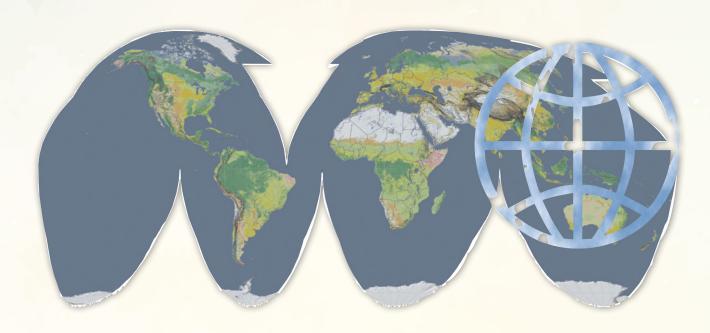
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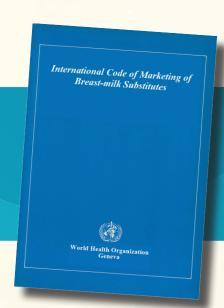
Annotated International Code of Marketing of Breastmilk Substitutes and subsequent WHA resolutions

Second Edition



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Code Essentials 1:

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International Baby Food Action Network International Code Documentation Centre

Code Essentials 1: Annotated International Code of Marketing of Breastmilk Substitutes and subsequent WHA resolutions

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Preface

Countries worldwide face tremendous challenges in promoting breastfeeding. One obstacle is the aggressive commercial promotion of breastmilk substitutes. While direct advertising for infant formula has stopped in many countries, more subtle forms of promotion continue. Mothers still receive samples and coupons and there is widespread advertising for follow-up formulas, growing-up milks and feeding bottles and teats. Obviously, this multi-million dollar marketing expenditure is in direct competition with breastfeeding.

The development of the **Code Essentials** series is one of many follow-up actions recommended at the WHO/UNICEF Consultation on Breastfeeding Protection, Promotion and Support held in Manila in June 2007. Due to its long-standing experience with Code implementation worldwide, ICDC was requested to prepare Code materials for different groups of actors; government officials, health educators and Code advocates. This is to support countries in the region in developing and strengthening legislative, regulatory or other effective measures to control the marketing of breastmilk substitutes.

As of the end 2017, many countries have taken action to give effect to the Code. There are laws and other regulatory measures in place at the national level but monitoring and enforcement remain a challenge. An ever-present industry influence to roll back and weaken any

form of regulation means that aggressive marketing of breastmilk substitutes persists as a threat to the promotion of breastfeeding. Code implementation and Code monitoring must therefore continue to be supported and documented.

Code Essentials 1 annotates and integrates the main messages of subsequent resolutions (1982-2016) into the analysis of the Code

Code Essentials 1: Annotated International Code of Marketing of Breastmilk Substitutes and relevant WHA resolutions (first

published in 2007) aims to develop a deeper understanding of Code provisions and subsequent World Health Assembly resolutions. This second edition of **Code Essentials 1** incorporates new guidelines, recommendations and guidance that have been developed over the last ten years. It annotates and integrates the main messages of subsequent resolutions (1982-2016) into the analysis of the Code.

Initial support the **Code Essential series** came from the UNICEF East Asia and Pacific Regional Office (EAPRO) and the WHO Western Pacific Regional Office. This second edition is produced and published with the support of UNICEF EAPRO.

Although prepared for the Asia Pacific region, this publication will be useful in other regions as the Code and resolutions are universal in their application.

IBFAN-ICDC Penang January 2018

This booklet is the first in a series of four on the International Code of Marketing of Breastmilk Substitutes and subsequent World Health Assembly resolutions. Each booklet, listed below, can stand independently and focuses on different categories of users.

Code Essentials 1: Annotated International Code of Marketing of Breastmilk Substitutes and subsequent WHA resolutions.

Code Essentials 2: Guidelines for Policy Makers on the Implementation of the International Code of Marketing of Breastmilk Substitutes and subsequent WHA resolutions.

Code Essentials 3: Responsibilities of Health Workers under the International Code of Marketing of Breastmilk Substitutes and subsequent WHA resolutions.

Code Essential 4: Complying with the International Code of Marketing of Breastmilk Substitutes and subsequent WHA resolutions. A Guide for Regulators and Compliance Staff.

"If breastfeeding did not already exist, someone who invented it today would deserve a dual Nobel Prize in medicine and economics. For while "breast is best" for lifelong health, it is also excellent economics. Breastfeeding is a child's first inoculation against death, disease, and poverty, but also their most enduring investment in physical, cognitive, and social cabacity."

Hansen, K. (2016). Breastfeeding: a smart investment in people and in economies. Retrieved from http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)00012-X/abstract

A brief introduction to the International Code of Marketing of Breastmilk Substitutes

History

During the 1960s and 70s, public attention was drawn to the decline in breastfeeding rates around the world. There was growing concern that aggressive marketing of breastmilk substitutes by baby food companies was contributing to an alarming decline in breastfeeding. Associated with this was an increase in malnutrition, morbidity and mortality among infants and young children worldwide.

The World Health Organization (WHO) and the United Nations Children's Fund (UNICEF), concerned with the decline in breastfeeding rates, jointly convened a Meeting on Infant and Young Child Feeding in Geneva in October 1979. Present at the meeting were governments, scientists, industry and non-governmental organisations. The final statement of that meeting stressed that society is responsible for the promotion of breastfeeding and for the protection of mothers from disruptive influences. It emphasised that poor infant feeding practices and their consequences are, to a large extent, a man-made problem, and a serious obstacle to social and economic development to not just the developing world but also the developed world.

The meeting 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."

Eighteen months and four drafts later, the World Health Assembly (WHA) at its 34th session adopted the International Code of Marketing of Breastmilk Substitutes, on 21 May 1981. It was adopted as a recommendation under the constitution of the World Health Organization.

The Code's legal status

Being a recommendation, it can be argued that the Code is not legally binding on Member States. However, as a WHO recommendation, it is an expression of the judgment of the collective membership of the highest authority on health and therefore carries strong moral or political weight and has persuasive authority. Moreover, the Convention on the Rights of the Child (CRC), which has been ratified by 196 state parties, mentions specifically the importance of breastfeeding in ensuring the child's right to the highest attainable standard of health. State parties thus have the responsibility to disseminate positive information about breastfeeding and to promote it through the health-care system, media and schools, as well as protecting the public from propaganda and misinformation through implementation of the Code.

At the country level, a deciding factor in the implementation of the Code is the political commitment to promote and protect breastfeeding. This requires giving effect to the principles and aim of the Code in their entirety, as a minimum measure, as stated in Resolution WHA 34.22 [1981]. Member States can do this by translating the Code into national legislation, regulations or other suitable measures, as appropriate to their social and legislative frameworks. Political commitment also implies monitoring compliance with national measures, imposition of sanctions and making available adequate human and other resources for follow-up.

Subsequent WHA resolutions

It must be noted that there is only one version of the Code. However, there have been a number of WHA resolutions adopted since 1981 that refer to the marketing and distribution of breastmilk substitutes. These resolutions clarify or extend on issues covered in the Code. When implementing the Code nationally, it must be read together with subsequent WHA resolutions. (For the sake of brevity, these are collectively referred to as the 'International Code' or as 'Code and resolutions'.)

Implementation at country level

To have legal effect at the national level, Member States must translate the International Code into national legislation, regulations or other suitable measures, as appropriate to their social and legislative frameworks. Resolution WHA 34.22 [1981] stressed that adoption of and adherence to the International Code is a **minimum requirement** and urged Member States to implement the International Code **"in its entirety."** They can adopt additional or stronger provisions than those set out in the International Code. National laws or codes must never be weaker or less complete than the International Code.

Global Strategy on Infant and Young Child Feeding

In 2002, WHO and UNICEF jointly formulated the Global Strategy on Infant and Young Child Feeding which was endorsed by Resolution WHA 55.25 [2002]. The Global Strategy is a guide for countries to develop approaches to improve the nutritional status of infants and young children through optimal feeding. The Global Strategy reaffirms the urgency of implementing the International Code as one of the key steps to achieve this objective, and lists the roles of governments, international organisations, industry and other concerned parties in achieving its targets.

Guidance on the inappropriate promotion of foods for infants and young children

In May 2012, resolution WHA 65.6 requested the Director-General of WHO "to provide clarification and guidance on the inappropriate promotion of foods for infants and young children" cited in resolution WHA 63.23 [2010]. A series of consultations resulted in a Guidance on the inappropriate promotion of foods for infants and young children (A69/7 Add.1). In May 2016, Member States adopted resolution WHA 69.9 [2016] that calls on countries to implement Guidance 69/7 Add.1. This is in response to a growing body of evidence which shows that the promotion of breastmilk substitutes and some commercial foods for infants and young children undermines optimal infant and young child feeding. The Guidance serves as a complement to existing tools, such as the International Code and subsequent relevant WHA resolutions, as well as the Global Strategy on Infant and Young Child Feeding. It encourages Member States to develop stronger national policies that protect children under the age of 36 months from marketing practices that could be detrimental to their health. The Guidance targets all commercially produced foods and beverages that are marketed as suitable for feeding infants and young children aged 6–36 months. The implications of the Guidance on the International Code are discussed in the annotations of the relevant Code articles.

"From tobacco, to sugar, to formula milk, the most vulnerable suffer when commercial interests collide with public health. Robust advertising regulation -- covering all milk products for children up to 3 years, and banning social media promotion -- is the next step to protect them."

Lancet Editorial. (2016). No ifs, no buts, no follow-on milk. Retrieved from http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)30599-2/fulltext

^{1.} The International Code of Marketing of Breastmilk Substitutes: Frequently Asked Questions (2017 Update), Geneva, Switzerland, World Health Organization; 2017. The resolutions are WHA 35.26, 37.30, 39.28, 41.11, 43.3, 45.34, 46.7, 47.5, 49.15, 54.2, 55.25, 58.32, 59.11, 59.21, 61.20, 63.23, 65.6, 69.9. There is also a decision adopted on maternal, infant and young child nutrition in 2014, WHA 67(9) that focused among other things on indicators to achieve global nutrition targets including Code implementation. Under Article 23 of the WHO Constitution, the normative weight given to resolutions and decisions is the same.

^{2.} A summary of the Code and subsequent resolutions appear in Annex 1 and Annex 2 respectively. ICDC's publication, "International Code of Marketing of Breastmilk Substitutes and relevant resolutions" contains a compilation of the full text of these documents in one handy volume.

Recent findings continue to support the case for breastfeeding

In January 2016, the British medical journal The Lancet published a major new series on breastfeeding that represents the most in-depth analysis done so far into the health and economic benefits of breastfeeding.³

The Breastfeeding Series evaluates global breastfeeding levels, trends and inequalities, in addition to the short- and long-term consequences of breastfeeding for both mother and child. It underscores the importance of policy interventions to increase and sustain breastfeeding levels. Results published in the Series reveal that:

- increasing breastfeeding to near-universal levels could save more than 800,000 lives every year, the majority of which are children under 6 months;
- nearly half of all diarrhoeal diseases and one-third of all respiratory infections in children in lowand middle-income countries could be prevented with increased rates of breastfeeding;
- children who are breastfeed perform better in intelligence tests, are less likely to be overweight or obese, and are less prone to diabetes later in life; and
- mothers who breastfeed reduce their risk of developing breast and ovarian cancers. At current breastfeeding rates, an estimated 20,000 deaths from breast cancer are prevented and an additional 20,000 mothers could be saved if rates improved.

The Series presents a strong economic case for investing in promoting and protecting breastfeeding worldwide. The global economic loss from lower cognition associated with not breastfeeding was more than US\$ 300 billion in 2012, equivalent to 0.49% of the world's gross national income.

Increasing breastfeeding rates would also cut treatment costs of common childhood illnesses such as pneumonia, diarrhoea and asthma. As a result, boosting breastfeeding rates of infants below 6 months of age to 90% in the United States, China, and Brazil would save each country's healthcare system at least US\$ 2.45 billion, US\$ 223.6 million and US\$6.0 million respectively.

Boosting breastfeeding rates to just 45% in the United Kingdom would save its healthcare system US\$ 29.5 million.

The review of the evidence and country case studies show that successful protection, promotion, and support of breastfeeding needs measures at many levels, whether it be legal and policy directives to social attitudes and norms, women's work and employment conditions, or health and services to support women and their families to breastfeed optimally. One action point proposed in the Series is to regulate the breastmilk substitute industry.

"Breastmilk substitutes are a multi-billion-dollar industry, the marketing of which undermines breastfeeding as the best feeding practice in early life. No new interventions are needed—the Code is an effective mechanism for action. However, much greater political commitment is needed to enact and enforce the relevant, comprehensive legislation and national investment to ensure implementation and accountability. Without these commitments, agreed principles of responsible marketing will continue to be violated"

Rollins, N. et al. (2016). "Why invest, and what it will take to improve breastfeeding practices?" Lancet; 387:491–504 at p.501

^{3.} The Lancet Breastfeeding Series (2016) comprises of (1) Victora, C. G., Bahl, R., Barros, A. J., França, G. V., Horton, S., Krasevec, J., ... & Group, T. L. B. S. (2016). Breastfeeding in the 21st century: epidemiology, mechanisms, and lifelong effect. The Lancet, 387(10017), 475-490 and (2) Rollins, N. C., Bhandari, N., Hajeebhoy, N., Horton, S., Lutter, C. K., Martines, J. C., ... & Group, T. L. B. S. (2016). Why invest, and what it will take to improve breastfeeding practices?. The Lancet, 387(10017), 491-504.

The State of the Code by Country

As of 2018, 170 countries have taken some kind of action at the national level: adopted a law (36 countries), many provisions law (31), few provisions law (61), policy or voluntary measures (12), some provisions in other laws or guidelines (13) and some provisions voluntary (17). Box 1 below explains the different classifications and lists countries in the first two categories.

In total, 85% of 198 countries have taken some action to implement the International Code. While this may look like an impressive percentage, the quality of national measures is uneven, and problems with monitoring and enforcement persist. 5

The annual worldwide baby food market exceeded USD 58 billion in 2014, with sales of formula milk totaling USD 44.8 billion. The market continues to grow, and global sales are expected to reach USD 70.6 billion by 2019.6 Alongside this growth, lack of Code implementation and weak laws have allowed inappropriate marketing practices to flourish. Only effective national legislation, properly enforced, can prevent commercial promotion from competing unfairly with breastfeeding. Worldwide, good laws are needed to give breastfeeding a fighting chance.

Box 1 - Extract from State of the Code by Country 2018. IBFAN-ICDC.

- **1. 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 and subsequent WHA resolutions.
- **2. Many provisions law:** These countries have enacted legislation or adopted regulations, decrees or other legally binding measures encompassing many provisions of the Code and subsequent WHA resolutions.
- **3. Few provisions law:** These countries have enacted legislation or adopted regulations, directives, decrees or other legally binding measures covering only few provisions of the Code or subsequent WHA resolutions.
- **4. Voluntary Code or policy:** In these countries the government has adopted all or most of the provisions of the Code and

subsequent WHA resolutions through a voluntary Code, a government policy or other non-binding measure. There are no enforcement mechanisms.

5. Some provisions in other laws or guidelines applicable to the health sector:

In these countries,

- i) the government has adopted some provisions of the Code and subsequent WHA resolutions in other laws in particular those pertaining to quality, labelling or consumer protection, or
- ii) the government has directives applicable to the health sector only.
- **6. Some provisions voluntary:** In these countries, the government has adopted some provisions of the Code and subsequent WHA resolutions through voluntary measures, official guidelines or other non-binding measures.
- 1. Countries with Law. Afghanistan, Albania, Armenia, Bahrain, Bangladesh, Benin, Bolivia, Botswana, Brazil, Cape Verde, Dominican Republic, Gabon, Gambia, Georgia, Ghana, India, Kosovo, Kuwait, Lebanon, Madagascar, Maldives, Mozambique, Nepal, Pakistan, Palau, Panama, Peru, Philippines, South Africa, Sri Lanka, Tanzania, Uganda, Venezuela, Vietnam, Yemen, Zimbabwe.
- 2. Countries with many provisions law. Azerbaijan, Burkina Faso, Burundi, Cambodia, Cameroon, Colombia, Comores, Congo Dem. Rep. of,Costa Rica, Cote d'Ivoire, Egypt, El Salvador, Fiji, Guatemala, Indonesia, Kenya, Kyrgyzstan, Malawi, Mali, Mexico, Mongolia, Myanmar, Nigeria, Rwanda, Saudi Arabia, Serbia, Syria, Tajikistan,Thailand, Tunisia, Zambia.

^{4.} IBFAN-ICDC. (2018). State of the Code by Country. Penang, Malaysia: IBFAN S/B.

^{5.} The governments that have successfully overcome barriers and challenges to adopt comprehensive Code-based legislation and taken monitoring and enforcement actions include Brazil, Botswana, India and the Philippines.

^{6.} Rollins, N.et al. (2016). "Why invest, and what it will take to improve breastfeeding practices?" Lancet; 387:491–504

Annotations to the International Code

The Code begins with a preamble that explains its purpose, underlying philosophy and objectives. The paragraphs of the preamble do not affect the wording of the Code in the parts where provisions are expressed in clear and unambiguous terms, but in parts where doubt arises, the preamble may be relied on to explain the intention of the drafters and the **spirit of the Code.**

Essentially, the preamble recognises the uniqueness and health-promoting properties of breastmilk as an unequalled and ideal food for infant development. It highlights the risks involved in inappropriate feeding practices, including the unnecessary and improper use of breastmilk substitutes, but acknowledges that in instances where mothers do not breastfeed or do so only partially, the use of breastmilk substitutes becomes necessary.

There is an overarching emphasis that even though these products should be accessible, they should never be marketed in ways that interfere with

breastfeeding in view of the vulnerability of infants in the early months of life and the risks involved with inappropriate feeding practices. The marketing of breastmilk substitutes must be subject to special treatment and usual marketing practices cannot be applied to them; hence the need for a Code.

The preamble underscores the need for governments to give legal effect to the Code's principles and aim. It is as

relevant today as it was in 1981 when the Code was adopted. Its far sightedness can be seen in the way the statements are able to capture the challenges which confront infant and young child feeding in the 21st century. In this context, the annotations to the preamble contain not only the basis for the statements in it, but also references to later developments and events that legitimise them many years later.

Both the preamble and the full text of the Code are reproduced in the following pages. Where pertinent, excerpts from subsequent WHA resolutions are paraphrased and included in italics after the relevant article of the Code. With the exception of Code Articles 2, 3, 6.6 and 6.7, where either no explanation or longer explanations are required, annotations are found in blue boxes positioned next to the relevant paragraphs.

In some organisations, notably WHO, the term "breast-milk substitutes" is spelled with a hyphen. In all ICDC publications, the spelling of "breastmilk", "breastfeeding" and "breastfed" has been standardised as one word instead of being hyphenated. This is consistent with the spelling used by IBFAN, UNICEF, the Oxford English Dictionary and many scientific articles nowadays. Words and phrases that are either key or contentious are *italicised* in the actual text and emphasised in **bold** in the annotations.

The International Code of Marketing of Breastmilk Substitutes

Full text of Code Preamble

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:

Annotations

The human right to food and nutrition is well established in international human rights law and principles. The foundation lies in the Universal Declaration of Human Rights [1948], which asserts in Article 25(1) that "everyone has the right to a standard of living adequate for the health and well-being of himself and his family including food..."

The Convention on the Rights of the Child (CRC,1990) links the human right to food and nutrition with the right to the best attainable standard of health (Article 24). It obliges governments to "ensure that all segments of society, in particular parents and children, are informed, of...the advantages of breastfeeding."

Various Human Rights Committees have commented on the need for Code implementation. For example -

In 2013, the Committee on the CRC released **General Comments No.15 and 16** that specifically urge State Parties to implement the Code and for industry to comply with it.

In 2016, the Committee on the Elimination of Discrimination against Women followed suit by issuing **CEDAW General Recommendation No. 34**, calling on State Parties to safeguard rural women's right to adequate health care by ensuring effective regulation of marketing of breastmilk substitutes and implementation and monitoring of the Code and resolutions.

In 2017, the Committee on Economic, Social and Cultural Rights (ESCR) issued **General Comment No. 24 on State Obligations under the International Covenant on ESCR in the Context of Business Activities** that stresses the obligation of State Parties to restrict marketing and advertising of breastmilk substitutes to protect public health in line with the Code and resolutions.

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

RECOGNISING 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:

RECOGNISING 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;

Annotations

The World Bank's 2006 report.

"Repositioning Nutrition as Central to Development: A Strategy for Large-Scale Action," affirmed the Code's preamble by stating that malnutrition and its irreversible consequences (reduced intelligence, stunted growth, poor academic performance, etc.), are the most damaging causative factors in the perpetuation of poverty. The report firmly states that preemptive action to prevent malnutrition, and therefore poverty, MUST occur during the first two years of life. Breastfeeding is recognised as the single most important long-term preventive measure that can be taken to combat malnutrition.

The Lancet Breastfeeding Series has data that further support the case for breastfeeding from **health and economic standpoints**. See p.4

In 1999, the Committee on Social, Economic and Cultural Rights, in adopting a General Comment on the Right to Adequate Food (E/C.12.1995/5), stated that Governments "...may need to take measures to maintain, adapt or strengthen dietary diversity and appropriate consumption and feeding patterns, including breastfeeding...", and highlighted the need for "legislation to enable breastfeeding, with regard to the regulation of marketing of breastmilk substitutes."

The Lancet Breastfeeding Series iterates that "political support and financial investment are needed to protect, promote, and support breastfeeding."

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;

RECOGNISING 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;

Annotations

Industry fought to include the term "legitimate market" during the Code's drafting process and it is used often to advance the argument against strong regulation. As an example, when breastmilk was found to be one transmission route for HIV, industry used the argument of 'legitimate market' to call for weaker national measures, ignoring the fact that the Code was never intended to ban the sale of breastmilk substitutes but to regulate marketing activities which discourage breastfeeding. The Code is now acknowledged to be of particular relevance in the context of HIV as it regulates the distribution of breastmilk substitutes to

prevent spillover to babies who would benefit from breastfeeding.

The Code also **protects artificially-fed children** by ensuring that labels carry necessary warnings for safe preparation and use. The Code ensures that the choice of product is made on the basis of independent medical advice.

Women avoid or stop breastfeeding for a variety of reasons. These can range from medical, cultural or psychological reasons to physical discomfort and inconvenience. Without support, many mothers turn to a bottle of formula. Multiplied across populations and involving multinational commercial interests, this situation has catastrophic consequences on breastfeeding rates and the health of subsequent generations. The marketing of breastmilk substitutes undermines breastfeeding as the optimal feeding practice in early life, and the Code is recognised by the Lancet's 2016 Breastfeeding Series as an effective tool to regulate this multi-billion-dollar industry.

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;

Annotations

After many years of controversy, the optimal period of exclusive breastfeeding is set at **six months** by resolution 54.2 [2001]. The WHO/UNICEF Global Strategy for Infant and Young Child Feeding (endorsed by resolution 55.25 [2002]) recommends that 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 or beyond.**

Women's productive and reproductive roles are duly recognised as a collective responsibility by the adoption of the ILO Maternity Protection Convention 2000 (no.183) which entitles women to 14 weeks paid maternity leave and lactating mothers to one or two paid breastfeeding breaks per working day. Resolution WHA 58.32 [2005] urges Member

Resolution WHA 58.32 [2005] urges Member States to implement a legal framework to promote both maternity leave and a supportive environment for six months exclusive breastfeeding.

Resolution WHA 58.32 [2005] recognises the need for parents and caregivers to be fully informed of evidence-based public health risks of **intrinsic contamination** of powdered infant formula, as well as the need for safe preparation, handling and storage of prepared infant formula. The resolution calls on governments to ensure that health workers, families and caregivers are provided with enough information and training on the preparation, use and handling of powdered infant formula in order to minimise health hazards, and that this information is conveyed through label warnings.

Guidelines issued by WHO on the safe preparation of powdered infant formula can be downloaded from http://www.who.int/foodsafety/publications/micro/pif2007/en/

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 organisations and other nongovernmental organisations 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, organisations of the United Nations system, non-governmental organisations, 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;

RECOGNISING 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:

Annotations

Education and social services are equally important in the promotion and protection of breastfeeding.

The Code protects breastfeeding as well as mothers who do not breastfeed.

WHA resolutions 49.15 [1996] and 58.32 [2005] warn against **conflicts of interest** regarding involvement of industry. In 2016, the UN General Assembly proclaimed 2016-2025 to be the UN **Decade of Action on Nutrition.** The goal of the Decade is to increase policy processes and activities across sectors at national, regional and global levels in order to implement the Rome Declaration on **Nutrition and Framework for Action** adopted by the second International Conference on Nutrition (ICN2). The Framework contains detailed recommended actions to promote, protect and support breastfeeding, including the adaptation and implementation of the Code and resolutions.

The Code protects breastfeeding by eliminating competition posed by the inappropriate marketing of breastmilk substitutes. The promotion and support of breastfeeding have to be carried out through other programmes in conjunction with Code implementation.

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 frameworks 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*;

Annotations

This paragraph of the Preamble (in addition to the sixth paragraph that mentions 'legitimate market') was proposed by the International Council of Infant Food Manufacturers. It must be noted that the **Global Strategy for Infant and Young Child Feeding** confines the role of manufacturers and distributors to:

- ensuring the **quality** of their products conforms to the applicable Codex Alimentarius standards and Code of Hygienic Practice for Foods for Infants and Children; and
- monitoring their marketing practices according to the principles and aim of the Code and resolutions, as well as national measures that give effect to these.⁷

The Code has been implemented nationally in many countries through binding legal measures. In others, the Code is implemented through non-binding measures, including voluntary agreements. The Senior Legal Officer⁸ at WHO responsible for the legal aspects of the Code between 1980 and 1997 has argued inter alia that non-binding measures may not be within the meaning of "other suitable measures" following the ejusdum generis⁹ rule (i.e., all measures should be binding).

In 2010, the WHA in resolution 63.23 expressed concerns at reports of the ineffectiveness of measures in some countries, particularly voluntary measures. The Director General of WHO was again requested to support Member States, on request, in their efforts to develop and/or strengthen legislative, regulatory or other effective measures to control marketing of breastmilk substitutes.

This call was reiterated in resolution WHA 65.60 [2012].

^{7.} Paragraph 44. The Global Strategy is formulated by WHO and UNICEF for countries to develop approaches to improve the nutritional status of infants and young children through optimal feeding. It was endorsed by resolution WHA 55.25 [2002].

^{8.} Shubber, S. (2011), "The WHO International Code of Marketing of Breastmilk Substitutes -History and Analysis" (pp. 215-221) London: Pinter & Martin.

^{9.} Latin phrase meaning "of the same kind or class". It is a canon of construction that when a general word or phrase follows a list of specifics, the general word or phrase will be interpreted to include only items of the same type as those listed.

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;

Annotations

The promotion of breastmilk substitutes competes directly with breastfeeding. It undermines women's confidence in breastfeeding and counteracts promotional activities for breastfeeding undertaken by national governments and public health agencies.

The conclusions of the Lancet Breastfeeding Series on the benefits of breastfeeding (see p.4) further confirm and elaborate upon the fact that exclusive breastfeeding with adequate and timely complementary feeding and continued breastfeeding for up to two years or beyond could save hundreds of thousands of lives. The Series also reaffirms the importance of "comprehensive national laws and regulations to curb inappropriate marketing practices with adequate monitoring and meaningful penalties to protect breastfeeding."

Thus, there is strong and compelling evidence to implement the International Code at the national level to ensure a level playing field for the promotion of breastfeeding.

THEREFORE:

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

Inappropriate marketing of food products is recognised as an important factor that negatively affects the choice of a mother to breastfeed her infant optimally. The ensuing 11 articles of the Code seek to create an overall environment that enables mothers to make the best possible feeding choice based on impartial information, free of commercial influences, and to be fully supported in doing so.¹⁰

"Those who suggest that direct advertising has no negative effect on breastfeeding should be asked to demonstrate that such advertising fails to influence a mother's decision about how to feed her infant."

Document WHA 47/1994/Rec/ Annex 1 on Health Implications of Direct Advertising of Infant Formula, paras 133-139.

^{10.} The International Code of Marketing of Breast-milk Substitutes: Frequently Asked Questions (2017 Update), Geneva, Switzerland, World Health Organization; at p. 5.

How the Code was adopted in 1981

In January 1981, the Executive Board (EB) of WHO held long discussions over the form of the Code. Should it be a regulation, binding on all Member States, or **a non-binding recommendation?** Most EB members wanted it to be a regulation but it was decided to send both versions to the World Health Assembly (May 1981).

The EB representative warned 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". Member States opted for a recommendation to get a better chance of fulfilling the purpose of the Code to contribute to improved infant and child health. However, even as a recommendation, consensus was not achieved. A vote became necessary and eventually the Code was overwhelmingly adopted by resolution WHA 34.22 [1981] with 118 Member States voting in favour, one against and three abstentions.

The resolution stresses that adoption and adherence to the Code is a **minimum requirement** and urges governments to translate the entire Code into national legislation or other suitable measures.

Every even year there is a Director–General's report on existing legislation and an evaluation of the effect of measures taken. The 18 subsequent relevant resolutions (including one 'decision') adopted since 1981 are intended to clarify the Code, and they must be read together for implementation into national measures. Summaries of the Code and resolutions appear in Annexes 1 and 2 respectively.

Full text of Code provisions

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.

Annotations

The protection of breastfeeding is the principal element of the Code's aim. Breastmilk substitutes become an alternative only when necessary, and even then marketing should be appropriate. The Code neither compels women to breastfeed nor prevents the sale of breastmilk substitutes. Instead, it aims to ensure that unbiased information about infant feeding is available so that parents can make decisions free of commercial influence.

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 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. It also applies to their quality and availability, and to information concerning their use.

This article determines whether or not a particular product is subject to the Code.

Manufacturers and distributors frequently advance the argument that the Code covers only infant formula. Article 2 does not support this narrow interpretation, as it specifically states that the Code applies to all kinds of products when marketed or otherwise represented to be suitable for use as partial or total replacement of breastmilk. See also definition of "breastmilk substitute" in Article 3.

Interpreting Article 2 on the scope of the Code

Until 2016, Article 2 was left open to interpretation. Companies expanded the range of products for feeding infants and young children in an attempt to exempt them from falling under the scope of the Code. Products like follow-up formula and growing-up milks which did not exist in the market when the Code was adopted became widely available and were promoted aggressively. The baby food industry advanced the argument that the term "breastmilk substitute" covers only infant formula. This narrow interpretation would allow companies to promote other products they market for infants and young children, even though these products are represented as breastmilk subtitutes. UNICEF, IBFAN and many other NGOs, on the other hand, advocated for a broad interpretation of the scope of the Code relying on the provisions of Article 2 and relevant World Health Assembly resolutions.

In May 2016, the WHO published a report¹¹ recommending that countries should broaden the range of designated products under the scope of their legislation to include all milk products intended and marketed as suitable for feeding children up to the age of 36 months. In the same month, the World Health Assembly issued the Guidance on ending the inappropriate promotion of foods for infants and young children.¹² The Guidance (welcomed by resolution WHA 69.9 [2016]) confirms that breastmilk substitutes should be understood to include any milks that are specifically marketed for the feeding of infants and young children up to the age of 3 years, including follow-up formula and growing-up milks. Resolution WHA 69.9 [2016] welcomes the Guidance as a means to further strengthen the Code and to protect optimal infant and young child feeding practices.

With these affirmative statements and recommendations, it becomes clear that both follow-up formula and growing-up milks are covered by the scope of the Code.

The scope of the Code can thus be explained as covering the following products:

- a. **Infant formula.** This includes milk or milk-like formulations that can be fed to infants from birth. It must be manufactured in accordance with relevant international or national standards. The upper age indication on the product label varies between countries but is usually between 6 and 12 months. The figure "1" is normally added onto the product name and label. There are various types of infant formula, including "special" formulas such as soy, lactose-free or low-birth-weight/ premature formulas and therapeutic milks.
- b. **Follow-up formula** (also referred to as 'follow-on milk'). This includes milk or milk-like formulations commonly marketed for babies from 6 months of age. It must be manufactured in accordance with relevant international or national standards. The upper age indication on the product label varies between countries and companies but is usually between 12 and 24 months. The figure "2" is normally added onto the product name and label.
- c. **Growing-up milk** (also called young child formula, toddler milk or formulated milk). This product is targeted at infants and young children from 1-year (sometimes younger) to 3-years of age. Usually, the product name is similar to a company's formula products with the figure "3" added onto the label. In some countries, the figure "1" is used which can confuse consumers, but companies do this to facilitate cross promotion of products with similar brand names and packaging designs. Since growing-up milks are marketed as suitable for feeding young children up to the age of 36 months, they fall under the Code definition of "breastmilk substitute". This is confirmed in the Guidance and is in line with the recommendation that breastfeeding should continue for up to 2 years or beyond.
- d. **Any other milk for children 0 to < 36 months**. The Guidance clarifies that any other milk (or products that could be used to replace milk, such as fortified soy milk), in either liquid or powdered form, are specifically marketed for feeding infants and young children 0 to < 36 months should be considered as breastmilk substitutes, and will be covered by the Code.¹³

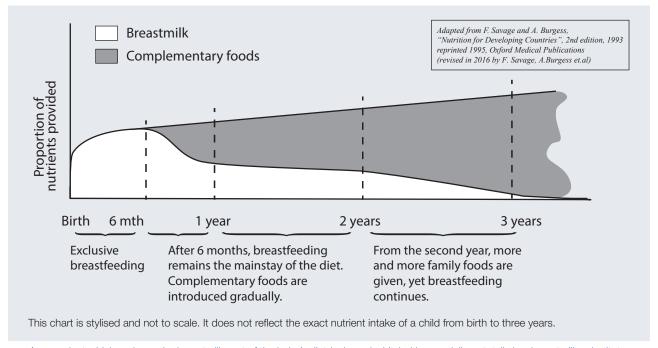
^{11.} WHO. UNICEF. IBFAN (2016). Marketing of Breastmilk Substitutes: National Implementation of the International Code: Status Report 2016. Geneva: World Health Organization.

^{12.} WHO (2016). A69/7 Add.1. Retrieved from: http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_7Add1-en.pdf

^{13.} Recommendation 2

- e. **Any other food or beverages targeted for infants under 6 months of age,** such as cereals, jarred foods, infant teas, juices and mineral water. Since resolution WHA 54.2 [2001] recommends exclusive breastfeeding for six months, followed by safe and appropriate complementary foods with continued breastfeeding for up to 2 years or beyond, any product represented as suitable for infants under 6 months necessarily replaces breastmilk.
- f. **Feeding bottles and teats** are also covered by the Code. This includes feeding bottles attached to breast pumps and other types of vessels comprising a container and a teat for infant feeding.
- g. **Complementary foods.** Complementary foods and beverages marketed for use after the age of 6 months generally fall outside the scope of the Code. However, if complementary foods are promoted or represented as suitable for infants less than 6 months, or in a manner that suggests they can be fed by bottle, then these products fall under the scope of the Code. WHA 69.9 [2016] calls on Member States to implement the Guidance which covers foods that are marketed as being suitable for infants and young children from the age of 6 months to 36 months. ¹⁴ The Guidance stipulates that complementary foods should not be promoted in any way that would cross-promote breastmilk substitutes, should not recommend or promote bottle feeding, should state the importance of continued breastfeeding for up to 2 years and beyond, and should not discourage breastfeeding. ¹⁵

The chart below serves as a helpful illustration on how any product, marketed or otherwise represented as suitable to replace the breastmilk part of the baby's diet, is a breastmilk substitute, and therefore falls under the scope of the Code.



Any product which replaces the breastmilk part of the baby's diet (coloured white) either partially or totally is a breastmilk substitute.

Countries with existing laws which do not extend to all the products verified by the Guidance as being covered by the Code should consider amending their laws to include them. They may also consider including the essential components of the Guidance into their laws. Those countries which have yet to implement a law should certainly integrate all elements of the Code and Guidance as a multi-faceted response to address the unethical promotion of breastmilk substitutes and other foods for infants and young children.

^{14.} Retrieved from http://apps.who.int/gb/ebwha/pdf files/WHA69/A69 R9-en.pdf

The Netcode monitoring and assessment toolkit: Protocol for ongoing monitoring systems. Geneva: World Health Organization; 2017. p.6. Retrieved from http://apps.who.int/iris/bitstream/10665/259441/1/9789241513180-eng.pdf?ua=1

The following resolutions are useful in clarifying the scope of the Code:

Resolution WHA 39.28 [1986]

The Director General of WHO is requested to direct the attention of Member States to the following:

- 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.

Editor's Note: At the time of adoption of the Code there were hardly any "follow-up" milks. All formulated milks were called infant formula, baby milks or other terms, like *laits industriels* ('manufactured milks') in French. Hence, the 1981 Code did not refer to follow-up milks, growing-up milks or others.

Resolution WHA 49.15 [1996]

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

Resolution WHA 54.2 [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...and to provide safe and appropriate complementary foods, with continued breastfeeding for up to two years of age or beyond, emphasising channels of social dissemination of these concepts in order to lead communities to adhere to these practices."

Resolution WHA 58.32 [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**.'

Resolution WHA 69.9 [2016]

This Resolution welcomes the Guidance on ending the inappropriate promotion of foods for infants and young children (A 69/7 Add.1). It reaffirms that breastmilk substitutes should be understood to include any milks that are specifically marketed for the feeding of infants and young children up to the age of 3 years including follow-up formula and growing-up milk.

It urges Member States "to take all necessary measures in the interest of **public health to end the inappropriate promotion of foods for infants and young children**, including, in particular, implementation of the guidance recommendations while taking into account existing legislation and policies, as well as international obligations."

• It calls upon "manufacturers and distributors of foods for infants and young children to end all forms of inappropriate promotion, as set forth in the guidance recommendations."

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 organisations 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, 16 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.

Editor's Note: There is no definition for follow-up formula or growing-up milk because these products hardly existed at the time of Code drafting. Terms not defined, such as advertising and promotion, are to be given their ordinary dictionary meaning. Countries are free to modify or add to those definitions according to their specific national needs.

The Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended For Infants (Codex Stan 72 – 1981, revised 2007) defines infant formula to mean a breastmilk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding. The Standard also states the application of the relevant section of the Standard should take into account the recommendations made in the International Code of Marketing of Breastmilk Substitutes (1981), the Global Strategy for Infant and Young Child Feeding and World Health Assembly resolution WHA54,2 (2001). In this context, the words "to between four to six months" should be modified to read "six months". See also annotations to Resolutions WHA 54.2 and 58.32 p.16.

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 the planning, provision, design and dissemination of information, or their control.

Article 4.1 implements the recommendation of the 1979 WHO/UNICEF meeting on Infant and Young Child Feeding that "every citizen has the right to correct, consistent information and education."

This right was reinforced in 1990 by the **Convention on the Rights of the Child** which 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..."

The government's responsibility is **to ensure** the provision of objective and consistent information on infant and young child feeding. This means that the information can be produced by the government itself, or by someone else, be it a company or an NGO, but the government must make sure that it is objective and consistent.

If a pamphlet designed to promote breastfeeding also promotes the use of breastmilk substitutes, such a pamphlet is not consistent. Information produced or sponsored by a manufacturer of breastmilk substitutes necessarily constitutes a **conflict of interest** because breastmilk and breastmilk substitutes are in direct competition. See also annotations under Article 4.3.

- **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.

Article 4.2 provides a list of elements that must be included in all information and educational materials. Countries can add additional requirements, such as in India, for example, who stipulate that information must be provided stating that breastfeeding helps space children and bottle feeding carries the risk of microbial contamination.

Ghana, Uganda and Zimbabwe require that information materials on formula feeding must explain cup-feeding.

Countries which implemented the Code or revised their national measures after 2002, such as Cambodia, Philippines and Vietnam, require information about exclusive and sustained breastfeeding as well as the proper introduction of complementary foods.

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 idealise the use of breastmilk substitutes.

The Code also protects children who are not breastfed. When information and educational materials refer to the use of infant formula, there is a need to warn parents and care givers about the financial, social or health hazards and implications which may arise from the use of infant formula and other breastmilk substitutes.

Any picture or text which may idealise the use of breastmilk substitutes are prohibited, and it is up to the competent authority at national level to decide what is **idealising**.

Resolution WHA 58.32 [2005]

Member States are urged 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 minimise health hazards;
- 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.

In 2002, it came into the public eye that powdered infant formula can be contaminated during the manufacturing process with dangerous pathogens such as *Enterobacter sakazakii* and *Salmonella enterica*. This intrinsic contamination can be deadly for newborns and very young babies.

Following several deaths and more evidence, resolution WHA 58.32 [2005] was adopted asking for warnings to health workers and caregivers, and where applicable, on labels. It has direct impact on Article 4.2.

Resolution WHA 61.20 [2008]

Member States are urged to implement, through application and wide dissemination, the WHO/FAO Guidelines on safe preparation, storage and handling of powdered infant formula in order to minimize the risk of bacterial infection and, in particular, ensure that the labelling of powdered formula conforms with the standards, guidelines and recommendations of the Codex Alimentarius Commission and taking into account resolution WHA 58.32.

The Food Safety Department in WHO working with FAO has issued **guidelines on safe preparation of powdered infant formula**, and Member States are urged by resolution WHA 61.20 [2008] to implement these guidelines and to ensure labelling conforms with Codex standards. These guidelines can be downloaded from http://www.who.int/foodsafety/publications/micro/pif2007/en/.

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.

This is one of the weaker areas of the Code. It covers the donation of materials such as booklets, books, posters and slides, and equipment such as DVD players and televisions which health authorities may need for purposes of information and education.

Companies often use these materials to indirectly promote their products or to cast doubts on the mother's ability to breastfeed. Equipment such as fridges, televisions and air conditioners are sometimes used as **enticements and rewards** for health workers and health facilities to promote breastmilk substitutes.

Resolution WHA 58.32 [2005]

Member states are urged 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.

The discretion governments have to request and approve donations of any infant and young child feeding (IYCF) materials from companies must be read in the light of resolution WHA 58.32 [2005], which requires governments and health professionals to avoid **conflicts of interest** in IYCF programmes.

Conflicts of interest are best avoided by neither requesting nor approving donations of IYCF materials that are sponsored by companies. This is to prevent an individual or an organisation (whether private or public) from being put in a position to exploit a professional or official capacity in some way for their personal or organisational benefit.

Guidance A 69/7 Add.1 [2016]

Companies that market foods for infants and young children should not create conflicts of interest in health facilities or throughout health systems. Among other things, companies should not

- donate or distribute equipment or services to health facilities.
- directly or indirectly provide education to parents and other caregivers on infant and young child feeding in health facilities.

(Recommendation 6)

Under the **Guidance on ending the inappropriate promotion of foods for infants and young children**, companies are called upon to stop creating situations of conflicts of interest in health facilities.

The donation of equipment and services and providing education to parents and caregivers are **prohibited without any qualifications** unlike in Code Article 4.3.

The Guidance can be relied upon to enhance national law provisions when implementing the International Code at country level.

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.

Resolution WHA 54.2 [2001]

Member States are urged 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.

Guidance A69/7 Add.1 [2016]

Definitions

- **8. Promotion** is broadly interpreted to include the communication of messages that are designed to persuade or encourage the purchase or consumption of a product or raise awareness of a brand. Promotional messages may be communicated through traditional mass communication channels. the Internet and other marketing media using a variety of promotional methods. In addition to promotional techniques aimed directly at consumers, measures to promote products to health workers or to consumers through other intermediaries are included. There does not have to be a reference to a brand name of a product for the activity to be considered as advertising or promotion.
- 9. Cross-promotion (also called brand crossover promotion or brand stretching) is a form of marketing promotion where customers of one product or service are targeted with promotion of a related product. This can include packaging, branding and labelling of a product to closely resemble that of another (brand extension). In this context, it can also refer to use of particular promotional activities for one product and/or promotion of that product in particular settings to promote another product.

• Recommendation 5.

There should be no cross-promotion to promote breastmilk substitutes indirectly via the promotion of foods for infants and young children.

Advertising and promotion of breastmilk substitutes have a harmful effect on breastfeeding and are prohibited without any qualification or exception.

Resolution WHA 54.2 [2001] addresses current concerns about modern communication methods and new marketing trends of using **nutrition and health claims** to promote breastmilk substitutes. In view of the increasing use of the internet, mobile phones and other means to promote products within the scope of the Code, Member States are urged to strengthen national mechanisms to ensure compliance with the Code and resolutions with regard to commercial promotion in all types of media.

The terms **advertising** and **promotion** are not defined in the Code, but the Guidance on ending the inappropriate promotion of foods for infants and young children is instructive. The Guidance defines "promotion" broadly and goes on to explain that promotional messages may be communicated through various communication channels using a variety of promotional methods. Most importantly, it was stressed that **there does not have to be a reference to a brand name of a product for an activity to be considered as advertising or promotion**.

The Guidance also introduces the concept of cross-promotion (also called brand crossover promotion or brand stretching), which includes packaging, branding and labelling of a product to closely resemble that of another (brand extension) and specifically prohibits it under Recommendation 5. This means that the packaging design, labelling and materials used for the promotion of complementary foods must be different to those used for breastmilk substitutes so that they cannot be used to indirectly promote breastmilk substitutes. For example, different colour schemes, designs, names, slogans and mascots other than company name and logo should be used.

The Guidance can be relied upon to enhance national law provisions when implementing the International Code at country level.

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.

Samples are single or small quantities of a product provided free of charge. Samples, therefore, are promotional by nature. The practice of distributing samples to pregnant women and mothers has a negative effect on breastfeeding as they will be tempted to try the free samples. Some mothers will not initiate breastfeeding, or if they have decided to breastfeed, they may mix-feed their babies, which inevitably leads to early cessation of breastfeeding.

- **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.

The list of promotional devices in Article 5.3 is not exhaustive. All promotion in shops intended to increase sales to the consumer is covered.

While special offers are forbidden, shops may reduce prices for the long term.

There are two weaknesses in this article. Firstly, the prohibition is limited to pregnant women and mothers. Family members who have influence over them are not similarly protected. Secondly, the phrase which may promote the use of breastmilk substitutes or bottle feeding gives leeway to excuses; manufacturers and distributors may offer gifts like music CDs or birthday presents. The rationale used is that such gifts do not directly promote breastmilk substitutes or bottle feeding but companies know the subliminal effect such practices have in procuring the goodwill and loyalty of pregnant women and mothers.

Many countries curtail such arguments by simply prohibiting any gift in their national legislation.

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.

Seeking contact implies an effort made on the part of marketing personnel towards pregnant women and mothers. It has been argued that if a mother herself initiates the contact, Article 5.5 would not apply. This interpretation downplays the words **indirect contact.** If manufacturers and distributors facilitate contact via mother and baby clubs etc., which mothers have to sign up for, this is deemed "indirect contact."

Guidance A69/7 Add.1 [2016]

Companies that market breastmilk substitutes should refrain from engaging in the direct or indirect promotion of their other food products for infants and young children by establishing relationships with parents and other caregivers. (Recommendation 5) Baby clubs, social media groups, childcare classes and contests are specifically mentioned in the Guidance on ending the inappropriate promotion of foods for infants and young children as methods of direct or indirect promotion that companies should refrain from engaging in.

"The trajectories of retail sales indicate that marketing strategies are effective, which emphasises the importance of comprehensive national laws and regulations to curb inappropriate marketing practices with adequate monitoring and meaningful penalties to protect breastfeeding"

Rollins, N.et al (2016). "Why invest, and what it will take to improve breastfeeding practices?" Lancet; 387:491–504, p.497

Article 6: Health Care System

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.

Lack of support from health workers for women who are considering, or who are breastfeeding, has been identified as a major obstacle to successful breastfeeding. The dearth of objective and consistent information opens up opportunities for company propaganda. This could be prevented if the health care system carries out its responsibility of providing health workers with appropriate information to encourage and facilitate breastfeeding. Lactation management courses or training in breastfeeding counseling provide a better understanding of health workers' responsibilities under the Code. The value of this Article is that it gives the responsibility of education, promotion and protection of breastfeeding to the health care system.

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.

Article 6.2 is designed to prevent overt or tacit medical endorsement of products and to remove any possible commercial influence from health care facilities. No part of the health care system (see definition in Article 3) can be used by anyone to promote breastmilk substitutes, feeding bottles or teats. This would include practices such as publicity, giving of samples, posters, brochures or gifts.

Article 6.2 applies the same ban as Article 5.1 at the level of health care facilities, but it allows scientific and factual information about products for health professionals. (See Article 7.2).

WHO and UNICEF launched the **Baby Friendly Hospital Initiative (BFHI)** in 1991 to encourage all hospitals to become centres of breastfeeding support. BFHI materials were revised in 2009 to include Code compliance as an additional criterion for BFHI accreditation.

For the creation of an enabling environment for breastfeeding in facilities which provide maternity and newborn services, a **2017 WHO Guideline** underscores the need for policies and guidelines to include provisions of the Code and resolutions. ¹⁷ This means there should be no promotion of breastmilk substitutes, feeding bottles, teats, pacifiers or dummies in any part, or by any staff of a facility providing maternity and newborn services. Health facilities, and their staff, should not give feeding bottles and teats or other products within the scope of the Code.

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.

Article 6.3 adds other specific types of promotional activities which are not allowed in any part of the health care system. The purpose of Article 6.3 is to remove any **association** which a mother may perceive **between the health care system and manufacturers and distributors**. It does not interfere with the donation of educational or information materials regulated by Article 4.3, or those allowed under Article 6.8.

^{17.} Guideline: protecting, promoting and supporting breastfeeding in facilities providing maternity and newborn services. Geneva: World Health Organization; 2017. Retrieved from: http://apps.who.int/iris/bitstream/10665/259386/1/9789241550086-eng.pdf?ua=1. At the time of writing, an implementation guide that will encompass the recommendations included in this guideline, including the Code, is expected to be published separately.

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.

WHA resolution 58.32 [2005]

Member States are urged to ensure that clinicians and other health care personnel are provided with enough information and training on the preparation, use and handling of powdered infant formula in order to minimise health hazards and are informed that powdered infant formula may contain pathogenic microorganisms and must be prepared and used appropriately...

Resolution WHA 61.20 [2008]

Member States are urged to implement, through application and wide dissemination, the WHO/FAO guidelines on safe preparation, storage and handling of powdered infant formula in order to minimise the risk of bacterial infection and, in particular, ensure that the labelling of powdered formula conforms with the standards, guidelines and recommendations of the Codex Alimentarius Commission and taking into account resolution WHA58.32 [2005].

6.6 Donations or low-price sales to *institutions* or organisations 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 organisations concerned. Such donations or low price sales should not be used by manufacturers or distributors as a sales inducement.

The rationale for this ban is to stop infiltration of health facilities by company staff. The employment of 'milk nurses' in the past gave companies easy access to mothers.

This restriction prevents contacts between manufacturers and distributors and mothers. Bottle feeding demonstrations should only be given in private sessions to mothers or family members in cases where breastfeeding is not an option.¹⁸ Information provided should include an explanation about the **health hazards** of improper use of breastmilk substitutes.

In the light of resolutions WHA 58.32 [2005] and 61.20 [2008], information regarding risks of **intrinsic contamination of powdered infant formula** should also be provided following the WHO/FAO guidelines on safe preparation, storage and handling of powdered infant formula, and in particular to ensure that the labelling of powdered formula conforms with Codex Standards.

(Refer also to annotations under Article 4.2)

At the time of drafting the Code there was a perceived need for free or low-cost supplies, but in 1985 the Director-General of WHO clarified that the "institutions and organisations" mentioned in Article 6.6 were intended to mean orphanages and social welfare organisations, not hospitals and maternities.

Article 6.6 has been superseded by subsequent resolutions. For further explanation, see p.27.

For a list of acceptable medical reasons for use of breastmilk substitutes, refer to this link -http://apps.who.int/iris/bitstream/10665/69938/1/WHO_FCH_ CAH_09.01_eng.pdf

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 organisation should take steps to ensure that supplies can be continued as long as the infants concerned need them. Donors, as well as institutions or organisations 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.

This provision acts as a warning to donors and recipients of the long-term implications of donated supplies made outside the health care system. Infants may need breastmilk substitutes for **as long as 12 months**. This is to prevent short term or one-off supplies being used as a promotional tactic and to avoid potential problems with accessibility, availability, affordability and sustainability.

This is another area where the Code is weak in curbing promotion. The argument has been advanced that this provision allows health care systems in poor countries to receive expensive medical equipment and materials donated by manufacturers or distributors, which they would otherwise not be able to afford. The name and logo of donor companies may appear on the equipment and materials but there should be no reference to brand names. This is not a sufficient safeguard against promotion, since the **name and logo** of some baby food companies are the same or indistinguishable from the name and logo of their products.

This provision also ignores the fact that conflicts of interest may arise when health care facilities receive expensive equipment and materials from companies. There is the danger of 'endorsement by association' and 'manipulation by assistance', as such donations call for some form of reciprocity which would adversely affect the promotion of breastfeeding.

Monitoring has revealed that donations of expensive equipment and materials are not offered to health care facilities in countries which need them most.

Guidance A69/7 Add.1 [2016]

Companies that market foods for infants and young children should not create conflicts of interest in health facilities or throughout health systems. Such companies, or their representatives, should not donate or distribute equipment or services to health facilities.

The donation or distribution of equipment or services to health facilities can lead to conflicts of interest and is prohibited without any qualifications unlike in Code Article 6.8.

The Guidance allows more clarity for drafters of national laws when implementing the International Code at country level.

The official stand on 'supplies' (Articles 6.6)

The number of infants who have to be fed on breastmilk substitutes is very small. The phrase **"infants who have to be fed on breastmilk substitutes"** in Article 6.6 refers to situations where there is no alternative but to use breastmilk substitutes to feed infants for survival, and not when mothers choose not to breastfeed. Such situations include the case of the mother having died or being critically ill, the abandonment of the child, the separation of mother and child due to natural or man-made disasters, inborn errors of metabolism and a select few maternal illnesses.¹⁹

Monitoring over many years showed that Article 6.6 was widely abused. Hospitals were flooded with free formula, causing a huge number of infants to be unnecessarily bottle-fed from birth. Due to its easy availability, nurses used formula instead of teaching mothers to breastfeed. About seven WHA resolutions addressed this problem, eventually **banning donation of supplies** to any part of the health care system.

The following WHA resolutions further clarify the issue of supplies:

Resolution WHA 39.28 [1986]

Member States are urged 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 subsidised supplies.'

Resolution WHA 43.3 [1990]

Recognising that in spite of resolution WHA 39.28, free and low cost supplies of infant formula continue to be available to hospitals and maternities with adverse consequences for breastfeeding; Member States are urged to ensure that the principles and aims of the International Code of Marketing of Breastmilk Substitutes are implemented and give full expression to the recommendations contained in resolution WHA 39.28.

Resolution WHA 45.34 [1992]

Member States are urged to take measures appropriate to national circumstances to end the donation or low-priced sale of supplies of breastmilk substitutes to health care facilities providing maternity services.

Resolution WHA 47.5 [1994]

Member States are called upon to "ensure that there are no donations of free or subsidised supplies in any part of the health care system".

The 1994 resolution effectively removed any remaining doubts about the need to stop the donation of free and low-cost supplies in health care facilities.

The UNICEF Protocol for Monitoring Cessation of Distribution of Free and Low Cost Supplies of Breastmilk Substitutes to Health Care Facilities (1993) prescribed the working definition of "low cost" to mean "sales at prices lower than **80 per cent of the retail price,** in the absence of a standard wholesale price."

^{19.} See Report of the Joint WHO/UNICEF Consultation Concerning "Infants who have to be fed on breastmilk substitutes", Geneva, 17-18 December 1985; WHO/MCH/NUT/86.1. Retrieved from: http://apps.who.int/iris/handle/10665/61126;

Supplies in emergency situations

Resolution WHA 47.5 [1994]

Member States to exercise extreme caution when planning, implementing or supporting emergency relief operations, 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 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,
- the supply is continued for as long as the infants concerned need it; and
- the supply is not used as a sales inducement.

Resolution WHA 63.23 [2010]

Member States are urged to ensure that national and international preparedness plans and emergency responses follow the evidence-based **Operational Guidance for Emergency Relief Staff and Programme Managers on Infant and Young Child Feeding in Emergencies**, which includes the protection, promotion and support for optimal breastfeeding, and the need to minimise the risks of artificial feeding, by ensuring that any required breastmilk substitutes are purchased, distributed and used according to strict criteria.

One of the key points of the **Operational Guidance for Emergency Relief Staff and Programme Managers Version 3.0 – October 2017 (OG-IFE)**²⁰ is that donations of breastmilk substitutes, complementary foods and feeding equipment should not be sought or accepted in emergencies; supplies should be purchased based on assessed need.

Section 6 of the OG-IFE discusses the subject of procurement and distribution of relevant products in ways which are Code compliant. It also stresses that there should be no promotion of infant formula at the point of distribution, including displays of products or items with company logos.

The criteria set out in resolution WHA 47.5 [1994] regarding donated supplies in emergency relief operations must be read in the light of the OG-IFE.

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.

WHA resolution 47.5 [1994]

Member States are urged to 'ensure that all health personnel concerned are trained in appropriate infant and young child feeding practices, including the application of the principles laid down in the joint WHO/UNICEF statement on breastfeeding and the role of maternity services.'

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.

Health workers are defined to include health professionals. Article 7.1 of the Code makes the health worker responsible for the encouragement and protection of breastfeeding. This responsibility prevents health workers from working together with manufacturers and distributors in any manner which will give rise to conflicts of interest, where the private interests of health workers conflict with their official responsibilities.

In some countries, the encouragement and protection of breastfeeding is formulated as an obligation imposed on the health worker, making compliance mandatory.

Manufacturers and distributors routinely cross the line between providing objective product information and blatant advertising. Information provided usually contains text and images which idealise the use of products. Charts and tables often show data from company research which is not supported by independent, peer reviewed research and studies. Thus, the need for health professionals to have product information must be offset against the harm that results from product promotion.

Article 7.2 sets down conditions which manufacturers and distributors must comply with when they disseminate information to health professionals. Information provided must be:

- restricted to "scientific and factual matters";
- disseminated to "health professionals" only;
- free from commercial bias and should not imply that bottle feeding is equivalent or superior to breastfeeding; and
- include the points specified in Article 4.2.

The term "health professionals" means those health workers belonging to a profession such as doctors, specialists, nurses and midwives. Health workers who are not so connected, such as auxiliary workers or traditional birth attendants, do not qualify to receive such information.

Still valid after all these years....

"The medical and nursing profession can sometimes be very naïve in their interactions with commercial companies, so that mixtures of "manipulation by assistance" (free sample; assistance with research funds; hospitality at meetings) ... are very frequently and successfully used as promotional methods, usually unperceived, minimised, or tolerated as such by the physicians, nurses, and nutritionists concerned"

Jellife, D.B, & Jellife, P. (1978, June 7) Human Milk in the Modern World.
Oxford, United Kingdom:
Oxford University Press ELBS.

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.

Benefits to health workers by manufacturers and distributors are often used to achieve goodwill and product endorsement. Even gifts of little monetary value can influence behaviour and health workers' advice about infant feeding. Health workers who receive gifts from manufacturers and distributors may feel obligated to recommend the donor company's product, either out of an obligation to reciprocate or simply due to familiarity with company name, brands and sales personnel. The phrase "inducement to promote **products**" makes the provision difficult to monitor, as it is not easy to prove **intent**. When implementing the Code and resolutions at the national level, it would be better to prohibit any gift outright.

See annotation under Article 7.5 regarding resolutions WHA 49.15 [1996], 58.32 [2005] and 69.7 [2016].

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.

The Code allows samples in only two situations:

- for the purpose of **professional** evaluation, or
- research at the institutional level.

Research at the institutional level may only be performed according to an approved research protocol. Professional evaluation is a little harder to control but it should be noted that Article 7.4 also has a safeguard against abuse: health workers who receive samples for professional evaluation or research cannot pass them on to pregnant women, mothers or 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.

WHA resolution 49.15 [1996]

Member States are urged 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.

WHA resolution 58.32 [2005]

Member States are urged 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. Article 7.5 allows for sponsorship and assistance for professional purposes and is another area where the Code is weak. The only requirement is the need for disclosure, both by the donor and recipient. There is no requirement for the institution concerned to agree to the sponsorship. **Disclosure** may bring sponsorship out into the open so that the institution concerned becomes aware of the contribution. It is assumed that the chances of bringing pressure to bear, by the donor on the recipient would be reduced by such disclosure. However, it does not eliminate the influence of industry **funding** on research or the behaviour of health professionals.

Concerns and questions about this type of contribution led the WHA to adopt resolution WHA 49.15 in 1996 and WHA 58.32 in 2005 to warn against conflicts of interest. The 1996 resolution calls for caution in accepting financial support for health professionals as it may create conflicts of interest. The need to avoid conflicts of interest is repeated in 2005, and expanded to cover **programmes**. The word "programme" is not explained, but using its ordinary dictionary meaning would cover a planned series of events or ongoing services. In the context of infant and young child nutrition, these can include support for research, community out-reach activities and multiple, ongoing and inter-dependent projects implemented within schools and colleges, medical or health education.

With these resolutions, the WHA expresses its concern about the risk of receiving financial contributions for the health worker. Such a risk is serious and should be addressed by Member States.

Guidance A69/7 Add.1 [2016]

Companies that market foods for infants and young children should not create conflicts of interest in health facilities or throughout health systems. Health workers, health systems, health professional associations and nongovernmental organisations should likewise avoid such conflicts of interest. (Recommendation 6)

Recommendation 6 of the Guidance on ending inappropriate promotion of foods for infants and young children repeats warnings against conflicts of interest. Health workers and health professional associations should not allow companies to sponsor meetings of health professionals and scientific meetings.

The Guidance can be used to enhance national law provisions when implementing the International Code at country level.

"Sponsorship by its nature creates a conflict of interests. Whether it takes the form of gift items, meals, or help with conference expenses, it creates a sense of obligation and a need to reciprocate in some way. The 'gift relationship' thus influences our attitude to the company and its products and leads to an unconscious unwillingness to think or speak ill of them. Even if individuals are uninfluenced by sponsorship and subsequently act wholly responsibly in relation to breast and formula feeding, by accepting sponsorship or speaking at an infant formula milk company meeting they still lend credibility to the company by the visible association of their name and position with that company."

Wright, C.M, & Waterston, A. J. R. (2006) Relationships between paediatricians and infant formula milk companies. Archives of Disease in Childhood; 91:383-385. Retrieved from: https://pdfs.semanticscholar.org/b0f0/61289b72dd3fee14213bffa5ee33c1a1ec4a.pdf

"Industries selling breastmilk substitutes and related products often sponsor health professional associations.... which might introduce conflicts of interest in their support of breastfeeding."

Rollins, N.et al (2016). "Why invest, and what it will take to improve breastfeeding practices?" Lancet; 387:491–504

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.

This provision is intended to regulate the aggressive marketing of products within the scope of the Code by company personnel. Any system that links volumes of sales and quotas to the calculation of bonuses is a strong inducement for marketing personnel to increase sales. Breastmilk substitutes, feeding bottles etc. are special products which should not be sold by inducement but bought when a decision to artificially feed a baby has been made after obtaining independent medical advice, free of commercial influence.

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.

This provision prevents the risk of conflict of interest which can arise when marketing staff are asked to give educational talks in the health care system. The ban applies to any function intended for the instruction of pregnant women or mothers in any field, be it breastfeeding, use of breastmilk substitutes, public health, hygiene and so on.

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.

Labels are important as they may be the only source of information about the product for the person who is caring for the baby. Article 9 is devoted to particular requirements for the labels of products under the scope that may not appear in general food labelling laws.

WHA resolution 55.25 [2002]

The Codex Alimentarius Commission is requested to promote the safe and proper use of processed foods for infants and young children at an appropriate age, including through adequate labelling, consistent with the policy of WHO, in particular the International Code of Marketing of Breastmilk Substitutes, WHA resolution 54.2, and other relevant resolutions of the Health Assembly.

The Codex Alimentarius Commission, which is the international food standards setting body, is urged to incorporate the provisions of the Code and resolutions when addressing issues related to the safe and proper use of processed foods for infants and young children. This includes appropriate labelling.

Guidance A69/7 Add.1 [2016]

- Labels of foods for infants and young children should include the appropriate age of introduction of the food (this must not be less than 6 months), state the importance of continued breastfeeding and not promote bottle feeding. (Recommendation 4)
- There should be no cross-promotion to promote breastmilk substitutes indirectly via the promotion of foods for infants and young children. (Recommendation 5)
- The labelling of complementary foods should not include any image, text or other representation that might suggest use for infants under the age of 6 months (including references to milestones and stages). The labelling must be different from those used for breastmilk substitutes so that they cannot be used in a way that also promotes breastmilk substitutes (for example, different colour schemes, designs, names, slogans and mascots.)

Use this Guidance when drafting national laws.

- **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;
- 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.

Unlike Article 9.1 which applies to all products within the scope of the Code, Article 9.2 applies **only to infant formula**.

Governments should decide which is the appropriate language for their country. It may be more than one. For example, Switzerland requires labels to be in German, French and Italian and Sri Lanka requires labels to be in Sinhala, Tamil and English.

Parts (a) to (d) of Article 9.2 set forth particular information that must appear on every label of infant formula in a clear and conspicuous manner.

Countries can impose more specific warnings and notices on labels.

Neither the container nor the label should have pictures of infants, nor should they have other pictures or text which may idealise 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 "humanised", "maternalised" 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."

The phrase "should not contain pictures or text which may idealise the use of infant formula" is intended to prevent consumers from being misled into believing that bottle feeding may be equivalent or superior to breastmilk.

Botswana requires that labels contain illustrations for cup feeding, while in Tanzania, labels shall not depict a feeding bottle.

WHA resolution 58.32 [2005]

Member States are urged to ensure that nutrition and health claims are not permitted for breastmilk substitutes, except where specifically provided for in national legislation, and also to impart 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.

Resolution WHA 58.32 [2005] addresses the concern that **nutrition and health claims** are often used to promote breastmilk substitutes. Member States are urged to ensure that such claims are **not permitted**. This recommendation was extended to foods for infants and young children in resolution WHA 63.23 [2010].

Resolution WHA 61.20 [2008]

Member States are urged to take food safety measures, including regulatory measures, to reduce the risk of intrinsic contamination of powdered infant formula. Resolution WHA 58.32 also requires manufacturers to give adequate warnings and information to consumers through explicit labelling, where applicable, so as to minimise the risk of contamination. Under resolution 61.20, the labelling of powdered formula must conform with the standards, guidelines and recommendations of the Codex Alimentarius Commission.

Resolution WHA 63.23 [2010] (reiterating the call made in resolution WHA 58.32 [2005])

Member States are urged to ensure that all nutrition and health claims are not permitted for foods for infants and young children, except where specifically provided for in relevant Codex Alimentarius standards or national legislation. Resolution WHA 61.20 [2008] calls for food safety regulations (such as for labelling) to warn about the risk of:

- intrinsic contamination of powdered infant formula by pathogenic microorganisms (such as Enterobacter sakazakii and Salmonella enterica) during the manufacturing process; and
- contamination during storage, preparation and handling.

- **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.

The purpose of requiring a special warning on the label on the use of an unmodified product as a breastmilk substitute is to alert the mother against using it for her baby.

Sweetened condensed milk and filled milks were often used to feed babies, and hence deserve a special mention as they are totally unsuitable for that purpose.

These labelling requirements are usually found in food laws and are applicable to all industrially packaged foods.

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 recognised standard.

This Article is fairly short as quality standards are covered under Codex Alimentarius. The Codex standards for various formulas and the Codex International Code of Hygienic Practice for Foods for Infants and Children are instruments aimed at securing the quality of breastmilk substitutes when used in international trade. Codex Standards provide a reasonable yardstick on the quality and composition of breastmilk substitutes.

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.

Since these products are exported to many countries, there is a need to ensure minimum quality standards worldwide.

Most countries rely on Codex Standards; they may, however, apply higher standards.

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.

From a legal perspective the Code has no direct effect at the national level, unless action is taken to implement it by the authorities. The Code is to be implemented as a 'minimum requirement' (Resolution WHA 34.22 [1981]) and in its 'entirety' (Resolution WHA 45.34 [1992]). Member States may expand on Code provisions following subsequent WHA resolutions. It must be noted that however strong the provisions in a national law or regulation, they will only work if there is effective enforcement.

WHA resolution 41.11 [1988]

WHO is requested to collaborate with Member States in providing legal and technical assistance in drafting and/or the implementation of national codes of marketing of breastmilk substitutes and other similar instruments.

WHA resolution 61.20 [2008]

WHO is requested to intensify support for the implementation of the International Code.

Member States may contact WHO for legal and technical assistance as WHO has been requested to intensify support for Code implementation.

Resolution WHA 63.23 [2010] (reiterated in WHA 65.60 [2012])

Member States are urged to develop and strengthen legislative and regulatory measures to control the marketing of breastmilk substitutes to give effect to the Code and resolutions.

In 2010, the World Health Assembly expressed concern over reports of the ineffectiveness of measures, particularly **voluntary measures**, and called on Member States to develop and improve controls over the marketing of breastmilk substitutes through **legislative**, **regulatory and or other effective measures**. A similar call was made in resolution WHA 65.60 as part of a comprehensive implementation plan on maternal, infant and young child nutrition.

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 organisations, professional groups, and consumer organisations should collaborate with governments to this end.

A country implementing the Code and resolutions will need to provide a well-structured mechanism for monitoring compliance. This will include the designation of a competent body to do so, the procedures for complaint investigation and the role of health associations, NGOs and individuals in the monitoring process.

WHA resolution 49.15 [1996]

Member States are urged 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.

Without effective monitoring and followup, previous achievements in restraining marketing practices can be eroded. Monitoring indicates whether a national measure giving effect to the Code and resolutions is being observed or not. For it to be objective and credible, the process of monitoring should be **transparent**, **independent and free from commercial influence**.

WHA resolution 59.21 [2006]

Member States are urged to support the call for action as contained in the Innocenti Declaration 2005 and the Director General of WHO is called upon to mobilise technical support for Member States in the implementation and independent monitoring of the Code and resolutions.

In 2006, on the occasion of the Code's 25th anniversary, WHO was again requested to provide technical support for independent monitoring.

WHA resolution 61.20 [2008]

Member States are urged to strengthen implementation of the International Code and relevant Health Assembly resolutions by scaling up efforts to monitor and enforce national measures in order to protect breastfeeding while keeping in mind the Health Assembly resolutions to avoid conflicts of interest.

Resolution WHA 61.20 [2008] reiterates the need for Member States to strengthen Code implementation by scaling up efforts to monitor and enforce national measures while **keeping in mind WHA resolutions to avoid conflicts of interest**.

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.

No matter what other parties are doing or not doing, **companies should conform to the provisions of the Code**. This obligation comes in addition to national monitoring mechanisms set up under Article 11.2, but also applies if there are none. **11.4** Nongovernmental 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.

NGOs, professional groups, institutions and individuals play an important role as watchdogs for public health and safety. These groups are in the forefront of action and likely to observe marketing activities of companies which are incompatible with the provisions of the Code. These groups therefore play a complementary role to governments, and are an important resource for monitoring Code violations.

As in Article 11.3, this provision emphasises that company staff at every level should be taught of their responsibility under the Code.

Articles 11.6 and 11.7 cover collective monitoring and are important in that they provide yearly feedback on the status of implementation and compliance with the Code by Member States. Every two years, the WHA shall receive a report on Code implementation and can put political or moral pressure on Member States to take action to implement, apply and monitor the Code.

International Code of Marketing of Breastmilk Substitutes and subsequent relevant World Health Assembly resolutions

A 10-point summary

1. Aim

To contribute to the provision of safe and adequate nutrition for infants by the protection and promotion of breastfeeding and the proper use of breastmilk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution.

2. Scope

Applies to breastmilk substitutes* 1 or any food being marketed or otherwise represented as a partial or total replacement for breastmilk. This includes:

- Infant formula
- Follow-up formula (sometimes referred to as 'follow-on milk') *
- Growing-up milk *
- Any other milk for children 0 < 36 months *
- Any other food or liquid (such as cereal, jarred food, infant tea, juice and mineral water) that is represented as suitable to be fed to infants less than six months of age. *

The International Code also applies to feeding bottles and teats.

3. Promotion

No advertising or promotion of above products to the public. No nutrition or health claims on products. *^ 2

4. Samples

No free samples to mothers, their families or health care workers.

5. Health care facilities

No promotion of products, i.e. no product displays, posters, calendars or distribution of promotional materials. No mothercraft nurses or similar company-paid personnel.

6. Health care workers

No gifts or samples to health care workers. Financial support and incentives should not create conflicts of interest. ^ 3

7. Supplies

No free or low-cost supplies of breastmilk substitutes to any part of the health care system. $^{\wedge}$ 4

8. Information

Information and education materials must explain the benefits of breastfeeding, the health hazards associated with bottle feeding and the costs of using infant formula. Product information must be factual and scientific. Governments to avoid conflicts of interest so materials under infant and young child programmes should not be sponsored by manufacturers and distributors. ^ 5

9. Labels

Product labels must clearly state the superiority of breastfeeding, the need for the advice of a health care worker and a warning about health hazards. No pictures of infants, other pictures, or text idealising the use of infant formula. Labels must have the warning that powdered infant formula may contain pathogenic microorganisms and must be prepared and used appropriately. ^ 5 Labels on complementary foods should not cross-promote breastmilk substitutes, should not promote bottle feeding, and should state the importance of continued breastfeeding. ^ 6

10. Quality

Unsuitable products, such as sweetened condensed milk, should not be promoted for babies. All products should be of a high quality (Codex Alimentarius Standards) and take account of the climatic and storage conditions of the country where they are used

Note: For the full text of Code and resolutions, see: www.who.int/nutrition/netcode/resolutions/en/

^(*) denotes products and definitions which are clarified by the WHO Guidance on ending the inappropriate promotion of foods for infants and young children Guidance A69/7 Add.1 which was welcomed by WHA Resolution 69.9 [2016].

^(^) denotes that Code provisions have been clarified and extended by subsequent World Health Assembly Resolutions which are summarised in Annex 2.

WHA49.15 [1996], WHA54.2 [2001] & WHA63.23 [2010]

² WHA58.32 [2005] & WHA63.23 [2010]

³ WHA49.15 [1996] & WHA58.32 [2005]

⁴ WHA47.5 [1994] v. WHA58.32 [2005]

⁵ WHA58.32 [2005]

⁶A69/7 Add.1

Relevant World Health Assembly resolutions summary

Year	Number	Resolutions
1981	WHA 34.22	• Stresses that adoption and adherence to the Code is a minimum requirement. Member States are urged to implement the Code through national legislation, regulations and other suitable measures.
1982	WHA35.26	• Recognises that commercial promotion of breastmilk substitutes contributes to an increase in artificial feeding and calls for renewed attention to implement and monitor the Code at national and international levels.
1984	WHA37.30	• Requests that the Director General work with Member States to implement and monitor the Code and to examine the promotion and use of foods unsuitable for infant and young child feeding.
1986	WHA39.28	 Urges Member States to ensure that the small amounts of breastmilk substitutes needed for a minority of infants are made available through normal procurement channels and not through free or subsidised supplies. Directs attention of Member States to the following: 1. Any food or drink given before complementary feeding is nutritionally required may interfere with breastfeeding and therefore should neither be promoted nor encouraged for use by infants during this period; 2. The practice of providing infants with follow up milks is "not necessary".
1988	WHA41.11	• Requests the Director General to provide legal and technical assistance to Member States in drafting national measures to implement the Code
1990	WHA43.3	 Highlights the WHO/UNICEF statement on "protection, promoting and supporting breastfeeding: the special role of maternity services" which led to the Baby-Friendly Hospital Initiative in 1992. Urges Member States to ensure that the principles and aim of the Code are given full expression in national health and nutrition policy and action.
1994	WHA47.5	 Reiterates earlier calls in 1986, 1990 and 1992 to end "free or low cost supplies" and extends the ban to all parts of the health care system. Provides guidelines on donation of breastmilk substitutes in emergencies.
1996	WHA49.15	Calls on Member States to ensure that: 1. complementary foods are not marketed for or used to undermine exclusive and sustained breastfeeding; 2. financial support to health professionals does not create conflicts of interests; 3. Code monitoring is carried out in an independent, transparent manner free from commercial interest.
2001	WHA 54.2	• Sets global recommendation of "6 months" exclusive breastfeeding, with safe and appropriate complementary foods and continued breastfeeding for up to two years or beyond.
2002	WHA55.25	• Endorses the Global Strategy on Infant and Young Child Feeding which confines the baby food manufacturers and distributors' role to: 1. ensuring quality of their products; 2. complying with the Code and subsequent WHA resolutions, as well as national measures. • Recognises the role of optimal infant feeding in reducing the risk of obesity. • Alerts that micronutrient interventions should not undermine exclusive breastfeeding.
2005	WHA58.32	 Asks Member States to: 1. ensure that nutrition and health claims for breastmilk substitutes are not permitted unless national/regional legislation allows; 2. be aware of the risks of intrinsic contamination of powdered infant formulas and to ensure this information be conveyed through label warnings; 3. 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.
2006	WHA59.11	• Member States to make sure the response to the HIV pandemic does not include non-Code compliant donations of breastmilk substitutes or the promotion thereof.
2006	WHA59.21	• Commemorates the 25th anniversary of the adoption of the Code; welcomes the 2005 Innocenti Declaration and asks WHO to mobilise technical support for Code implementation and monitoring.
2008	WHA61.20	• Urges Member States to: 1. scale up efforts to monitor and enforce national measures and to avoid conflicts of interest; 2. investigate the safe use of donor milk through human milk banks for vulnerable infants, mindful of national laws, cultural and religious beliefs.
2010	WHA63.23	 Urges Member States to: 1. strengthen implementation of the Code and resolutions, the Global Strategy on Infant and Young Child Feeding, the Baby-Friendly Hospital Initiative, the Operational Guidance for Emergency Relief Staff; 2. end all forms of inappropriate promotion of foods for infants and young children and that nutrition and health claims should not be permitted on these foods. Urges corporations to comply fully with responsibilities under the Code and resolutions.
2012	WHA65.6	 Urges Member States to put into practice the comprehensive implementation plan on maternal, infant and young child nutrition, including: 1. developing or strengthening legislative, regulatory or other measures to control the marketing of breastmilk substitutes; 2. establishing adequate mechanisms to safeguard against potential conflicts of interest in nutrition action. Requests the Director General to: 1. provide clarification and guidance on the inappropriate promotion of foods for infants and young children as mentioned in WHA63.23; 2. develop processes and tools to safeguard against possible conflicts of interest in policy development and implementation of nutrition programmes.
2014	WHA67(9)	This decision which has the same normative weight as a resolution focused on indicators to monitor the Maternal, Infant and Young Child Nutrition (MIYCN) Plan which includes increasing the rate of exclusive breastfeeding to at least 50% by 2025 as a global target. The indicator for regulation of marketing is the number of countries with legislation or regulations fully implementing the Code and Resolutions.
2016	WHA69.9	This Resolution welcomes the WHO Guidance on ending the inappropriate promotion of foods for infants and young children. It calls upon 1. Member States to take all necessary measures to implement the Guidance 2. Manufacturers and distributors of foods for infants and young children to adhere to the Guidance. The Guidance clarified that follow-up milks and growing up milks are covered by the Code and should be treated as such when implementing the International Code of Marketing of Breastmilk Substitutes and relevant resolutions. The Guidance also recommends that there should be no cross-promotion to promote breastmilk substitutes via the promotion of foods for infants and young children.



About IBFAN

The International Baby Food Action Network (IBFAN) was founded in October 1979 and is now a coalition of 273 citizen groups in 168 developing and industrialised nations.

- IBFAN works for better child health and nutrition through the promotion of breastfeeding and the elimination of irresponsible marketing of infant foods, bottles and teats.
- The Network helped to develop the WHO/UNICEF Code of Marketing of Breastmilk Substitutes and is determined to see marketing practices everywhere change accordingly.
- IBFAN has successfully used boycotts and adverse publicity to press companies into more ethical behaviour. IBFAN also helps to promote and support breastfeeding in other ways.



About ICDC

The International Code Documentation Centre (ICDC) was set up in 1985 to keep track of Code implementation worldwide.

- ICDC collects, analyses and evaluates national laws and draft laws.
- ICDC also conducts courses on Code implementation and Code monitoring and maintains a database on Code violations worldwide.
- From 1991 to 2017, ICDC trained over 2000 government officials from 148 countries in drafting sound legislation to protect breastfeeding.
- ICDC publishes a global monitoring report, Breaking the Rules, Stretching the Rules and a State of the Code by Country chart every three years.

IBFAN-ICDC

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