Population.
Ministry:	Ministry of Public Health and Population.
Competent Authority:	Department of Nutrition, Ministry of Public Health and Population, and all ministries, institutions, entities and governmental agencies charged with the implementation of these Regulations according to enforced laws and regulations.
Infant formula:	Any infant food made as per the certified specifications and standards of the Yemen Authority of Specifications, Standard, and Quality Control, or in the absence of any national standards, the standards of *Codex Alimentarius* on baby foods, in order to satisfy the normal nutritional requirements of infants up to six months of age and adapted to their physiological characteristics.

Complementary food (weaning food):	Any food manufactured, prepared locally, or imported, according to specifications and standards certified by the Authority, suitable as a complement to breastfeeding or infant formula when either becomes insufficient to satisfy nutritional requirements of infants starting from 6 months of age.
Marketing:	The promotion of a product, its distribution, selling, advertising, product public relations and information services.
Label:	Any indication, instruction, sign, pictorial or descriptive matter, written, engraved or embossed on a product that is subject to the present Regulations.
Health worker:	Any person either technical or non-technical in any component of the health care system including volunteers, members of non-governmental organisations and workers in the private health sector.
Container:	Any form of packaging of products for sale as a normal retail unit including wrappers.
Samples:	Limited or small quantities of the products provided without cost.
Supplies (subsidized or free of charge):	Quantities of the product provided for use over a long period of time, either free or at low price for social purposes, including those given to families in need.
Manufacturer:	Any company or body involved in manufacturing or importing a product within the scope of these Regulations.
Distributor:	A person, natural or legal, engaged in the wholesale or retail trade for the marketing of a product within the scope of these Regulations.
Marketing agent:	Any person whose functions include the marketing of products within the scope of these Regulations.
Health care system:	Institutions of the Health Ministry, or any other governmental or non-governmental organisation, engaged directly or indirectly in health care within the Republic. Pharmacies, drug storages, and sales outlets for products within the scope of these Regulations are not considered as part of the health care system.
Pacifier (soother):	Manufactured teat made for sucking by children.
Bottle:	Feeding bottle made of glass or plastic.
Infant:	Child under the age of 12 months.
Young children:	Children aged between one and up to two years.
Authority:	The Yemen Authority of Specifications, Standards and Quality Control.
Regulations:	Breastfeeding Promotion and Protection Regulations.

Section II
Objectives and scope

Article (3) These Regulation aim to contribute to the provision of safe and adequate nutrition for infants and young children by demonstrating the importance of breastfeeding and promoting its practice and by ensuring the quality, proper

use and appropriate marketing of food products that are either locally produced or imported, for infants and young children.

Article (4) These Regulations are applied to:

1- Marketing and it its associated practices (trade and advertisement) of the following products:
   a. Milk and infant formulae.
   b. Dairy products and other foods and drinks exclusively used for children up to two years of age.
   c. Complementary foods marketed or presented as suitable, either with or without modification, for use as partial or total substitute for breastmilk.
   d. All types of feeding bottles and pacifiers.
2- Quality, safety, and availability of these products.
3- Information on the use of these products.
4- All food products covered by these Regulations which preparations, materials and their pictures are used in marketing.

Chapter Two
Quality and standards of food, labels, feeding bottles and pacifiers
Section I
Quality and standards of food and labelling

Article (5) Manufacturing, importing or marketing of products within the scope of these Regulations are prohibited unless the products meet the specifications and standards issued by the Authority.

Article (6) Labels should be designed in conformity with specifications and standards issued by the Authority. They should provide essential instructions for the proper use of products and should not discourage the practice of breastfeeding.

Article (7) Manufacturers and distributors of infant formulae should include the following information, in Arabic, on the label:

1- "Important Notice" or its equivalent, followed by the following two statements:
   a. Breastmilk is complete food and contains all essential nutrients for infants; it raises the immunity of infants against diseases especially diarrhoea.
   b. This product should not be used without consulting a specialist doctor. It is preferable to use cup and spoon when feeding infants and young children with this product.
2- Instructions for appropriate preparation and proper use, presented in easily understandable words and drawings.
3- Warning against health hazards of inappropriate preparation or feeding the product to infants below six months of age (for complementary foods).
4- The use of simple symbols to clarify the age at which the product can be used.
5- It should not include pictures of infants or young children, or statements or graphics that discourage or inhibit the practice of breastfeeding or which idealise the use of the product for infant feeding.
6- It should include the feeding schedule in the instructions for use.

7- In addition, it should be mentioned that starting complementary foods does not mean that breastfeeding should cease and that complementary foods do not have the equivalent nutritive value of breastmilk.

Article (8) With the exception of infant formulae and complementary foods, labels of other foods within the scope of these Regulations should meet the following conditions:

1- It should not include pictures of infants or young children, or statements or other graphics that discourage or inhibit the practice of breastfeeding or suggest the possibility of using or modifying them to satisfy the needs of the infant.
2- Warning against using them for infant feeding

Article (9) Labels of food products within the scope of these Regulations should also include the following:

1- Ingredients.
2- Composition/analysis of the product.
3- Required storage conditions before and after opening the container.
4- Names and addresses of the manufacturer and distributor.
5- Date of production and expiry.

Section II
Feeding bottles and pacifiers

Article (10) Manufacturing or importing feeding bottles and teats are prohibited unless they meet the specifications and standards issued by the Authority and have written on their affixed label the following information in Arabic:

1- Breastmilk is a complete food and contains all essential nutrients for infants and raises as well, the immunity of infants against diseases and diarrhea.
2- Should not be used without consulting of a specialist doctor.
3- Instructions on cleaning and sterilizing, using words and drawings easy to understand.
4- Indicate that feeding by cup and spoon is safer than sucking the feeding bottle.
5- Name and address of the manufacturer or the distributor.
6- These products should not include statements, pictures or sketches, or any other graphics that advertise or promote bottle feeding.
7- In the absence of labeling, a brochure should be enclosed in the product container.

Article (11) Manufacturing, importing, and marketing of either locally made or imported separate teats (pacifiers) that are not used for infant bottle feeding are prohibited.

Chapter Three
Advertising and promotion

Article (12) Manufacturers and distributors of products covered by provisions of these Regulations are not allowed to:

1- Publicly advertise and promote products within the scope of these Regulations in any form or way.
2- Provide the public with samples of products within the scope of these Regulations, either directly or indirectly.
3- Distribute to the public any gifts, materials, donations or devices that could promote the use of milks or foods other than breastmilk.

Chapter Four
Health care system, and health information and education
Section I
Health care system

Article (13) The Ministry and its institutions shall take the appropriate measures to promote and protect breastfeeding, and provide health workers with information and advice on the importance, support and promotion of breastfeeding.

Article (14) The use of any of the health care facilities for the purpose of display, advertising, or distribution of infant formulae and other foods within the scope of these Regulations are prohibited.

Article (15) Deliveries occurring in hospitals, health centres and units should observe the following instructions:

a. Help and advice to mothers on the necessity of starting breastfeeding immediately after delivery, and ensuring the appropriate measures for babies to be breastfed.
b. Prohibition against feeding the child with anything other than colostrum and breastmilk. Water, any other fluids or milk substitutes shall not be given to the child, from the feeding bottle, while the child and mother are in a hospital or in a health centre, except in special cases and under the supervision of a specialist doctor.
c. Prohibition against giving the mother any medication that can reduce breastmilk supply, except in extreme necessity and by decision of a specialist doctor. Contraceptives that contain oestrogen shall not be given to the mother, particularly during the first six months since it might reduce her breastmilk supply when the child is totally dependent on it.
d. Education of mothers on breastfeeding advantages and its essential role in birth spacing and that increased frequency and duration of breastfeeding, especially during the night, increases breastmilk supply.
e. The mother should be given the chance to stay with her newborn in the incubation room for some time, if needed.
f. Infant formula shall not be fed to children below six months of age unless it is medically prescribed by a specialist doctor.

Article (16) Instructions in the preceding article shall be disseminated among community members through appropriate channels considering deliveries that take place outside health facilities or in private homes.

Article (17) Health care system policy shall encourage exclusive breastfeeding up to sixth months of age when additional feeding is required; recommend the use of cup and spoon and ban the use of feeding bottles.

Section II
Health workers

Article (18) Health workers in the health care system shall implement provisions of these Regulations that relate to the promotion, protection and support of breastfeeding. They are responsible for providing information to mothers in order to encourage breastfeeding.

Article (19) Health workers are not allowed to accept any financial or material incentives from manufacturers or distributors, directly or indirectly, nor accept samples of infant formulae or any other foods, within the scope of these Regulations except for the purpose of research at the institutional level.

Article (20) Any donations for health workers offered by manufacturers and distributors of the products within the scope of these Regulations (such as study tours, fellowships and research grants), shall be subject to the approval by the Ministry.

Section III
Health information and education

Article (21) No authority or institution is authorized to issue any information and educational materials on infant and young child nutrition and on other products within the scope of these Regulations , as well as on pregnant and lactating mothers nutrition, unless they have previously been submitted to the Ministry for scientific clearance and in conformity with the objectives of these Regulations

Chapter Five
Sanctions and special provisions
Section I
Sanctions

Article (22) Without prejudice to stronger sanctions specified in other enforced laws, anyone who infringes the provisions of these Regulations shall be punished as provided in this Article:

1- Violation of the provisions of Articles 10, 12 and 18 shall be subject to a fine not exceeding ten thousand Rials.
2- Violation of the provisions of Articles 5, 6, 7 and 9 shall be subject to a fine not exceeding ten thousand Rials.

Article (23) Sanctions in sub- paragraph (2) of the previous article do not exclude confiscation of prohibited products and, in case of non- compliance with approved specifications and standards, their destruction shall be at the expense of the offender in accordance with applicable rules and procedure. Alternatively, these products shall be returned to their place of origin if imported, or to their site of production if locally produced.

Article (24) Sanctions are doubled in case of repeat offences. The court may order the offender not to engage in any activity related to food, infant food and child

products, either temporarily or permanently, in accordance with applicable laws and regulations.

Article (25) The offender shall be held responsible for any act or offence leading to any crime under law and shall be accountable for damages to third parties in accordance with the rules of criminal law and other enforced legislation.

Section II
Final provisions

Article (26) The total amounts raised from applying sanctions under Articles 22, 23, 24 and 25 of these Regulations shall be handed to the public treasury.

Article (27) The Minister, in coordination with concerned sectors, shall issue decrees for the enforcement of these Regulations.

Article (28) This Cabinet Decree enters into force from the date of issue and shall be published in the official gazette.

Issued in Prime Minister Office
On 24/ Shawal/ 1422 Hegira
8 January 2002

Abdulqader BAJAMMAL
The Prime Minister

Appendix B

The International Code of Marketing of Breastmilk Substitutes

World Health Organization

Geneva
1981

The *International Code of Marketing of Breastmilk Substitutes* is reprinted with the permission of the World Health Organization.

Introduction

THE WORLD HEALTH ORGANIZATION (WHO) and the United Nations Children's Fund (UNICEF) have for many years emphasized the importance of maintaining the practice of breastfeeding – and of reviving the practice where it is in decline – as a way to improve the health and nutrition of infants and young children. Efforts to promote breastfeeding and to overcome problems that might discourage it are a part of the overall nutrition and maternal and child health programmes of both organizations and are a key element of primary health care as a means of achieving health for all by the year 2000.

A variety of factors influence the prevalence and duration of breastfeeding. The Twenty-seventh World Health Assembly, in 1974, noted the general decline in breastfeeding in many parts of the world, related to sociocultural and other factors including the promotion of manufactured breastmilk substitutes, and urged "Member countries to review sales promotion activities on baby foods and to introduce appropriate remedial measures, including advertisement codes and legislation where necessary".[1]

The issue was taken up again by the Thirty-first World Health Assembly in May 1978. Among its recommendations were that Member States should give priority to preventing malnutrition in infants and young children by, *inter alia*, supporting and promoting breastfeeding, taking legislative and social action to facilitate breastfeeding by working mothers, and "regulating inappropriate sales promotion of infant foods that can be used to replace breastmilk".[2]

Interest in the problems connected with infant and young child feeding and emphasis on the importance of breastfeeding in helping to overcome them have, of course, extended well beyond WHO and UNICEF. Governments, nongovernmental organizations, professional associations, scientists, and manufacturers of infant foods have also called for action to be taken on a world scale as one step towards improving the health of infants and young children.

In the latter part of 1978, WHO and UNICEF announced their intention of organizing jointly a meeting on infant and young child feeding, within their existing programmes, to try to make the most effective use of this groundswell of opinion. After thorough consideration of how to ensure the fullest participation, the meeting was convened in Geneva from 9 to 12 October 1979 and was attended by some 150

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[1] Resolution WHA27.43 (*Handbook of Resolutions and Decisions of the World Health Assembly and the Executive Board,* Volume II, 4th ed., Geneva, 1981, p.58)

[2] Resolution WHA31.47 (*Handbook of Resolutions and Decisions...* Volume II, 4th ed., p.62)

representatives of governments, organizations of the United Nations system and other intergovernmental bodies, nongovernmental organizations, the infant food industry, and experts in related disciplines. The discussions were organized on five main themes: the encouragement and support of breastfeeding; the promotion and support of appropriate and timely complementary feeding (weaning) practices with the use of local food resources; the strengthening of education, training and information on infant and young child feeding; the promotion of the health and social status of women in relation to infant and young child health and feeding; and the appropriate marketing and distribution of breastmilk substitutes.

The Thirty-third World Health Assembly, in May 1980, endorsed in their entirety the statement and recommendations agreed by consensus at this joint WHO/UNICEF meeting and made particular mention of the recommendation that "there should be an international code of marketing of infant formula and other products used as breastmilk substitutes", requesting the Director-General to prepare such a code "in close consultation with Member States and with all other parties concerned".[3]

To develop an international code of marketing of breastmilk substitutes in accordance with the Health Assembly's request, numerous and lengthy consultations were held with all interested parties. Member States of the World Health Organization and groups and individuals who had been represented at the October 1979 meeting were requested to comment on successive drafts of the code, and further meetings were held in February and March and again in August and September of 1980. WHO and UNICEF placed themselves at the disposal of all groups in an effort to foster a continuing dialogue on both the form and the content of the draft code and to maintain as a basic minimum content those points which had been agreed upon by consensus at the meeting in October 1979.

In January 1981, the Executive Board of the World Health Organization, at its sixty-seventh session, considered the fourth draft of the code, endorsed it, and unanimously recommended [4] to the Thirty-fourth World Health Assembly the text of a resolution by which it would adopt the code in the form of a recommendation rather than as a regulation.[5] In May 1981, the Health Assembly debated the issue after it had been introduced by the representative of the Executive Board.[6] It adopted the code, as proposed, on 21 May by 118 votes in favour to 1 against, with 3 abstentions.[7]

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[3] See resolution WHA33.32, reproduced in Annex 2.

[4] See resolution EB67.R12, reproduced in Annex 1.

[5] The legal implications of the adoption of the code as a recommendation or as a regulation are discussed in a report on the code by the Director-General of WHO to the Thirty-fourth World Health Assembly; this report is contained in document WHA34/1981/REC/1, Annex 3.

[6] See Annex 3 for excerpts from the introductory statement by the representative of the Executive Board.

[7] See Annex 1 for the text of resolution WHA34.22, by which the code was adopted. For the verbatim record of the discussion at the fifteenth plenary meeting, on 21 May 1981, see document WHA34/1981/REC/2.

International Code of Marketing of Breastmilk Substitutes

CONTENTS

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 socio-economic status and their roles as mothers;

Conscious that breastfeeding is an unequalled way of providing ideal food for the healthy growth and development of infants; that it forms a unique biological and emotional basis for the health of both mother and child; that the anti-infective properties of breastmilk help to protect infants against disease; and that there is an important relationship between breastfeeding and child-spacing;

Recognizing that the encouragement and protection of breastfeeding 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 breastfeeding is an important aspect of primary health care;

Considering that when mothers do not breastfeed, 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 breastfeeding;

Recognizing further that inappropriate feeding practices lead to infant malnutrition, morbidity and mortality in all countries, and that improper practices in the marketing of breastmilk 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 breastmilk substitutes;

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

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 breastfeeding, and providing objective and consistent advice to mothers and families about the superior value of breastfeeding, 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 breastfeeding, and in the appropriate use of complementary foods;

Aware that families, communities, women's organizations and other nongovernmental organizations have a special role to play in the protection and promotion of breastfeeding and in ensuring the support needed by pregnant women and mothers of infants and young children, whether breastfeeding 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 breastmilk 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 breastmilk substitutes, the marketing of breastmilk substitutes requires special treatment, which makes 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 breastfeeding, and by ensuring the proper use of breastmilk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution.

Article 2. Scope of the Code

The Code applies to the marketing, and practices related thereto, of the following products: breastmilk substitutes, including infant formula; other milk products, foods and beverages, including bottlefed complementary foods, when marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breastmilk; feeding bottles 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:

"Breastmilk substitute"	means	any food being marketed or otherwise represented as a partial or total replacement for breastmilk, whether or not suitable for that purpose.
"Complementary food"	means	any food, whether manufactured or locally prepared, suitable as a complement to breastmilk 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 "breastmilk 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 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 breastmilk 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 products 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 clear information on all the following points: *(a)* the benefits and superiority of breastfeeding; *(b)* maternal nutrition, and the preparation for and maintenance of breastfeeding; *(c)* the negative effect on breastfeeding of introducing partial bottle-feeding; *(d)* the difficulty of reversing the decision not to breastfeed; 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 breastmilk substitutes. Such materials should not use any pictures or text which may idealize the use of breastmilk 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 provi-

sion 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 breastmilk 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 breastfeeding 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 service 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 breastmilk 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 breastfeeding; 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 breastfeeding. 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 breastfeeding.

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 breastfeeding; *(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. They may, however, have graphics for easy identification of the product as a breastmilk substitute and for illustrating methods of preparation. The terms "humanized", "maternalized" or similar terms should not be used. Inserts giving additional information about 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 1

Resolutions of the Executive Board at its Sixty-seventh Session and of the Thirty-fourth World Health Assembly on the International Code of Marketing of Breastmilk Substitutes

Resolution EB67.R12
Draft International Code of Marketing of Breastmilk Substitutes

The Executive Board,

Having considered the report by the Director-General on the Draft International Code of Marketing of Breastmilk Substitutes;

1. ENDORSES in its entirety the Draft International Code prepared by the Director-General;

2. FORWARDS the Draft International Code to the Thirty-fourth World Health Assembly;

3. RECOMMENDS to the Thirty-fourth World Health Assembly the adoption of the following resolution:

28 January 1981

[The text recommended by the Executive Board was adopted by the Thirty-fourth World Health Assembly, on 21 May 1981, as resolution WHA34.22, reproduced overleaf.]

[*Editor's note: In this book, Resolution 34.22 is reproduced on pages 304-05.*]

Annex 2

[*Editor's note: Annex 2 is Resolution 33.32, which is reproduced on pages 301-03 of this book*]

ICDC Commentary

The following statement delivered by Dr. Tolbjørn Mork to Committee A of the World Health Assembly on 20 May 1981 was made into an Annex to the World Health Organization's original publication of the International Code of Marketing of Breastmilk Substitutes. Dr. Mork's statement served to introduce the draft International Code to the WHA prior to the final debate and vote on its adoption.

Members of the infant food industry have often quoted parts of the statement as support for their position that the International Code applies only to the marketing of infant formula and not to other products, such as follow-up milks and infant cereals. Yet the underlined portion of the statement, which industry lobbyists leave out, reflects the wording of Article 2 (Scope) of the International Code and explains that whether or not a product is included in the scope depends on how it is marketed or otherwise represented.

It should also be noted that reference to "four to six months" as the period for exclusive breastfeeding was made prior to 2001, when the WHA recommended exclusive breastfeeding for six months as a global public health recommendation.

Annex 3

Excerpts from the Introductory Statement by the Representative of the Executive Board to the Thirty-fourth World Health Assembly on the Subject of the Draft International Code of Marketing of Breastmilk Substitutes[1]

The topic "infant and young child feeding" was extensively reviewed and discussed in May 1980 at the Thirty-third World Health Assembly, and it has also been extensively discussed this morning. Delegates will recall last year's Health Assembly's resolution WHA33.32 to this effect, which was adopted unanimously and which among other things requested the Director-General "to prepare an international code of marketing of breastmilk substitutes in close consultation with Member States and with other parties concerned". The need for such a code and the principles on which it should be developed were thus unanimously agreed upon at last year's Health Assembly.[2] It should therefore not be necessary in our deliberations today to repeat this review and these discussions.

There are two issues before the Committee today: firstly, the content of the code; and secondly, the question of whether the code should be adopted as a regulation in the sense of Articles 21 and 22 of the WHO Constitution or as a recommendation in the sense of Article 23.

The proposal now before the Committee in document A34/8 is the fourth distinct draft of the code; it is the result of a long process of consultations carried out with Member States and other parties concerned, in close cooperation with UNICEF. Few, if any, issues before the Executive Board and the Health Assembly have been the object of such extensive consultations as has the draft code.

. . .

[1] This statement by Dr. Tolbjørn Mork (Director-General of Health Services, Norway), representative of the Executive Board, was delivered before Committee A on 20 May 1981. The summary records of the discussion of this topic at the thirteenth, fourteenth and fifteenth meetings of Committee A are contained in document WHA34/1981/REC/3.

[2] See document WHA33/1980/REC/1, Annex 6; document WHA33/1980/REC/2, page 327; and document WHA33/1980/REC/3, pages 67-95 and 200-204.

During the Executive Board's discussion on this item at its sixty-seventh session, in January 1981, many members addressed themselves to the aim and the principles of the code and stressed that, as presently drafted, it constituted the minimum acceptable requirements concerning the marketing of breastmilk substitutes. Since even at this late date, as reflected in recent newspaper articles, some uncertainty persists with respect to the content of the code, particularly its scope, I believe it would be useful to make some remarks on this point. I hasten to remind delegates, however, that the scope of the code was not the source of difficulty during the Board's discussion.

The scope of the draft code is defined in Article 2. During the first four to six months of life, breastmilk alone is usually adequate to sustain the normal infant's nutritional requirements. Breastmilk may be replaced (substituted for) during this period by *bona fide* breastmilk substitutes, including infant formula. Any other food, such as cow's milk, fruit juices, cereals, vegetables, or any other fluid, solid or semi-solid food intended for infants and given after this initial period, can no longer be considered as a replacement for breastmilk (or as its *bona fide* substitute). Such foods only *complement* breastmilk or breastmilk substitutes, and are thus referred to in the draft code as complementary foods. They are also commonly called weaning foods or breastmilk supplements.

Products other than *bona fide* breastmilk substitutes, including infant formula, are covered by the code only when they are "marketed or otherwise represented to be suitable ... for use as a partial or total replacement of breastmilk". Thus the code's references to products used as partial or total replacements for breastmilk are not intended to apply to complementary foods *unless* these foods are actually marketed – as breastmilk substitutes, including infant formula, are marketed – as being suitable for the partial or total replacement of breastmilk. So long as the manufacturers and distributors of the products do not promote them as being suitable for use as partial or total replacements for breastmilk, the code's provisions concerning limitations on advertising and other promotional activities do not apply to these products.

The Executive Board examined the draft code very carefully.[3] Several Board members indicated that they considered introducing amendments in order to strengthen it and to make it still more precise. The Board considered, however, that the adoption of the code by the Thirty-fourth World Health Assembly was a matter of great urgency in view of the serious situation prevailing, particularly in developing countries, and that amendments introduced at the present stage might lead to a postponement of the adoption of the code. The Board therefore unanimously recommended to this Thirty-fourth World Health Assembly the adoption of the code as presently drafted, realizing that it might be desirable or even necessary to revise the code at an early date in the light of the experience obtained in the implementation of its various provisions. This is reflected in operative paragraph 5(4) *(see page 25)* of the recommended resolution contained in resolution EB67.R12.

The second main question before the Executive Board was whether it should recommend the adoption of the code as a recommendation or as a regulation. Some Board members expressed a clear preference for its adoption as a regulation in the sense of Articles 21 and 22 of the WHO Constitution. It became clear, however, that, although there had not been a single dissenting voice in the Board with regard either to the need for an international code or to its scope or content, opinion was divided on the question of a recommendation versus a regulation.

It was stressed that any decision concerning the form the code should take should be based on an appreciation of which alternative had the better chance of fulfilling the purpose of the code – that is, to contribute to improved infant and child nutrition and health. The Board agreed that the moral force of a unanimous recommendation could be such that it would be more persuasive than a regulation that had gained less than unanimous support from Member States. It was considered, however, that the implementation of the code should be closely monitored according to the existing WHO constitutional procedures; that future Assemblies should assess the situation in the light of reports from Member States;

[3] The summary record of the Board's discussions is contained in document EB67/1981/REC/2, pages 306-322.

and that the Assembly should take any measures it judged necessary for its effective application.

After carefully weighing the different points raised during its discussion, the Board unanimously adopted resolution EB67.R12, which contains the draft resolution recommended for adoption by the World Health Assembly. In this connexion I wish to draw the Committee's particular attention to the responsibilities outlined in the draft resolution: those of Member States, the regional committees, the Director-General, the Executive Board, and the Health Assembly itself for appropriate follow-up action once the code has been adopted.

In carrying out their responsibilities, Member States should make full use of their Organization – at global, regional and country levels – by requesting its technical support in the preparation of national legislation, regulations or other appropriate measures, and in the monitoring of the application of the code.

. . .

I think that I can best reflect the sentiments of the Board by closing my introduction with a plea for consensus on the resolution as it was unanimously recommended to the World Health Assembly by the Board. We are not today dealing with an economic issue of particular importance only to one or a few Member States. 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.

(*emphasis added)*

Appendix C

Relevant Resolutions of the World Health Assembly

ICDC Commentary

The text of all of the World Health Assembly resolutions on infant and young child feeding are reproduced here with underlined text and annotations to highlight portions that are relevant to implementation of the International Code. Two of the resolutions, 1994 and 1996, include the easy-to-read comments from UNICEF's Nutrition Section. The text of the resolutions is complete and unaltered except that the hyphens have been removed from the words "breastfeeding" and "breastmilk", consistent with the spelling used by IBFAN, UNICEF and many scientific publications.

WHA27.43 1974

The Twenty-seventh World Health Assembly,

Noting the general decline in breastfeeding, related to socio-cultural and environmental factors, including the mistaken idea caused by misleading sales promotion that breastfeeding is inferior to feeding with manufactured breastmilk substitutes;

Observing that this decline is one of the factors contributing to infant mortality and malnutrition, in particular in the developing world; and

Realizing that mothers who feed their babies with manufactured foods are often unable to afford an adequate supply of such foods and that even if they can afford such foods the tendency to malnutrition is frequently aggravated because of lack of understanding of the amount and correct and hygienic preparation of the food which should be given to the child,

. . .

URGES Member countries to review sales promotion activities on baby foods and to introduce appropriate remedial measures, including advertisement codes and legislation where necessary.

(emphasis added)

WHA31.47 1978

The Thirty-first World Health Assembly,

. . .

Recommends that Member States give the highest priority to . . . preventing malnutrition in . . . infants and young children by supporting and promoting breastfeeding; . . . (by taking) legislative and social action to facilitate breastfeeding by working mothers . . . .

and . . . regulating inappropriate sale and promotion of infant foods that can be used to replace breastmilk;

. . .

(emphasis added)

WHA33.32 1980

The Thirty-third World Health Assembly,

Recalling resolutions WHA27.43 and WHA31.47 which in particular reaffirmed that breastfeeding is ideal for the harmonious physical and psychosocial development of the child, that urgent action is called for by governments and the Director-General in order to intensify activities for the promotion of breastfeeding and development of actions related to the preparation and use of weaning foods based on local products, and that there is an urgent need for countries to review sales promotion activities on baby foods and to introduce appropriate remedial measures, including advertisement codes and legislation, as well as to take appropriate supportive social measures for mothers working away from their homes during the lactation period;

Recalling further resolutions WHA31.55 and WHA32.42 which emphasized maternal and child health as an essential component of primary health care, vital to the attainment of health for all by the year 2000;

Recognizing that there is a close interrelationship between infant and young child feeding and social and economic development, and that urgent action by governments is required to promote the health and nutrition of infants, young children and mothers, *inter alia* through education, training and information in this field;

Noting that a joint WHA/UNICEF Meeting on Infant and Young Child Feeding was held from 9 to 12 October 1979, and was attended by representatives of governments, the United Nations system and technical agencies, nongovernmental organizations active in the area, the infant food industry and other scientists working in this field;

1. ENDORSES in their entirety the statement and recommendations made by the joint WHO/UNICEF Meeting, namely on the encouragement and support of breastfeeding; the promotion and support of appropriate weaning practices; the strengthening of education, training and information; the promotion of the health and social status of women in relation to infant and young child feeding; and the appropriate marketing and distribution of breastmilk substitutes. This statement and these recommendations also make clear the responsibility in this field incumbent on the health services, health personnel, national authorities, women's and other nongovernmental organizations, the United Nations agencies and the infant-food industry, and stress the importance for countries to have a coherent food and nutrition policy and the need for pregnant and lactating women to be adequately nourished; the joint Meeting also recommended that "There should be an international code of marketing of infant formula and other products used as breastmilk substitutes. This should be supported by both exporting and importing countries and observed by all manufacturers. WHO and UNICEF are requested to organize the process for its preparation, with the involvement of all concerned parties, in order to reach a conclusion as soon as possible";

2. RECOGNIZES the important work already carried out by the World Health Organization and UNICEF with a view to implementing these recommendations and the preparatory work done on the formulation of a draft international code of marketing of breastmilk substitutes;

3. URGES countries which have not already done so to review and implement resolutions WHA27.43 and WHA32.42;

4. URGES women's organizations to organize extensive information dissemination campaigns in support of breastfeeding and healthy habits;

5. REQUESTS the Director-General:

(1) to cooperate with Member States on request in supervising or arranging for the supervision of the quality of infant foods during their production in the country concerned, as well as during their importation and marketing;

(2) to promote and support the exchange of information on laws, regulations, and other measures concerning marketing of breastmilk substitutes;

6. FURTHER REQUESTS the Director-General to intensify his activities for promoting the application of the recommendations of the joint WHO/UNICEF Meeting and, in particular:

(1) to continue efforts to promote breastfeeding as well as sound supplementary feeding and weaning practices as a prerequisite to healthy child growth and development;

(2) to intensify coordination with other international and bilateral agencies for the mobilization of the necessary resources for the promotion and support of activities related to the preparation of weaning foods based on local products in countries in need of such support and to collate and disseminate information on methods of supplementary feeding and weaning practices successfully used in different cultural settings;

(3) to intensify activities in the field of health education, training and information on infant and young child feeding, in particular through the preparation of training and other manuals for primary health care workers in different regions and countries;

(4) to prepare an international code of marketing of breastmilk substitutes in close consultation with Member States and with all other parties concerned including such scientific and other experts whose collaboration may be deemed appropriate, bearing in mind that:

(a) the marketing of breastmilk substitutes and weaning foods must be viewed within the framework of the problems of infant and young child feeding as a whole;

(b) the aim of the code should be to contribute to the provision of safe and adequate nutrition for infants and young children, and in particular to promote breastfeeding and ensure, on the basis of adequate information, the proper use of breastmilk substitutes, if necessary;

(c) the code should be based on existing knowledge of infant nutrition;

(d) the code should be governed *inter alia* by the following principles:

(i) the production, storage and distribution, as well as advertising, of infant feeding products should be subject to national legislation or regulations, or other measures as appropriate to the country concerned;

(ii) relevant information on infant feeding should be provided by the health care system of the country in which the product is consumed;

(iii) products should meet international standards of quality and presentation, in particular those developed by the Codex Alimentarius Commission, and their labels should clearly inform the public of the superiority of breastfeeding;

(5) to submit the code to the Executive Board for consideration at its sixty-seventh session and for forwarding with its recommendations to the Thirty-fourth World Health Assembly, together with proposals regarding its promotion and implementation, ei-

ther as a regulation in the sense of Articles 21 and 22 of the Constitution of the World Health Organization or as a recommendation in the sense of Article 23, outlining the legal and other implications of each choice;

(6) to review the existing legislation in different countries for enabling and supporting breastfeeding, especially by working mothers, and to strengthen the Organization's capacity to cooperate on the request of Member States in developing such legislation;

(7) to submit to the Thirty-fourth World Health Assembly, in 1981, and thereafter in even years, a report on the steps taken by WHO to promote breastfeeding and to improve infant and young child feeding, together with an evaluation of the effect of all measures taken by WHO and its Member States.

(emphasis added) 23 May 1980

ICDC Commentary

This is the resolution by which the WHA adopted the International Code. The resolution stresses that adoption and adherence to the International Code is a minimum requirement, that Member States should give full support to the implementation of the Code in its entirety, and urges Member States to translate the International Code into national legislation, regulations or other suitable measures.

WHA34.22 1981

The Thirty-fourth World Health Assembly,

Recognizing the importance of sound infant and young child nutrition for the future health and development of the child and adult;

Recalling that breastfeeding is the only natural method of infant feeding and that it must be actively protected and promoted in all countries;

Convinced that governments of Member States have important responsibilities and a prime role to play in the protection and promotion of breastfeeding as a means of improving infant and young child health;

Aware of the direct and indirect effects of marketing practices for breastmilk substitutes on infant feeding practices;

Convinced that the protection and promotion of infant feeding, including the regulation of the marketing of breastmilk substitutes, affect infant and young child health directly and profoundly, and are a problem of direct concern to WHO;

Having considered the draft International Code of Marketing of Breastmilk Substitutes prepared by the Director-General and forwarded to it by the Executive Board;

Expressing its gratitude to the Director-General and to the Executive Director of the United Nations Children's Fund for the steps they have taken in ensuring close consultation with Member States and with all other parties concerned in the process of preparing the draft International Code;

Having considered the recommendation made thereon by the Executive Board at its sixty-seventh session;

Confirming resolution WHA33.32, including the endorsement in their entirety of the statement and recommendations made by the joint WHO/UNICEF Meeting on Infant and Young Child Feeding held from 9 to 12 October 1979;

Stressing that the adoption of and adherence to the International Code of Marketing of Breastmilk Substitutes is a minimum requirement and only one of several important actions required in order to protect healthy practices in respect of infant and young child feeding;

1. ADOPTS, in the sense of Article 23 of the Constitution, the International Code of Marketing of Breastmilk Substitutes annexed to the present resolution;

2. URGES all Member States:

   (1) to give full and unanimous support to the implementation of the recommendations made by the joint WHO/UNICEF Meeting on Infant and Young Child Feeding and 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;

(2) to translate the International Code into national legislation, regulations or other suitable measures;

(3) to involve all concerned social and economic sectors and all other concerned parties in the implementation of the International Code and in the observance of the provisions thereof;

(4) to monitor the compliance with the Code;

3. DECIDES that the follow-up to and review of the implementation of this resolution shall be undertaken by regional committees, the Executive Board and the Health Assembly in the spirit of resolution WHA33.17;

4. REQUESTS the FAO/WHO Codex Alimentarius Commission to give full consideration, within the framework of its operational mandate, to action it might take to improve the quality standards of infant foods, and to support and promote the implementation of the International Code;

5. REQUESTS the Director-General:

(1) to give all possible support to Member States, as and when requested, for the implementation of the International Code, and in particular in the preparation of national legislation and other measures related thereto in accordance with operative subparagraph 6(6) of resolution WHA33.32;

(2) to use his good offices for the continued cooperation with all parties concerned in the implementation and monitoring of the International Code at country, regional and global levels;

(3) to report to the Thirty-sixth World Health Assembly on the status of compliance with and implementation of the Code at country, regional and global levels;

(4) 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.

(emphasis added)

21 May 1981

ICDC Commentary

In this resolution the WHA recognises that commercial marketing of breastmilk substitutes contributed to an increase in artificial feeding and calls for renewed attention to implement and monitor the International Code at the national and international level.

WHA35.26 1982

The Thirty-fifth World Health Assembly,

Recalling resolution WHA33.32 on infant and young child feeding and resolution WHA34.22 adopting the International Code of Marketing of Breastmilk Substitutes;

Conscious that breastfeeding is the ideal method of infant feeding and should be promoted and protected in all countries;

Concerned that inappropriate infant feeding practices result in greater incidence of infant mortality, malnutrition and disease, especially in conditions of poverty and lack of hygiene;

Recognizing that commercial marketing of breastmilk substitutes for infants has contributed to an increase in artificial feeding;

Recalling that the Thirty-fourth World Health Assembly adopted an international code intended, *inter alia*, to deal with these marketing practices;

Noting that, while many Member States have taken some measures related to improving infant and young child feeding, few have adopted and adhered to the International Code as a "minimum requirement" and implemented it "in its entirety", as called for in resolution WHA34.22;

1. URGES 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;

2. REQUESTS the Director-General:

   (1) to design and coordinate a comprehensive programme of action to support Member States in their efforts to implement and monitor the Code and its effectiveness;

   (2) to provide support and guidance to Member States as and when requested to ensure that the measures they adopt are consistent with the letter and spirit of the International Code;

   (3) to undertake, in collaboration with Member States, prospective surveys, including statistical data of infant and young child feeding practices in the various countries, particularly with regard to the incidence and duration of breastfeeding.

(emphasis added)

14 May 1982

ICDC Commentary

In this resolution, the WHA again requests the Director-General to work with Member States to implement and monitor the International Code and to examine the promotion and use of foods unsuitable for infant and young child feeding.

WHA37.30 1984

The Thirty-seventh World Health Assembly,

Recalling resolutions WHA27.43, WHA31.47, WHA33.32, WHA34.22 and WHA35.26, which dealt with infant and young child feeding;

Recognizing that the implementation of the International Code of Marketing of Breastmilk Substitutes is one of the important actions required in order to promote healthy infant and young child feeding;

Recalling the discussion on infant and young child feeding at the Thirty-sixth World Health Assembly, which concluded that it was premature to revise the International Code at that time;

Having considered the Director-General's report, and noting with interest its contents;

Aware that many products unsuitable for infant feeding are being promoted for this purpose in many part of the world, and that some infant foods are being promoted for use at too early an age, which can be detrimental to infant and young child health;

1. ENDORSES the Director-General's report;

2. URGES continued action by Member States, WHO, nongovernmental organizations and all other interested parties to put into effect measures to improve infant and young child feeding, with particular emphasis on the use of foods of local origin;

3. REQUESTS the Director-General:

   (1) to continue and intensify collaboration with Member States in their efforts to implement and monitor the International Code of Marketing of Breastmilk Substitutes as an important measure at the national level;

   (2) to support Member States in examining the problem of the promotion and use of foods unsuitable for infant and young child feeding, and ways of promoting the appropriate use of infant foods;

   (3) to submit to the Thirty-ninth World Health Assembly a report on the progress in implementing this resolution, together with recommendations for any other measures needed to further improve sound infant and young child feeding practices.

(emphasis added) 17 May 1984

ICDC Commentary

In this resolution, the WHA clarifies Article 6.6 of the International Code concerning donations or low-price supplies of products within the scope of the Code. Prior to the 1986 WHA, a meeting of experts had examined the use of donated and low-price supplies and concluded that because, "only very small quantities of breastmilk substitutes are . . . required" they should be "acquired through normal purchasing channels", and not given to maternities and hospitals for free or at low cost. The WHA adopted this recommendation. Later WHA resolutions in 1990, 1992 and 1994 strengthened this recommendation. WHA39.28 also notes that early introduction of food or drink may interfere with breastfeeding and that follow-up milks are "not necessary".

WHA39.28 1986

The Thirty-ninth World Health Assembly,

Recalling resolutions WHA27.43, WHA31.47, WHA33.32, WHA34.22, WHA35.26 and WHA37.30 which dealt with infant and young child feeding;

Having considered the progress and evaluation report by the Director-General on infant and young child nutrition;[1]

Recognizing that the implementation of the International Code of Marketing of Breastmilk Substitutes is an important contribution to healthy infant and young child feeding in all countries;

Aware that today, five years after the adoption of the International Code, many Member States have made substantial efforts to implement it, but that many products unsuitable for infant feeding are nonetheless being promoted and used for this purpose; and that sustained and concerted efforts will therefore continue to be necessary to achieve full implementation of and compliance with the International Code as well as the cessation of the marketing of unsuitable products and the improper promotion of breastmilk substitutes;

Noting with great satisfaction the guidelines concerning the main health and socioeconomic circumstances in which infants have to be fed on breastmilk substitutes,[2] in the context of Article 6, paragraph 6, of the International Code;

Noting further the statement in the guidelines, paragraph 47: "Since the large majority of infants born in maternity wards and hospitals are full term, they require no nourishment other than colostrum during their first 24-48 hours of life - the amount of time often spent by a mother and her infant in such an institutional setting. Only small quantities of breastmilk substitutes are ordinarily required to meet the needs of a minority of infants in these facilities, and they should only be available in ways that do not interfere with the protection and promotion of breastfeeding for the majority";

1. ENDORSES the report of the Director-General;[1]

2. URGES Member States:

   (1) to implement the Code if they have not yet done so;

   (2) to ensure that the practices and procedures of their health care systems are consistent with the principles and aim of the International Code;

(3) to make the fullest use of all concerned parties - health professional bodies, nongovernmental organizations, consumer organizations, manufacturers and distributors - generally, in protecting and promoting breastfeeding and, specifically, in implementing the Code and monitoring its implementation and compliance with its provisions;

(4) to seek the cooperation of manufacturers and distributors of products within the scope of Article 2 of the Code, in providing all information considered necessary for monitoring the implementation of the Code;

(5) to provide the Director-General with complete and detailed information on the implementation of the Code;

(6) to ensure that the small amounts of breastmilk substitutes needed for the minority of infants who require them in maternity wards and hospitals are made available through the normal procurement channels and not through free or subsidized supplies;

3. REQUESTS the Director-General:

(1) to propose a simplified and standardized form for use by Member States to facilitate the monitoring and evaluation by them of their implementation of the Code and reporting thereon to WHO, as well as the preparation by WHO of a consolidated report covering each of the articles of the Code;

(2) to specifically direct the attention of Member States and other interested parties to the following:

(a) any food or drink given before complementary feeding is nutritionally required may interfere with the initiation or maintenance of breastfeeding and therefore should neither be promoted nor encouraged for use by infants during this period;

(b) the practice being introduced in some countries of providing infants with specially formulated milks (so-called “follow-up milks”) is not necessary.

[1] Document WHA39/1986/REC/1, or Document A39/8
[2] Document WHA39/1986/REC/1, or Document A39/8 Add. 1

(emphasis added) 16 May 1986

ICDC Commentary

In this resolution, the WHA requests the Director-General to provide legal and technical assistance to Member States in drafting or implementing national measures to implement the International Code.

WHA41.11 1988

The Forty-first World Health Assembly,

Having considered the report by the Director-General on infant and young child nutrition;

Recalling resolutions WHA33.32, WHA34.22 and WHA39.28 on infant and young child feeding and nutrition, and resolutions WHA37.18 and WHA39.31 on the prevention and control of vitamin A deficiency and xerophthalmia, and of iodine deficiency disorders;

Concerned at continuing decreasing breastfeeding trends in many countries, and committed to the identification and elimination of obstacles to breastfeeding;

Aware that appropriate infant and young child nutrition could benefit from further broad national, community and family interventions;

1. COMMENDS governments, women's organizations, professional associations, consumer and other nongovernmental groups, and the food industry for their efforts to promote appropriate infant and young child nutrition, and encourages them, in cooperation with WHO, to support national efforts for coordinated nutrition programmes and practical action at country level to improve the health and nutrition of women and children;

2. URGES Member States:

   (1) to develop or enhance national nutrition programmes, including multisectoral approaches, with the objective of improving the health and nutritional status of their populations, especially that of infants and young children;

   (2) to ensure practices and procedures that are consistent with the aim and principles of the International Code of Marketing of Breastmilk Substitutes, if they have not already done so;

3. REQUESTS the Director-General to continue to collaborate with Member States, through WHO regional offices and in collaboration with other agencies of the United Nations system, especially FAO and UNICEF:

   (1) in identifying and assessing the main nutrient and dietary problems, developing national strategies to deal with them, applying these strategies, and monitoring and evaluating their effectiveness;

   (2) in establishing effective nutritional status surveillance systems in order to ensure that all the main variables which collectively determine nutritional status are properly addressed;

   (3) in compiling, analysing, managing and applying information that they have gathered on the nutritional status of their populations;

(4) in monitoring, together with other maternal and child health indicators, changes in the prevalence and duration of full and supplemented breastfeeding with a view to improving breastfeeding rates;

(5) in developing recommendations regarding diet, including timely complementary feeding and appropriate weaning practices, which are appropriate to national circumstances;

(6) in providing legal and technical assistance, upon request from Member States, in the drafting and/or the implementation of national codes of marketing of breastmilk substitutes, or other similar instruments;

(7) in designing and implementing collaborative studies to assess the impact of measures taken to promote breastfeeding and child nutrition in Member States.

(emphasis added) 11 May 1988

ICDC Commentary

Despite Resolution WHA39.28, "free supplies" to health care facilities continued. In this resolution, the WHA again calls for effective measures to end the industry practice of giving free or low-cost supplies of breastmilk substitutes to hospitals and maternities.

The resolution also highlights the WHO/UNICEF statement on "Protecting, promoting and supporting breastfeeding: The special role of maternity services", which led to the Baby-Friendly Hospital Initiative in 1992.

WHA43.3 1990

The Forty-third World Health Assembly,

Recalling resolutions WHA33.32, WHA34.22, WHA35.26, WHA37.30, WHA39.28 and WHA41.11 on infant and young child feeding and nutrition;

Having considered the report of the Director-General on infant and young child nutrition;[1]

Reaffirming the unique biological properties of breastmilk in protecting against infections, in stimulating the development of the infant's own immune system, and in limiting the development of some allergies;

Recalling the positive impact of breastfeeding on the physical and emotional health of the mother, including its important contribution to child-spacing;

Convinced of the importance of protecting breastfeeding among groups and populations where it remains the infant-feeding norm, and promoting it where it is not, through appropriate information and support, as well as recognizing the special needs of working women;

Recognizing the key role in protecting and promoting breastfeeding played by health workers, particularly nurses, midwives and those in child health/family planning programmes, and the significance of the counselling and support provided by mothers' groups;

Recognizing that, in spite of resolution WHA39.28, free or low-cost supplies of infant formula continue to be available to hospitals and maternities, with adverse consequences for breastfeeding;

Reiterating its concern over the decreasing prevalence and duration of breastfeeding in many countries;

1. THANKS the Director-General for his report;

2. URGES Member States:

   (1) to protect and promote breastfeeding, as an essential component of their overall food and nutrition policies and programmes on behalf of women and children, so as to enable all infants to be exclusively breastfed during the first four to six months* of life;

* *Editor's note:* In 2001, the WHA recommended exclusive breastfeeding for six months followed by continued breastfeeding for up to two years and beyond.

(2) to promote breastfeeding, with due attention to the nutritional and emotional needs of mothers;

(3) to continue monitoring breastfeeding patterns, including traditional attitudes and practices in this regard;

(4) to enforce existing, or adopt new, maternity protection legislation or other suitable measures that will promote and facilitate breastfeeding among working women;

(5) to draw the attention of all who are concerned with planning and providing maternity services to the universal principles affirmed in the joint WHO/UNICEF statement[2] on breastfeeding and maternity services that was issued in 1989;

(6) to ensure that the principles and aim of the International Code of Marketing of Breastmilk Substitutes and the recommendations contained in resolution WHA39.28 are given full expression in national health and nutrition policy and action, in cooperation with professional associations, women's organizations, consumer and other nongovernmental groups, and the food industry;

(7) to ensure that families make the most appropriate choice with regard to infant feeding, and that the health system provides the necessary support;

3. REQUESTS the Director-General, in collaboration with UNICEF and other international and bilateral agencies concerned:

(1) to urge Member States to take effective measures to implement the recommendations included in resolution WHA39.28;

(2) to continue to review regional and global trends in breastfeeding patterns, including the relationship between breastfeeding and child-spacing;

(3) to support Member States, on request, in adopting measures to improve infant and young child nutrition, *inter alia* by collecting and disseminating information on relevant national action of interest to all Member States; and to mobilize technical and financial resources to this end.

[1] Document WHA43/1990/REC/1, p.35

[2] *Protecting, promoting and supporting breastfeeding: the special role of maternity services.* A joint WHO/UNICEF statement, Geneva, World Health Organization, 1989

(emphasis added) 14 May 1990

ICDC Commentary

In this resolution, the WHA once again, calls for an end to free and low-cost supplies as a step towards full implementation of the International Code. It also introduces and welcomes the Baby-Friendly Hospital Initiative and the operational targets of the Innocenti Declaration. It is the first time WHA uses the phrase "about 6 months" in defining the recommended duration of exclusive breastfeeding. It was not until the 2001 WHA54.2 that WHA recommended exclusive breastfeeding for a full six months.

WHA45.34 1992

The Forty-fifth World Health Assembly,

Having considered the report of the Director-General on infant and young child nutrition;

Recalling resolutions WHA33.32, WHA34.22, WHA35.26, WHA37.30, WHA39.28, WHA41.11 and WHA43.3 concerning infant and young child nutrition, appropriate feeding practices and related questions;

Reaffirming that the International Code of Marketing of Breastmilk Substitutes is a minimum requirement and only one of several important actions required in order to protect healthy practices in respect of infant and young child feeding;

Recalling that products that may be promoted as a partial or total replacement for breastmilk, especially when these are presented as suitable for bottle feeding, are subject to the provisions of the International Code;

Reaffirming that during the first four to six months* of life no food or liquid other than breastmilk, not even water, is required to meet the normal infant's nutritional requirements, and that from the age of about six months infants should begin to receive a variety of locally available and safely prepared foods rich in energy, in addition to breastmilk, to meet their changing nutritional requirements;

Welcoming the leadership of the Executive Heads of WHO and UNICEF in organizing the "baby-friendly" hospital initiative, with its simultaneous focus on the role of health services in protecting, promoting and supporting breastfeeding and on the use of breastfeeding as a means of strengthening the contribution of health services to safe motherhood, child survival, and primary health care in general, and endorsing this initiative as a most promising means of increasing the prevalence and duration of breastfeeding;

Expressing once again its concern about the need to protect and support women in the workplace, for their own sakes but also in the light of their multiple roles as mothers and care-providers, *inter alia*, by applying existing legislation fully for maternity protection, expanding it to cover any women at present excluded or, where appropriate, adopting new measures to protect breastfeeding;

Encouraged by the steps being taken by infant-food manufacturers towards ending the donation or low-price sale of supplies of infant formula to maternity wards and hospitals, which would constitute a step towards full implementation of the International Code;

* *Editor's note:* In 2001, the WHA recommended exclusive breastfeeding for six months followed by continued breastfeeding for up to two years and beyond.

Being convinced that charitable and other donor agencies should exert great care in initiating, or responding to, requests for free supplies of infant foods;

Noting that the advertising and promotion of infant formula and the presentation of other products as breastmilk substitutes, as well as feeding-bottles and teats, may compete unfairly with breastfeeding which is the safest and lowest-cost method of nourishing an infant, and may exacerbate such competition and favour uninformed decision-making by interfering with the advice and guidance to be provided by the mother's physician or health worker;

Welcoming the generous financial and other contributions from a number of Member States that enabled WHO to provide technical support to countries wishing to review and evaluate their own experiences in giving effect to the International Code,

1. THANKS the Director-General for his report;

2. URGES Member States:

   (1) to give full expression at national level to the operational targets contained in the Innocenti Declaration, namely:

      (a) by appointing a national breastfeeding coordinator and establishing a multisectoral breastfeeding committee;

      (b) by ensuring that every facility providing maternity services applies the principles laid down in the joint WHO/UNICEF statement on the role of maternity services in protecting, promoting and supporting breastfeeding;

      (c) by taking action to give effect to the principles and aim of the International Code of Marketing of Breastmilk Substitutes and subsequent relevant Health Assembly resolutions in their entirety;

      (d) by enacting legislation and adopting means for its enforcement to protect the breastfeeding rights of working women;

   (2) to encourage and support all public and private health facilities providing maternity services so that they become "baby- friendly":

      (a) by providing the necessary training in the application of the principles laid down in the joint WHO/UNICEF statement;

      (b) by encouraging the collaboration of professional associations, women's organizations, consumer and other nongovernmental groups, the food industry, and other competent sectors in this endeavour;

   (3) to take measures appropriate to national circumstances aimed at ending the donation or low-priced sale of supplies of breastmilk substitutes to health-care facilities providing maternity services;

   (4) to use the common breastfeeding indicators developed by WHO, with the collaboration of UNICEF and other interested organizations and agencies, in evaluating the progress of their breastfeeding programmes;

   (5) to draw upon the experiences of other Member States in giving effect to the International Code;

3. REQUESTS the Director-General:

(1) to continue WHO's productive collaboration with its traditional international partners, in particular UNICEF, as well as other concerned parties including professional associations, women's organizations, consumer groups and other nongovernmental organizations and the food industry, with a view to attaining the Organization's goals and objectives in infant and young child nutrition;

(2) to strengthen the Organization's network of collaborating centres, institutions and organizations in support of appropriate national action;

(3) to support Member States, on request, in elaborating and adapting guidelines on infant nutrition, including complementary feeding practices that are timely, nutritionally appropriate and biologically safe and in devising suitable measures to give effect to the International Code;

(4) to draw the attention of Member States and other intergovernmental organizations to new developments that have an important bearing on infant and young child feeding and nutrition;

(5) to consider, in collaboration with the International Labour Organization, the options available to the health sector and other interested sectors for reinforcing the protection of women in the workplace in view of their maternal responsibilities, and to report to a future Health Assembly in this regard;

(6) to mobilize additional technical and financial resources for intensified support to member States.

(emphasis added) 14 May 1992

ICDC Commentary

In this resolution, the WHA extends the ban on free and low-cost supplies to all parts of the health care system. In addition, WHA no longer refers to the period of 4 to 6 months, but now states that complementary feeding is appropriate from the age of "about 6 months". It also provides useful guidelines on infant feeding in emergency situations.

WHA47.5 1994

Comments provided by Nutrition Cluster UNICEF, New York June 1994

The Forty-seventh World Health Assembly,

Having considered the report by the Director-General on infant and young child nutrition;

Recalling resolutions WHA33.32, WHA34.22, WHA35.26, WHA37.30, WHA39.28, WHA41.11, WHA43.3, WHA45.34 and WHA46.7 concerning infant and young child nutrition, appropriate feeding practices and related questions;

WHA34.22 includes International Code of Marketing of Breastmilk Substitutes.

Reaffirming its support for all these resolutions and reiterating the recommendations to Member States contained therein;

All Member States reaffirm the Code.

Bearing in mind the superiority of breastmilk as the biological norm for nourishing infants, and that a deviation from this norm is associated with increased risks to the health of infants and mothers;

1. THANKS the Director-General for his report;

2. URGES Member States to take the following measures;

   (1) to promote sound infant and young child nutrition, in keeping with their commitment to the World Declaration and Plan of Action for Nutrition,[1] through coherent effective intersectoral action, including:

World Declaration urges that all women be enabled to breastfeed exclusively for the first months and to continue breastfeeding, with complementary foods, for up to two years or more.

   (a) increasing awareness among health personnel, nongovernmental organizations, communities and the general public of the importance of breastfeeding and its superiority, to any other infant feeding method;

All other infant feeding methods are inferior.

   (b) supporting mothers in their choice to breastfeed by removing obstacles and preventing interference that they may face in health services, the workplace, or the community;

Eliminate obstacles and interference wherever they exist, to protect mother's freedom of choice.

   (c) ensuring that all health personnel concerned are trained in appropriate infant and young child feeding practices, including the application of the prin-

ciples laid down in the joint WHO/UNICEF statement on breastfeeding and the role of maternity services;[2]

(d) fostering appropriate complementary feeding practices from the age of about six months,

About six months of exclusive breastfeeding is encouraged, not four-to-six months as previously recommended.

emphasizing continued breastfeeding

Breastfeeding with complementary foods continues from six months to two years.

and frequent feeding with safe and adequate amounts of local foods.

Foods from the local family diet, enriched and softened, can give adequate complementation to sustained breastfeeding.

(2) to ensure that there are no donations of free or subsidized supplies of breastmilk substitutes

No free or subsidized foods or beverages represented as partial or total replacements for breastmilk. This includes, for example, normal newborn formulas, soy or hypoallergenic formulas, preterm formulas, special formulas, and follow-up or second stage milks or formulas.[3]

and other products covered by the International Code of Marketing of Breastmilk Substitutes

For example, no free or subsidized glucose or vitamin drinks, fruit drinks and teas for infants, nor bottle-fed foods including milk products, cereals, and cereal mixtures labelled to replace milk feedings.
No free or subsidized feeding bottles or teats.[4]

in any part of the health care system;

Covers all public and private health care settings and health workers serving mothers, infants and pregnant women, including:

- *maternity wards and clinics;*
- *newborn/neonatal special care units;*
- *pediatric wards and hospitals;*
- *MCH and family planning clinics;*
- *private doctors' offices and practices;*
- *nurseries and child-care institutions.*[5]

(3) to exercise extreme caution when planning, implementing or supporting emergency relief operations ,

In emergency relief operations, protect and support breastfeeding.

by protecting, promoting and supporting breastfeeding for infants, and ensuring that donated supplies of breastmilk substitutes or other products covered by the scope of the International Code be given only if all the following conditions apply;

Infants can receive donated formula and other products covered by the Code only if all three conditions are fulfilled.

(a) infants have to be fed on breastmilk substitutes, as outlined in the guidelines concerning the main health and socioeconomic circumstances in which infants have to be fed on breastmilk substitutes,[6]

(b) the supply is continued for as long as the infants concerned need it;

Each infant given a donated breastmilk substitute is assured of a full ongoing supply.

(c) the supply is not used as a sales inducement;

Donations that help to open new markets or increase sales may not be made.

(4) to inform the labour sector, and employers' and workers' organizations, about the multiple benefits of breastfeeding for infants and mothers, and the implications for maternity protection in the workplace;

3. REQUESTS the Director-General:

(1) to use his good offices for cooperation with all parties concerned in giving effect to this and related resolutions of the Health Assembly in their entirety;

(2) to complete development of a comprehensive global approach and programme of action to strengthen national capacities for improving infant and young child feeding practices; including the development of methods and criteria for national assessment of breastfeeding trends and practices:

(3) to support Member States, at their request, in monitoring infant and young child feeding practices and trends in health facilities and households, in keeping with new standard breastfeeding indicators;

New indicators track "exclusive" breastfeeding, timely complementary feeding, and sustained breastfeeding at 20-23 months.[7]

(4) to urge Member States to initiate the Baby Friendly Hospital Initiative and to support them, at their request, in implementing this Initiative, particularly in their efforts to improve educational curricula and in-service training for all health and administrative personnel concerned;

Training of health staff for BFHI is urged.

(5) to increase and strengthen support to Member States, at their request, in giving effect to the principles and aim of the International Code and all relevant resolutions, and to advise Member States on a framework which they may use in monitoring their application, as appropriate to national circumstances;

Stronger support to implementation and monitoring of Code and cessation of free and low-cost supplies.

(6) to develop, in consultation with other concerned parties and as part of WHO's normative function, guiding principles for the use in emergency situations of breastmilk substitutes or other products covered by the International Code which the competent authorities in Member States may use, in the light of national circumstances, to ensure the optimal infant-feeding conditions;

(7) to complete, in cooperation with selected research institutions, collection of revised reference data and the preparation of guidelines for their use and interpretation, for assessing the growth of breastfed infants;

(8) to seek additional technical and financial resources for intensifying WHO's support to Member States in infant feeding and in the implementation of the International Code and subsequent relevant resolutions.

[1] *World Declaration and Plan of Action for Nutrition,* FAO/WHO, International Conference on Nutrition, Rome, December 1992.

[2] *Protecting, promoting and supporting breastfeeding: the special role of maternity services.* A joint WHO/UNICEF statement. Geneva, World Health Organization, 1989.

[3] Breastmilk substitutes means any food being marketed or otherwise represented as a partial or total replacement for breastmilk, whether or not suitable for that purpose. *(International Code of Marketing of Breastmilk Substitutes,* Article 3.)

[4] The Code applies to the marketing, and practices related thereto, of the following products: breastmilk 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 breastmilk; feeding bottles and teats. *(International Code of Marketing of Breastmilk Substitutes,* Article 2.)

[5] Health care system means governmental, non-governmental 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. *(International Code of Marketing of Breastmilk Substitutes,* Article 3.)

[6] Document WHO A39/8 Add.1, 10 April 1986. These guidelines provide suggestions for health care management which permits continued breastfeeding or breastmilk feeding in many situations.

[7] Documents WHO/CDD/SER/91.14 *Indicators for assessing breastfeeding practices* and WHO/CDR/93.1 UNICEF/SM/93.1 *Indicators for assessing health facility practices that affect breastfeeding.*

(emphasis added) 9 May 1994

ICDC Commentary

In this resolution, the WHA calls on Member States to ensure that,

- *complementary foods are not marketed for or used in ways that undermine exclusive and sustained breastfeeding;*
- *financial support (such as sponsorship) to health professionals does not create conflicts of interests; and*
- *monitoring the application of the International Code is carried out in an independent, transparent manner free from commercial interest.*

WHA49.15 1996

Comments provided by Nutrition Section UNICEF, New York June 1994

The Forty-ninth World Health Assembly,

Having considered the summary report by the Director-General on infant feeding and young child nutrition;

Recalling resolutions WHA33.32, WHA34.22, WHA39.28, and WHA45.34 among others concerning infant and young child nutrition, appropriate feeding practices and other related questions;

WHA34.22 includes the International Code of Marketing of Breastmilk Substitutes ("the Code").

Recalling and reaffirming the provisions of resolution WHA47.5 concerning infant and young child nutrition, including the emphasis on fostering appropriate complementary feeding practices,

Member states reaffirm the recommendation of about 6 months of exclusive breastfeeding, and continued breastfeeding wtih complementary foods such as those from the local family diet continuing from 6 months to 2 years.

Concerned that health institutions and ministries may be subject to subtle pressure to accept, inappropriately, financial or other support for professional training in infant and child health;

Acceptance of inappropriate funding may influence the objectivity of training in infant and child health.

Noting the increasing interest in monitoring the application of the International Code of Marketing of BreastMilk Substitutes and subsequent relevant Health Assembly resolutions,

1. THANKS the Director-General for his report;[1]

2. STRESSES the continued need to implement the International Code of Marketing of Breastmilk Substitutes, subsequent relevant resolutions of the Health Assembly, the Innocenti Declaration, and the World Declaration and Plan of Action for Nutrition;

Reaffirms support for all existing strategies for the protection of breastfeeding, including Code implementation, the ending of free and low-cost supplies, the transformation of maternity facilities and the provision of maternity entitlements.

3. URGES Member States to take the following measures:

(1) to ensure that complementary foods are not marketed for or used in ways that undermine exclusive and sustained breastfeeding.

Marketing of complementary foods in ways that undermine exclusive breastfeeding until about 6 months and sustained breastfeeding (6-24 months) is inappropriate.

(2) to ensure that the financial support for professionals working in infant and young child health does not create conflicts of interest, especially with regard to the WHO/UNICEF Baby Friendly Hospital Initiative;

The interests of manufacturers may conflict with those of breastfeeding mothers and their children. Sponsorship or other financial assistance from the infant feeding industry may interfere with professionals' unequivocal support for BFHI and breastfeeding.

(3) to ensure that monitoring the application of the International Code and subsequent relevant resolutions is carried out in a transparent, independent manner, free from commercial influence.

Manufacturers should monitor their own marketing practices. Other monitoring efforts by nongovernmental organizations, professional groups, institutions and individuals should not receive financial support from manufacturers or distributors.

(4) to ensure that the appropriate measures are taken including health information and education in the context of primary health care, to encourage breastfeeding;

Breastfeeding is to be actively promoted throughout society as well as throughout the primary health care system.

(5) to ensure that the practices and procedures of their health care systems are consistent with the principles and aims of the International Code of Marketing of Breastmilk Substitutes;

The Code should be complied with throughout health care systems in all countries.

(6) to provide the Director-General with complete and detailed information on the implementation of the Code;

All States should report to WHO on the progress they have made to implement the Code.

4. REQUESTS the Director-General to disseminate, as soon as possible, to Member States document WHO/NUT/96.4 (currently in preparation) on the guiding principles for feeding infants and young children during emergencies.

[1] Document A49/4

(emphasis added) 25 May 1996

ICDC Commentary

In this resolution, the WHA put an end to the debate regarding the optimal period of exclusive breastfeeding by establishing the period of six months as a global public health recommendation. The WHA also clarified its policy regarding HIV and infant feeding by recommending that HIV-positive mothers breastfeed exclusively for the first months of life, unless replacement feeding is acceptable, feasible, affordable, sustainable and safe; in which case replacement feeding is recommended. Use of breastmilk substitutes by HIV-positive mothers should be free from commercial influence.

WHA54.2 2001

The Fifty-fourth World Health Assembly,

Recalling resolutions WHA33.32, WHA34.22, WHA35.26, WHA37.30, WHA39.28, WHA41.11 WHA43.3, WHA45.34, WHA46.7, WHA47.5 and WHA49.15 on infant and young child nutrition, appropriate feeding practices and related questions;

Deeply concerned to improve infant and young child nutrition and to alleviate all forms of malnutrition in the world, because more than one-third of under-five children are still malnourished - whether stunted, wasted, or deficient in iodine, vitamin A, iron or other micronutrients - and because malnutrition still contributes to nearly half of the 10.5 million deaths each year among preschool children worldwide;

Deeply alarmed that malnutrition of infants and young children remains one of the most severe global public health problems, at once a major cause and consequence of poverty, deprivation, food insecurity and social inequality, and that malnutrition is a cause not only of increased vulnerability to infection and other diseases, including growth retardation, but also of intellectual, mental, social and developmental handicap, and of increased risk of disease throughout childhood, adolescence and adult life;

Recognizing the right of everyone to have access to safe and nutritious food, consistent with the right to adequate food and the fundamental right of everyone to be free from hunger, and that every effort should be made with a view to achieving progressively the full realization of this right;

Acknowledging the need for all sectors of society - including governments, civil society, health professional associations, nongovernmental organizations, commercial enterprises and international bodies - to contribute to improved nutrition for infants and young children by using every possible means at their disposal, especially by fostering optimal feeding practices, incorporating a comprehensive multisectoral, holistic and strategic approach;

Noting the guidance of the Convention on the Rights of the Child, in particular Article 24, which recognizes, *inter alia*, the need for access to and availability of both support and information concerning the use of basic knowledge of child health and nutrition, and the advantages of breastfeeding for all segments of society, in particular parents and children;

Conscious that despite the fact that the International Code of Marketing of Breastmilk Substitutes and relevant, subsequent Health Assembly resolutions state that there should be no advertising or other forms of promotion of products within its scope, new modern communication methods, including electronic means, are currently increasingly being used to promote such products; and conscious of the need for the Codex Alimentarius Commission to

take the International Code and subsequent relevant Health Assembly resolutions into consideration in dealing with health claims in the development of food standards and guidelines;

Mindful that 2001 marks the twentieth anniversary of the adoption of the International Code of Marketing of Breastmilk Substitutes, and that the adoption of the present resolution provides an opportunity to reinforce the International Code's fundamental role in protecting, promoting and supporting breastfeeding;

Recognizing that there is a sound scientific basis for policy decisions to reinforce activities of Member States and those of WHO; for proposing new and innovative approaches to monitoring growth and improving nutrition; for promoting improved breastfeeding and complementary feeding practices, and sound culture specific counselling; for improving the nutritional status of women of reproductive age, especially during and after pregnancy; for alleviating all forms of malnutrition; and for providing guidance on feeding practices for infants of mothers who are HIV-positive;

Noting the need for effective systems for assessing the magnitude and geographical distribution of all forms of malnutrition, together with their consequences and contributing factors, and of foodborne diseases; and for monitoring food security;

Welcoming the efforts made by WHO, in close collaboration with UNICEF and other international partners, to develop a comprehensive global strategy for infant and young child feeding, and to use the ACC Sub-Committee on Nutrition as an interagency forum for coordination and exchange of information in this connection,

1. THANKS the Director-General for the progress report on the development of a new global strategy for infant and young child feeding;

2. URGES Member States:

   (1) to recognize the right of everyone to have access to safe and nutritious food, consistent with the right to adequate food and the fundamental right of everyone to be free from hunger, and that every effort should be made with a view to achieving progressively the full realization of this right and to call on all sectors of society to cooperate in efforts to improve the nutrition of infants and young children;

   (2) to take necessary measures as States Parties effectively to implement the Convention on the Rights of the Child, in order to ensure every child's right to the highest attainable standard of health and health care;

   (3) to set up or strengthen interinstitutional and intersectoral discussion forums with all stakeholders in order to reach national consensus on strategies and policies including reinforcing, in collaboration with ILO, policies that support breastfeeding by working women, in order substantially to improve infant and young child feeding and to develop participatory mechanisms for establishing and implementing specific nutrition programmes and projects aimed at new initiatives and innovative approaches;

   (4) to strengthen activities and develop new approaches to protect, promote and support exclusive breastfeeding for six months as a global public health recommendation, taking into account the findings of the WHO expert consultation on optimal duration of exclusive breastfeeding,[1] and to provide safe and appropriate complementary foods, with continued breastfeeding for up to two years of age or beyond, emphasizing channels of social dissemination of these concepts in order to lead communities to adhere to these practices;

   (5) to support the Baby-Friendly Hospital Initiative and to create mechanisms, including regulations, legislation or other measures, designed, directly and indirectly, to sup-

port periodic reassessment of hospitals, and to ensure maintenance of standards and the Initiative's long-term sustainability and credibility;

(6) to improve complementary foods and feeding practices by ensuring sound and culture specific nutrition counselling to mothers of young children, recommending the widest possible use of indigenous nutrient-rich foodstuffs; and to give priority to the development and dissemination of guidelines on nutrition of children under two years of age, to the training of health workers and community leaders on this subject, and to the integration of these messages into strategies for health and nutrition information, education and communication;

(7) to strengthen monitoring of growth and improvement of nutrition, focusing on community-based strategies, and to strive to ensure that all malnourished children, whether in a community or hospital setting, are correctly diagnosed and treated;

(8) to develop, implement or strengthen sustainable measures including, where appropriate, legislative measures, aimed at reducing all forms of malnutrition in young children and women of reproductive age, especially iron, vitamin A and iodine deficiencies, through a combination of strategies that include supplementation, food fortification and diet diversification, through recommended feeding practices that are culture-specific and based on local foods, as well as through other community-based approaches;

(9) to strengthen national mechanisms to ensure global compliance with the International Code of Marketing of Breastmilk Substitutes and subsequent relevant Health Assembly resolutions, with regard to labelling as well as all forms of advertising, and commercial promotion in all types of media, to encourage the Codex Alimentarius Commission to take the International Code and relevant subsequent Health Assembly resolutions into consideration in developing its standards and guidelines; and to inform the general public on progress in implementing the Code and subsequent relevant Health Assembly resolutions;

(10) to recognize and assess the available scientific evidence on the balance of risk of HIV transmission through breastfeeding compared with the risk of not breastfeeding, and the need for independent research in this connection; to strive to ensure adequate nutrition of infants of HIV-positive mothers; to increase accessibility to voluntary and confidential counselling and testing so as to facilitate the provision of information and informed decision-making; and to recognize that when replacement feeding is acceptable, feasible, affordable, sustainable and safe, avoidance of all breastfeeding by HIV-positive women is recommended; otherwise, exclusive breastfeeding is recommended during the first months of life; and that those who choose other options should be encouraged to use them free from commercial influences;

(11) to take all necessary measures to protect all women from the risk of HIV infection, especially during pregnancy and lactation;

(12) to strengthen their information systems, together with their epidemiological surveillance systems, in order to assess the magnitude and geographical distribution of malnutrition, in all its forms, and of foodborne disease;

3. REQUESTS the Director-General:

(1) to give, greater emphasis to infant and young child nutrition, in view of WHO's leadership in public health, consistent with and guided by the Convention on the Rights of the Child and other relevant human rights instruments, in partnership with ILO, FAO,

UNICEF, UNFPA and other competent organizations both within and outside the United Nations system;

(2) to foster, with all relevant sectors of society, a constructive and transparent dialogue in order to monitor progress towards implementation of the International Code of Marketing of Breastmilk Substitutes and subsequent relevant Health Assembly resolutions, in an independent manner and free from commercial influence, and to provide support to Member States in their efforts to monitor implementation of the Code;

(3) to provide support to Member States in the identification, implementation and evaluation of innovative approaches to improving infant and young child feeding, emphasizing exclusive breastfeeding for six months as a global public health recommendation, taking into account the findings of the WHO expert consultation on optimal duration of exclusive breastfeeding,[1] the provision of safe and appropriate complementary foods, with continued breastfeeding up to two years of age or beyond, and community-based and cross-sector activities;

(4) to continue the step-by-step country- and region-based approach to developing the new global strategy on infant and young child feeding, and to involve the international health and development community, in particular UNICEF, and other stakeholders as appropriate:

(5) to encourage and support further independent research on HIV transmission through breastfeeding and on other measures to improve the nutritional status of mothers and children already affected by HIV/AIDS;

(6) to submit the global strategy for consideration to the Executive Board at its 109th session in January 2002 and to the Fifty-fifth World Health Assembly (May 2002).

[1] As formulated in the conclusions and recommendations of the expert consultation (Geneva, 28 to 30 March 2001) that completed the systematic review of the optimal duration of exclusive breastfeeding (see document A54/INF.DOC./4).

(emphasis added) 18 May 2001

ICDC Commentary

In this resolution, the WHA reiterates the advantages of exclusive breastfeeding for six months and the need to improve complementary feeding. It also endorses the Global Strategy for Infant and Young Child Feeding, which calls for renewed commitment by governments to implement the International Code and to protect and promote optimal feeding of infants and young children. The WHA also makes a connection between optimal infant feeding and reduced risks of obesity. Furthermore it alerts Member States to ensure that micronutrient interventions and marketing of nutritional supplements should not undermine exclusive breastfeeding and optimal complementary feeding.

WHA55.25 2002

The Fifty-fifth World Health Assembly,

Having considered the draft global strategy for infant and young-child feeding;

Deeply concerned about the vast numbers of infants and young children who are still inappropriately fed and whose nutritional status, growth and development, health and very survival are thereby compromised;

Conscious that every year as much as 55% of infant deaths from diarrhoeal disease and acute respiratory infections may be the result of inappropriate feeding practices, that less than 35% of infants worldwide are exclusively breastfed for even the first four months of life, and that complementary feeding practices are frequently ill-timed, inappropriate and unsafe;

Alarmed at the degree to which inappropriate infant and young-child feeding practices contribute to the global burden of disease, including malnutrition and its consequences such as blindness and mortality due to vitamin A deficiency, impaired psychomotor development due to iron deficiency and anaemia, irreversible brain damage as a consequence of iodine deficiency, the massive impact on morbidity and mortality of protein-energy malnutrition, and the later-life consequences of childhood obesity;

Recognizing that infant and young-child mortality can be reduced through improved nutritional status of women of reproductive age, especially during pregnancy, and by exclusive breastfeeding for the first six months of life, and with nutritionally adequate and safe complementary feeding through introduction of safe and adequate amounts of indigenous foodstuffs and local foods while breastfeeding continues up to the age of two years or beyond;

Mindful of the challenges posed by the ever-increasing number of people affected by major emergencies, the HIV/AIDS pandemic, and the complexities of modern lifestyles coupled with continued promulgation of inconsistent messages about infant and young-child feeding;

Aware that inappropriate feeding practices and their consequences are major obstacles to sustainable socioeconomic development and poverty reduction;

Reaffirming that mothers and babies form an inseparable biological and social unit, and that the health and nutrition of one cannot be divorced from the health and nutrition of the other;

Recalling the Health Assembly's endorsement (resolution WHA33.32), in their entirety, of the statement and recommendations made by the joint WHO/UNICEF Meeting on Infant and Young Child Feeding held in 1979; its adoption of the International Code of Marketing of

Breastmilk Substitutes (resolution WHA34.22), in which it stressed that adoption of and adherence to the Code were a minimum requirement; its welcoming of the Innocenti Declaration on the Protection, Promotion and Support of Breastfeeding as a basis for international health policy and action (resolution WHA44.33); its urging encouragement and support for all public and private health facilities providing maternity services so that they become "baby-friendly" (resolution WHA45.34); its urging ratification and implementation of the Convention on the Rights of the Child as a vehicle for family health development (resolution WHA46.27); and its endorsement, in their entirety, of the World Declaration and Plan of Action for Nutrition adopted by the International Conference on Nutrition (resolution WHA46.7);

Recalling also resolutions WHA35.26, WHA37.30, WHA39.28, WHA41.11, WHA43.3, WHA45.34, WHA46.7, WHA47.5, WHA49.15 and WHA54.2 on infant and young-child nutrition, appropriate feeding practices and related questions;

Recognizing the need for comprehensive national policies on infant and young-child feeding, including guidelines on ensuring appropriate feeding of infants and young children in exceptionally difficult circumstances;

Convinced that it is time for governments to renew their commitment to protecting and promoting the optimal feeding of infants and young children,

1. ENDORSES the global strategy for infant and young-child feeding;

2. URGES Member States, as a matter of urgency:

   (1) to adopt and implement the global strategy, taking into account national circumstances, while respecting positive local traditions and values, as part of their overall nutrition and child health policies and programmes, in order to ensure optimal feeding for all infants and young children, and to reduce the risks associated with obesity and other forms of malnutrition;

   (2) to strengthen existing, or establish new, structures for implementing the global strategy through the health and other concerned sectors, for monitoring and evaluating its effectiveness, and for guiding resource investment and management to improve infant and young-child feeding;

   (3) to define for this purpose, consistent with national circumstances:

      (a) national goals and objectives,

      (b) a realistic timeline for their achievement,

      (c) measurable process and output indicators that will permit accurate monitoring and evaluation of action taken and a rapid response to identified needs;

   (4) to ensure that the introduction of micronutrient interventions and the marketing of nutritional supplements do not replace, or undermine support for the sustainable practice of, exclusive breastfeeding and optimal complementary feeding;

   (5) to mobilize social and economic resources within society and to engage them actively in implementing the global strategy and in achieving its aims and objectives in the spirit of resolution WHA49.15;

3. CALLS UPON other international organizations and bodies, in particular ILO, FAO, UNICEF, UNHCR, UNFPA and UNAIDS, to give high priority, within their respective mandates and programmes and consistent with guidelines on conflict of interest, to provision of support

to governments in implementing this global strategy, and invites donors to provide adequate funding for the necessary measures;

4. REQUESTS the Codex Alimentarius Commission to continue to give full consideration, within the framework of its operational mandate, to action it might take to improve the quality standards of processed foods for infants and young children and to promote their safe and proper use at an appropriate age, including through adequate labelling, consistent with the policy of WHO, in particular the International Code of Marketing of Breast-milk Substitutes, resolution WHA54.2, and other relevant resolutions of the Health Assembly;

5. REQUESTS the Director-General:

   (1) to provide support to Member States, on request, in implementing this strategy, and in monitoring and evaluating its impact;

   (2) to continue, in the light of the scale and frequency of major emergencies worldwide, to generate specific information and develop training materials aimed at ensuring that the feeding requirements of infants and young children in exceptionally difficult circumstances are met;

   (3) to strengthen international cooperation with other organizations of the United Nations system and bilateral development agencies in promoting appropriate infant and young-child feeding;

   (4) to promote continued cooperation with and among all parties concerned with implementing the global strategy.

(emphasis added)

18 May 2002

ICDC Commentary

In this resolution, the WHA asks Member States to ensure that nutrition and health claims are not permitted for breastmilk substitutes unless they are allowed by national legislation. It also draws attention to the risks of intrinsic contamination of powdered infant formulas with microorganisms and recommends that this information be conveyed through label warnings. In addition WHA reiterates its concern that sponsorship of health professionals can create conflicts of interest and expands the warning to encompass financial support for programmes as well. WHA also re-emphasises the call to protect, promote and support exclusive breastfeeding for six months and continued breastfeeding for up to two years and beyond and to fully implement the WHO/UNICEF Global Strategy for Infant and Young Child Feeding.

WHA58.32 2005

The Fifty-eighth World Health Assembly,

Recalling the adoption by the Health Assembly of the International Code of Marketing of Breastmilk Substitutes (resolution WHA34.22), resolutions WHA39.28, WHA41.11, WHA46.7, WHA47.5, WHA49.15, WHA54.2 on infant and young child nutrition, appropriate feeding practices and related questions, and particularly WHA55.25, which endorses the global strategy for infant and young child feeding;

Having considered the report on infant and young-child nutrition;

Aware that the joint FAO/WHO expert meeting on *Enterobacter sakazakii* and other microorganisms in powdered infant formula held in 2004 concluded that intrinsic contamination of powdered infant formula with *E. sakazakii* and *Salmonella* had been a cause of infection and illness, including severe disease in infants, particularly preterm, low birth-weight or immunocompromised infants, and could lead to serious developmental sequelae and death;[1]

Noting that such severe outcomes are especially serious in preterm, low birth-weight and immunocompromised infants, and therefore are of concern to all Member States;

Bearing in mind that the Codex Alimentarius Commission is revising its recommendations on hygienic practices for the manufacture of foods for infants and young children;

Recognizing the need for parents and caregivers to be fully informed of evidence-based public-health risks of intrinsic contamination of powdered infant formula and the potential for introduced contamination, and the need for safe preparation, handling and storage of prepared infant formula;

Concerned that nutrition and health claims may be used to promote breastmilk substitutes as superior to breastfeeding;

Acknowledging that the Codex Alimentarius Commission plays a pivotal role in providing guidance to Member States on the proper regulation of foods, including foods for infants and young children;

Bearing in mind that on several occasions the Health Assembly has called upon the Commission to give full consideration, within the framework of its operational mandate, to evidence-based action that it might take to improve the health standards of foods, consistent with the aims and objectives of relevant public health strategies, particularly WHO's global strategy for infant and young-child feeding (resolution WHA55.25) and Global Strategy on Diet, Physical Activity and Health (resolution WHA57.17);

Recognizing that such action requires a clear understanding of the respective roles of the Health Assembly and the Codex Alimentarius Commission, and that of food regulation in the broader context of public health policies;

Taking into account resolution WHA56.23 on the joint FAO/WHO evaluation of the work of the Codex Alimentarius Commission, which endorsed WHO's increased direct involvement in the Commission and requested the Director-General to strengthen WHO's role in complementing the work of the Commission with other relevant WHO activities in the areas of food safety and nutrition, with special attention to issues mandated in Health Assembly resolutions,

1. URGES Member States:

(1) to continue to protect, promote and support exclusive breastfeeding for six months as a global public health recommendation, taking into account the findings of the WHO Expert Consultation on optimal duration of exclusive breastfeeding,[2] and to provide for continued breastfeeding up to two years of age or beyond, by implementing fully the WHO global strategy on infant and young-child feeding that encourages the formulation of a comprehensive national policy, including where appropriate a legal framework to promote maternity leave and a supportive environment for six months' exclusive breastfeeding, a detailed plan of action to implement, monitor and evaluate the policy, and allocation of adequate resources for this process;

(2) to ensure that nutrition and health claims are not permitted for breastmilk substitutes, except where specifically provided for in national legislation;[3]

(3) to ensure that clinicians and other health-care personnel, community health workers and families, parents and other caregivers, particularly of infants at high risk, are provided with enough information and training by health-care providers, in a timely manner on the preparation, use and handling of powdered infant formula in order to minimize health hazards; are informed that powdered infant formula may contain pathogenic microorganisms and must be prepared and used appropriately; and, where applicable, that this information is conveyed through an explicit warning on packaging;

(4) to ensure that financial support and other incentives for programmes and health professionals working in infant and young-child health do not create conflicts of interest;

(5) to ensure that research on infant and young-child feeding, which may form the basis for public policies, always contains a declaration relating to conflicts of interest and is subject to independent peer review;

(6) to work closely with relevant entities, including manufacturers, to continue to reduce the concentration and prevalence of pathogens, including *Enterobacter sakazakii*, in powdered infant formula;

(7) to continue to ensure that manufacturers adhere to Codex Alimentarius or national food standards and regulations;

(8) to ensure policy coherence at national level by stimulating collaboration between health authorities, food regulators and food standard-setting bodies;

(9) to participate actively and constructively in the work of the Codex Alimentarius Commission;

(10) to ensure that all national agencies involved in defining national positions on public health issues for use in all relevant international forums, including the Codex Alimentarius Commission, have a common and consistent understanding of health policies adopted by the Health Assembly, and to promote these policies;

2. REQUESTS the Codex Alimentarius Commission:

(1) to continue to give full consideration, when elaborating standards, guidelines and recommendations, to those resolutions of the Health Assembly that are relevant in the framework of its operational mandate;

(2) to establish standards, guidelines and recommendations on foods for infants and young children formulated in a manner that ensures the development of safe and appropriately labelled products that meet their known nutritional and safety needs, thus reflecting WHO policy, in particular the WHO global strategy for infant and young child feeding and the International Code of Marketing of Breastmilk Substitutes and other relevant resolutions of the Health Assembly;

(3) urgently to complete work currently under way on addressing the risk of microbiological contamination of powdered infant formula and establish appropriate microbiological criteria or standards related to *E. sakazakii* and other relevant microorganisms in powdered infant formula; and to provide guidance on safe handling and on warning messages on product packaging;

3. REQUESTS the Director-General:

(1) in collaboration with FAO, and taking into account the work undertaken by the Codex Alimentarius Commission**,** to develop guidelines for clinicians and other health-care providers, community health workers and family, parents and other caregivers on the preparation, use, handling and storage of infant formula so as to minimize risk, and to address the particular needs of Member States in establishing effective measures to minimize risk in situations where infants cannot be, or are not, fed breastmilk;

(2) to take the lead in supporting independently reviewed research, including by collecting evidence from different parts of the world, in order to get a better understanding of the ecology, taxonomy, virulence and other characteristics of *E. sakazakii*, in line with the recommendations of the FAO/WHO Expert Meeting on *E. sakazakii* and other Microorganisms in Powdered Infant Formula, and to explore means of reducing its level in reconstituted powdered infant formula;

(3) to provide information in order to promote and facilitate the contribution of the Codex Alimentarius Commission, within the framework of its operational mandate, to full implementation of international public health policies;

(4) to report to the Health Assembly each even year, along with the report on the status of implementation of the International Code of Marketing of Breastmilk Substitutes and the relevant resolutions of the Health Assembly, on progress in

the consideration of matters referred to the Codex Alimentarius Commission for its action.

[1] FAO/WHO Expert Meeting on *E. sakazakii* and other Microorganisms in Powdered Infant Formula: Meeting Report. Microbiological Risk Assessment Series No. 6, 2004, p. 37.

[2] As formulated in the conclusions and recommendations of the Expert Consultation (Geneva, 28-30 March 2001) that completed the systematic review of the optimal duration of exclusive breastfeeding (see document A54/INF.DOC./4).

[3] The reference to national legislation also applies to regional economic integration organizations.

(emphasis added) 25 May 2005





Appendix D

The Innocenti Declaration

INNOCENTI DECLARATION

On the Protection, Promotion and Support of Breastfeeding

RECOGNISING that

Breastfeeding is a unique process that:

- provides ideal nutrition for infants and contributes to their healthy growth and development;
- reduces incidence and severity of infectious diseases, thereby lowering infant morbidity and mortality;
- contributes to women's health by reducing the risk of breast and ovarian cancer, and by increasing the spacing between pregnancies;
- provides social and economic benefits to the family and the nation;
- provides most women with a sense of satisfaction when successfully carried out; and that

Recent research has found that:

- these benefits increase with increased exclusiveness [1] of breastfeeding during the first six months of life, and thereafter with increased duration of breastfeeding with complementary foods, and
- programme interventions can result in positive changes in breastfeeding behaviour;

The Innocenti Declaration was produced and adopted by participants at the WHO/UNICEF policymakers' meeting on "Breastfeeding in the 1990s: A Global Initiative", co-sponsored by the United States Agency for International Development (A.I.D) and the Swedish International Development Authority (SIDA), held at the Spedale degli Innocenti, Florence, Italy, on 30 July – 1 August 1990. The Declaration reflects the content of the original background document for the meeting and the views expressed in group and plenary sessions.

[1] Exclusive breastfeeding means that no other drink or food is given to the infant; the infant should feed frequently and for unrestricted periods.

WE THEREFORE DECLARE that

As a global goal for optimal maternal and child health and nutrition, all women should be enabled to practise exclusive breastfeeding and all infants should be fed exclusively on breastmilk from birth to 4 – 6 months of age.* Thereafter, children should continue to be breastfed, while receiving appropriate and adequate complementary foods, for up to two years of age or beyond. This child-feeding ideal is to be achieved by creating an appropriate environment of awareness and support so that women can breastfeed in this manner.

Attainment of the goal requires, in many countries, the reinforcement of a "breastfeeding culture" and its vigorous defence against incursions of a "bottle-feeding culture." This requires commitment and advocacy for social mobilization, utilizing to the full the prestige and authority of acknowledged leaders of society in all walks of life.

Efforts should be made to increase women's confidence in their ability to breastfeed. Such empowerment involves the removal of constraints and influences that manipulate perceptions and behaviour towards breastfeeding, often by subtle and indirect means. This requires sensitivity, continued vigilance, and a responsive and comprehensive communications strategy involving all media and addressed to all levels of society. Furthermore, obstacles to breastfeeding within the health system, the workplace and the community must be eliminated.

Measures should be taken to ensure that women are adequately nourished for their optimal health and that of their families. Furthermore, ensuring that all women also have access to family planning information and services allows them to sustain breastfeeding and avoid shortened birth intervals that may compromise their health and nutritional status, and that of their children.

All governments should develop national breastfeeding policies and set appropriate national targets for the 1990s. They should establish a national system for monitoring the attainment of their targets, and they should develop indicators such as the prevalence of exclusively breastfed infants at discharge from maternity services, and the prevalence of exclusively breastfed infants at four months of age.

National authorities are further urged to integrate their breastfeeding policies into their overall health and development policies. In so doing they should reinforce all actions that protect, promote and support breastfeeding within complementary programmes such as prenatal and perinatal care, nutrition, family planning services, and prevention and treatment of common maternal and childhood diseases. All healthcare staff should be trained in the skills necessary to implement these breastfeeding policies.

* *Editor's note:* After the adoption of the Innocenti Declaration, both UNICEF and the WHA recommended exclusive breastfeeding for a full six months as a global health recommendation. *See, e.g,* Resolution WHA54.2 (2001)

OPERATIONAL TARGETS:

All governments by the year 1995 should have:

- appointed a national breastfeeding coordinator of appropriate authority, and established a multisectoral national breastfeediung committee composed of representatives from relevant government departments, non-governmental organizations and health professional associations;
- ensured that every facility providing maternity services fully practices all ten of the *Ten Steps to Successful Breastfeeding* set out in the joint WHO/UNICEF statement [2] "Protecting, promoting and supporting breastfeeding: the special role of maternity services";
- taken action to give effect to the principles and aim of all Articles of the International Code of Marketing of Breastmilk Substitutes and subsequent relevant World Health Assembly resolutions in their entirety; and
- enacted imaginative legislation protecting the breastfeeding rights of working women and established means for its enforcement.

We also call upon international organizations to:

- draw up action strategies for protecting, promoting and supporting breastfeeding, including global monitoring and evaluation of their strategies;
- support national situation analyses and surveys and the development of national goals and targets for action; and
- encourage and support national authorities in planning, implementing, monitoring and evaluating their breastfeeding policies.

[2] World Health Organization, Geneva, 1989.

Appendix E

Global Strategy for Infant and Young Child Feeding

ICDC Commentary

The following excerpt from the 2002 Global Strategy for Infant and Young Child Feeding sets forth the operational targets. The Global Strategy delineates the roles of "governments, international organizations and other concerned parties" in achieving these targets. Paragraph 44 is also reproduced here as it shows that the role of infant food companies is limited to ensuring the quality of their products and to compliance with the International Code, relevant WHA resolutions and relevant national measures.

Global Strategy for Infant and Young Child Feeding

(relevant paragraphs)

Achieving the strategy's objectives

30. A first step to achieving the objectives of this strategy is to reaffirm the relevance = indeed the urgency = of the four operational targets of the Innocenti Declaration on the Protection, Promotion and Support of Breastfeeding:

    [*Editor's note:* The four operational targets of the Innocenti Declaration appear in Appendix D of this Handbook.]

33. With these considerations in mind, the global strategy includes as a priority for all governments the achievement of the following additional operational targets:

    - to develop, implement, monitor and evaluate a comprehensive policy on infant and young child feeding, in the context of national policies and programmes for nutrition, child and reproductive health, and poverty reduction;
    - to ensure that the health and other relevant sectors protect, promote and support exclusive breastfeeding for six months and continued breastfeeding up to two years of age or beyond, while providing women access to the support they require – in the family, community and workplace – to achieve this goal;
    - to promote timely, adequate, safe and appropriate complementary feeding with continued breastfeeding;
    - to provide guidance on feeding infants and young children in exceptionally difficult circumstances, and on the related support required by mothers, families and other caregivers;
    - to consider what new legislation or other suitable measures may be required, as part of a comprehensive policy on infant and young child feeding, to give effect to the principles and aim of the International Code of Marketing of Breastmilk Substitutes and to subsequent relevant Health Assembly resolutions.

Commercial enterprises

44. Manufacturers and distributors of industrially processed foods intended for infants and young children also have a constructive role to play in achieving the aim of this strategy. They should ensure that processed food products for infants and children, when sold, meet applicable Codex Alimentarius standards and the Codex Code of Hygienic Practice for Foods for Infants and Children. In addition, all manufacturers and distributors of products within the scope of the International Code of Marketing of Breastmilk Substitutes, including feeding bottles and teats, are responsible for monitoring their marketing practices according to the principles and aim of the Code. They should ensure that their conduct at every level conforms to the Code, subsequent relevant Health Assembly resolutions, and national measures that have been adopted to give effect to both.

(references deleted)

Appendix F

Laws, Regulations and Voluntary Measures implementing all or parts of the International Code

Laws, Regulations and Voluntary Measures implementing all or parts of the International Code

Albania
Law for Promotion and Protection of Breastfeeding, Nº 8528, 23 September 1999

Argentina
Resolución Nº 54/1997, Acéptase el Código Internacional de Comercialización de sucedáneos de la Leche Materna de la Organización Mundial de la Salud, Ginebra, 1981; y sus modificaciones posteriores introducidas en la 47º Asamblea Mundial de la Salud, Undécima Reunión Plenaria, 9 de mayo de 1994, publicada 5 junio 1997

Province of Buenos Aires, Argentina
Argentina Provincial Regulations, Province of Buenos Aires, Decision Nº 024/98 Implementing Ministerial Resolution Nº 4477/97 (on the Implementation of the International Code of Marketing of Breastmilk Substitutes) and Annex, Guidelines for applying Ministerial Resolution Nº 4477/97 in the Health Care System of the Province of Buenos Aires, 1998

Armenia
Law of the Republic of Armenia on Advertisements, 1999, (applicable sections)

Australia
Marketing in Australia of Infant Formulas: Manufacturers and Importers, May 1992

Austria
Verordnung 531/1995, Säuglingsanfangsnahrung und Folgennahrung (CELEX Nº 391L0321), 8 Augustus 1995

Azerbaijan
Law of the Azerbaijan Republic on Feeding of Infants and Young Children, 17 June 2003

Bahrain
Decree Nº 4 of 1995 concerning the Control of Use, Marketing and Promotion of Breastmilk Substitutes, 8 Feb 1995, Nº 2150

Bangladesh
Breastmilk Substitutes (Regulation of Marketing) Ordinance Nº 33, 24 May 1984, *amended* 1990

Breastmilk Substitutes (Regulation of Marketing) Rules 1993, 13 September 1993

Belgium
Arrêté Royal modifiant l'Arrêté Royal du 18 février 1991 relatif aux denrées alimentaires destinées à une alimentation particulière, 27 septembre 1993, (publié 5 janvier 1994), *amended* 1997

Benin
Décret N° 97-643, portant réglementation de la commercialisation des substituts du lait maternel et des aliments pour nourrissons, 31 décembre 1997.

Bolivia
Reglamento de Comercialización de Sucedáneos de la Leche Materna, agosto 1984

Botswana
Marketing of Foods for Infants and Young Children Regulations, Statutory Instrument Nº 37 of 2005, 8 June 2005

Brazil
Norma Brasileira de Comercialização de Alimentos para Lactentes e Crianças de Primeira Infância, Bicos, Chupetas e Mamadeiras, Portaria Nº 2051 de 8 de novembro, 2001

Regulamento Técnico Chupetas, Bicos, Mamadeiras e Protetores de Mamilo, Resolução-RDC N° 221 de 5 de agosto de 2002

Regulamento Técnico para Promoção Comercial dos Alimentos para Lactentes e Crianças de primeira Infância, Resolução-RDC N° 222 de 5 de agosto de 2002

Burkina Faso
Décret Nº 93-279/PRES/SASF/MICM portant commercialisation et pratiques y afférentes des produits de substitution du lait maternel, 27 septembre 1993

Cameroon
Arrêté Interministeriel Nº 040 portant sur la réglementation de la commercialisation des substituts du lait maternel, 6 octobre 1993

China
Rules Governing the Administration of Marketing of Breastmilk Substitutes, 1 October 1995

Colombia
Ministerio de Salud, Decreto Nº 1397, 24 agosto 1994

Costa Rica
Leyes Nº 7430, Fomento de la Lactancia Materna, 21 octubre 1994

Decretos Nº 24576-S, Reglamento a la Ley de Fomento de la Lactancia Materna, 13 septiembre 1995

Denmark
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