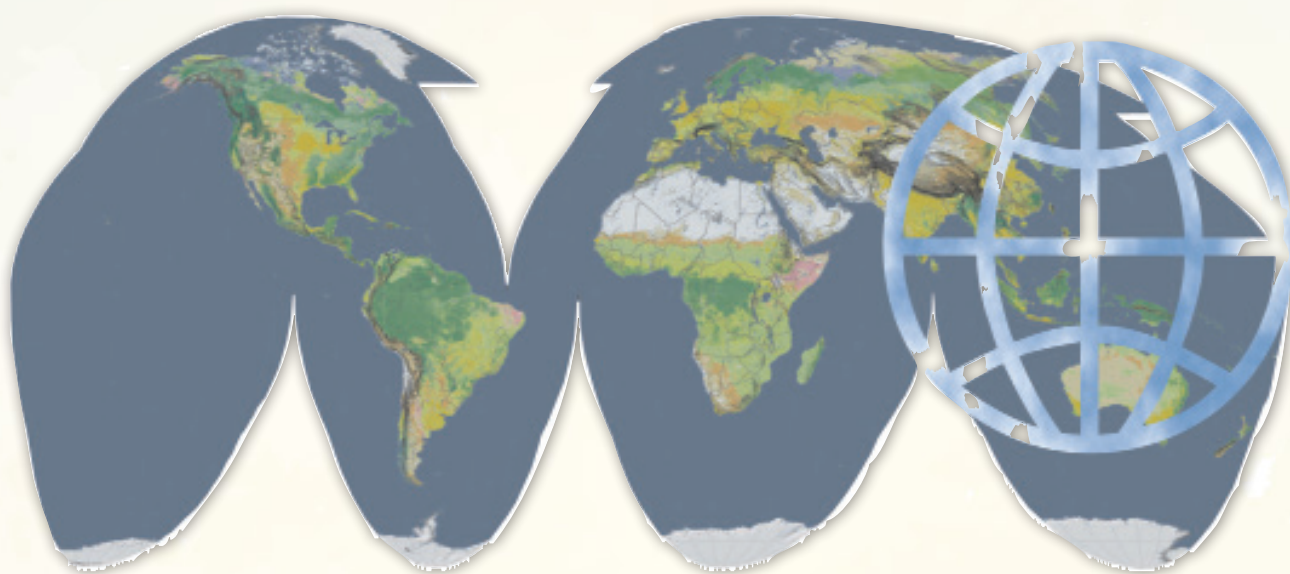


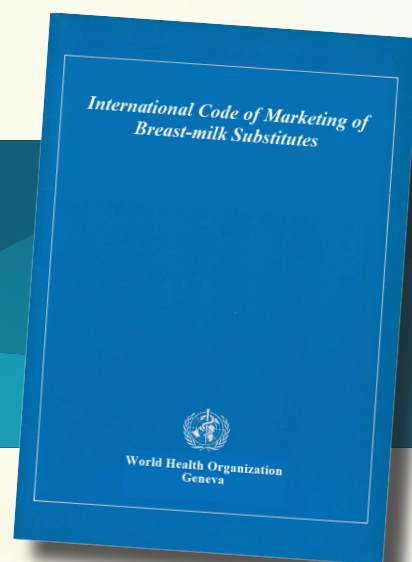
Code Essentials 3:

Responsibilities of Health Workers under the International Code of Marketing of Breastmilk Substitutes and subsequent World Health Assembly resolutions

Second Edition



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CODE
DOCUMENTATION CENTRE

Code Essentials 3:

Responsibilities of Health
Workers under the
International Code of
Marketing of Breastmilk
Substitutes and subsequent
World Health Assembly
Resolutions

Second Edition



International Baby Food Action Network
International Code Documentation Centre

Code Essentials 3: Responsibilities of Health Workers under the International Code of Marketing of Breastmilk Substitutes and subsequent World Health Assembly Resolutions.

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"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 capacity."

Hansen, K. (2016). Breastfeeding: a smart investment in people and in economies. *Lancet*, 387, 416.

Preface

For hundreds of thousands of years, breastfeeding has been the biologic norm for feeding our infants and for ensuring their survival. The wide-ranging benefits of breastfeeding mirror the sophisticated nature of breastmilk itself. It is a living substance which fulfils all of a baby's nutritional requirements from birth to six months and breastfeeding continues to confer benefits on infants and young children between six to 24 months and beyond. Breastmilk contains a huge range of bioactive molecules that play a key role in healthy microbial colonisation, in protection against infection and inflammation and also in organ development. In addition breastmilk is dynamic; its composition changes through the breastfeeding period, diurnally, and even within feeds. Breastmilk is safe, clean, always at the right temperature, inexpensive and nearly every mother has more than enough for her baby.

Given the above, it is perhaps unsurprising that no breastmilk substitute can equal breastmilk, whether in terms of nutrition, enzymes, growth factors, hormones, immunologic properties, infant growth and development or in maternal health outcomes. The benefits of breastmilk and breastfeeding simply cannot be replaced or replicated.

Unfortunately, breastfeeding is nowadays not the societal norm. In many settings, modern feeding alternatives have meant that the importance of breastmilk and breastfeeding has been undermined. The fact that marketing of breastmilk substitutes negatively impacts breastfeeding is well documented. Likewise, the fact that a large proportion of marketing expenditure by manufacturers and distributors of breastmilk substitutes, feeding bottles and teats is devoted to the health care system and health workers is well established.

Health workers must recognise their role in promoting and protecting breastfeeding. They are a primary source of trusted information for pregnant women and mothers, and decisions on infant feeding are often made on their advice. The attitude of health workers towards the marketing practices of manufacturers and distributors, and how they interact with these companies, influence the advice they give. This in turn impacts on how successfully mothers initiate and maintain breastfeeding.

Many health workers are unaware of the existence of the Code. Those who are aware about the Code find difficulty in piecing it together with subsequent World Health Assembly resolutions. Hence, they are unable to establish an appropriate position to take when confronted with commercial practices that undermine breastfeeding.

Code Essentials 3: Responsibilities of Health Workers under the International Code of Marketing of Breastmilk Substitutes and subsequent World Health Assembly

resolutions (CE 3) is written to address this difficulty. CE 3 sets out how health workers should operate. It shows they have the responsibility to not only promote and support breastfeeding but to also protect it by rejecting all forms of commercial activities designed to undermine it.

CE 3 also makes a strong case for health workers to avoid situations which may give rise to conflicts of interest due to the position of trust they hold with their patients. Professional associations that provide focus and support for health workers in the area of maternal and child health will find CE 3 illuminating, especially if they try to steer away from conflicts of interest.

ICDC published the original version of CE 3 in 2009 with the support of UNICEF East Asia and Pacific Regional Office (EAPRO) and the WHO Western Pacific Regional Office. This second edition is made possible with the continued support of UNICEF EAPRO. Although intended for the Asia Pacific region, CE 3 is useful in all parts of the world, as the Code and subsequent World Health Assembly resolutions are universal.

Readers are advised to check if there is a national Code-based law in their country to determine the full extent of their roles and responsibilities under national legislation, if any. Where there is no such law, the minimum standards set by the Code and resolutions should form the basis of best practice policies in all health care settings and the ethical guidelines of health workers' associations.

IBFAN-ICDC
Penang
April 2018

This is the third in a series of four booklets on the International Code of Marketing of Breastmilk Substitutes and subsequent World Health Assembly resolutions. Each one can stand on its own and is aimed at 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 Implementing 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 Essentials 4: *Complying with the International Code of Marketing of Breastmilk Substitutes and subsequent WHA resolutions. A guide for Regulators and Compliance Staff.*

"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 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. C, et.al. (2016). Why invest, and what it will take to improve breastfeeding practices?. The Lancet, 387(10017), 491-504.

A. Background to the Code

A brief history¹

The link between the promotion of breastmilk substitutes, the declining rate of breastfeeding worldwide and the associated increases in infant undernutrition, morbidity and mortality has not always been clear.

Dr. Cicely Williams, a paediatrician working in Singapore in the late 1930s, was the first health professional to make the link. In 1939, she addressed the Rotary Club with a hard-hitting speech entitled **"Milk and Murder."** She decried the promotion of sweetened condensed milk, and stated that **"misguided propaganda on infant feeding should be punished as the most criminal form of sedition and these deaths should be regarded as murder."**

Dr. Williams later became the first Director of Maternal and Child Health of WHO, and was one of the first proponents of the importance of breastfeeding. Despite Dr. Williams' efforts, it took another 50 years before breastfeeding became an acceptable topic for government action.

In the aftermath of World War II, sales of breastmilk substitutes, feeding bottles and teats flourished. Mistaken ideas about infant feeding were spread among health professions, which resulted in a general loss of belief in the importance of breastfeeding for infant, child and adult health. The social construct that formula feeding was the norm, and is as good as or better than breastfeeding, spread from industrialised nations, and set the stage for an alarming and persistent global trend.

The growing popularity of choosing formula feeding over breastfeeding brought dire consequences to the health and well-being of infants and young children. Particularly in developing countries, the fall in breastfeeding rates brought with it increased malnutrition, morbidity and mortality. Despite illnesses and deaths, governments were providing free or low-cost supplies of infant formula through state and welfare distribution systems, being influenced by the health profession's misperception that breastmilk substitutes were scientifically equal to breastmilk or that many mothers could not breastfeed.

Industrialised countries were somewhat buffered from the acute negative effects of formula feeding because of improvements in the supply of water, sanitation and housing in the 1950s. Widespread access to health services and rapid medical treatment also meant that most babies could withstand the mortality risks of formula feeding, albeit at a high cost to the healthcare system.

In the 1960s, the early warnings by Dr. Cicely Williams began to be echoed by others in the health care profession, namely **Dr. Derrick Jelliffe** of the Nutrition Institute in Jamaica. He coined the term **"commerciogenic malnutrition"** to describe the impact of industry marketing on infant health.

In 1974, a British charity, War on Want, published **"The Baby Killer"**, a report on the consequences of commercial promotion of breastmilk substitutes in the developing world. A Swiss non-governmental organisation (NGO), Arbeitsgruppe Dritte Welt, subsequently published a German translation but changed the title into *Nestlé Tötet Babies* (literal translation "Nestlé Kills Babies").

1. This part is a modified summary from Sokol, E. (2005). The Code Handbook, 2nd Edition. Penang, Malaysia: IBFAN S/B.

Nestlé filed a libel suit against the NGO, which attracted global publicity and dramatically raised awareness around the issue. Two years and many hearings later, Nestlé dropped three of the four charges but maintained the libel suit on the title of the book. The NGO was found guilty of libel because there was no proof that Nestlé killed babies in the criminal sense. The judge imposed a mere token fine, and warned Nestlé to change its marketing practices.

The years that followed saw increasing public attention to the promotion of breastmilk substitutes. There was press and media coverage, professional discussions, a law suit in the United States involving Mead Johnson and highly publicised US Senate Hearings. A long-standing boycott against Nestlé, the world's largest baby food manufacturer, began in the late 1970's and continues until this day.

Adoption of the Code

Following this ground swell of action, WHO and UNICEF jointly hosted an international meeting on infant and young child feeding in October 1979. The participants of the 1979 Meeting, including industry representatives, adopted by consensus a **Statement on Infant and Young Child Feeding and Recommendations**. One of the most significant recommendations states:

“There should be an international code of marketing of infant formula and other products used as breastmilk substitutes.”

The significance the participants accorded to the impact of marketing is evident in another one of the recommendations, which states:

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

The 1979 meeting was followed by debates and negotiations with experts, governments, NGOs and industry around the drafting of a code of marketing. The final text of the Code was a compromise among differing interests. It is thus weaker than the ideal, and some articles and definitions are open to interpretation, even today.

The Code was adopted by resolution WHA 34.22 at the World Health Assembly (WHA) in 1981. It represents an important milestone as it established a set of minimum standards for responsible marketing.

Every even year, the WHA discusses infant nutrition and adopts resolutions that clarify or extend on issues covered in the Code. Like the Code, they are recommendations of the WHA, and thus the Code and resolutions must be considered together.²

Relevance of the Code today

The Code is just as relevant today, if not more, than when it was adopted in 1981. Knowledge on the importance of infant and young child nutrition, particularly breastfeeding, has vastly surpassed what was known in 1981. For a long while after the Code was adopted, the recommendation for exclusive breastfeeding was four to six months. There was resistance to extend the period of exclusive breastfeeding to six months even though there was ample scientific evidence to support a "six months" recommendation mainly because manufacturers and distributors saw the original recommendation as an important window for marketing.

This controversy ended in 2001 when the WHA,³ after much debate, adopted resolution WHA 54.2 which sets the optimal period of exclusive breastfeeding unequivocally at six months.

2. 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 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.

3. Retrieved from http://www.who.int/nutrition/topics/WHA54.2_jcyn_en.pdf.

This global public health recommendation was reiterated in the 2002 **Global Strategy for Infant and Young Child Feeding**⁴ which stresses 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 of age or beyond.”

The Global Strategy is a response to the remaining high number of deaths of children in the developing world from malnutrition, and the realisation that the majority of these deaths can be prevented through exclusive breastfeeding. It reaffirms the utmost importance of implementing the Code and resolutions as one key step to improve infant and young child feeding, and ultimately, child survival.

When the Code was first adopted, concern was mostly focused on problems associated with formula feeding in conditions where access to clean water, fuel and facilities to boil water and sterilise equipment were lacking. Whilst these problems traditionally associated with formula feeding still exist, there is now increasing awareness of inherent risks of formula feeding, even in affluent settings. For example, in industrialised countries, infants who are not breastfed are nearly five times more likely to be hospitalised in their first year due to gastrointestinal and respiratory illness compared to those that are breastfed.⁵

In January 2016, The Lancet, a British medical journal, published a major series on breastfeeding. It represents the most in-depth analysis into the health and economic benefits of breastfeeding to date. The first paper⁶ in **the Lancet Breastfeeding Series** confirms that breastfeeding confers many benefits upon mother, child and society. Being breastfed is associated with lower morbidity and mortality, increased intelligence, and probable reductions in overweight and diabetes. For the breastfeeding woman, it can prevent breast cancer, improve birth spacing, and might also reduce the risk of ovarian cancer and diabetes. According to the Lancet, the deaths of over 800 000 children and 20 000 mothers could be averted each year through universal breastfeeding, as well as yielding savings of US\$300 billion. The second paper⁷ affirmatively states that knowledge of the breastmilk substitute market and its marketing practices are essential for understanding the competing environment in which efforts to protect, promote, and support breastfeeding operate. Its review of the evidence and country case studies show that successful protection, promotion, and support of breastfeeding demand measures to be taken at many levels, whether it be legal and policy directives, women's work and employment conditions, or services to support women and their families to breastfeed optimally.

One of the six “action points” proposed by the Lancet is to regulate the multi-billion-dollar breastmilk substitute industry. In this respect, the Code is recognised as an effective mechanism for action. No new interventions are needed, but greater political commitment is necessary to enact and enforce the relevant comprehensive legislation.

In May 2016, the World Health Assembly issued the **Guidance on ending the inappropriate promotion of foods for infants and young children**⁸ (the 2016 Guidance) as a response to a growing body of evidence that shows that the promotion of breastmilk substitutes and some commercial foods for infants and young children undermines progress in optimal infant and young child feeding.

4. The Global Strategy is jointly 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]. Retrieved from <http://www.who.int/nutrition/publications/infantfeeding/9241562218/en/>.

5. Talayero, J. M. P., Lizán-García, M., Puime, Á. O., Muncharaz, M. J. B., Soto, B. B., Sánchez-Palomares, M., ... & Rivera, L. L. (2006). Full breastfeeding and hospitalization as a result of infections in the first year of life. *Pediatrics*, 118(1), e92-e99.

6. 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.

7. 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.

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

The 2016 Guidance serves as a complement to the Code and resolutions as well as the Global Strategy to protect optimal infant and young child feeding practices.⁹

Overview of the Code

The intent of the Code is to protect babies, mothers and health workers from inappropriate marketing of breastmilk substitutes, feeding bottles and teats, and it seeks to eliminate man-made obstacles to breastfeeding which result from direct and indirect promotion of these products.

The Code contains a preamble and 11 articles. As of 2016, there are also 18 related WHA resolutions and one 'decision' (2014)² which must be read together with the Code (for the sake of brevity, these are collectively referred to as the 'International Code' or as 'Code and resolutions').

The Code and resolutions:

- ban all advertising and promotion of products under the scope of the Code to the general public;
- ban samples and gifts to mothers and health workers;
- require information materials to advocate for breastfeeding, to warn about risks of formula feeding and to NOT contain pictures of babies or text that idealise the use of products;
- ban the use of the health care system to promote products;
- ban free or low-cost supplies of products;
- allow health professionals to receive samples but only for research purposes;
- demand that product information be factual and scientific;
- ban sales incentives for products and contact with mothers;
- require that labels inform fully about the correct use of infant formula and the hazards of unnecessary or improper use; and
- require labels to NOT discourage breastfeeding.

A summary of the Code and resolutions appear in Annex 1 and Annex 2 respectively.¹⁰

The breastmilk substitutes industry uses aggressive marketing tactics to target pregnant women, new mothers and health workers. Such promotion often includes false claims that formula is equal or superior to breastfeeding, can improve digestive problems, or will ensure that babies sleep through the night – all of which erode women's confidence in breastfeeding. These unethical practices negatively impact breastfeeding outcomes, particularly when promoted by health workers.

UNICEF (2016). From the first hour of life - Making the case for improved infant and young child feeding everywhere. New York, NY.

9. WHO (2016) Policy Brief on World Health Assembly Resolution on the Inappropriate Promotion of Foods for Infants and Young Children. Retrieved from <http://www.who.int/nutrition/netcode/WHA-Policy-brief.pdf>.

10. ICDC's 2016 publication, "International Code of Marketing of Breastmilk Substitutes and relevant WHA resolutions", contains a compilation of the full text of these documents in one handy volume. Also available in the publication is an addendum containing the Guidance on ending the inappropriate promotion of foods for infants and young children (A69/7 Add. 1).

Giving effect to the Code

A large number of countries have already incorporated provisions of the Code into a national law or policy. Many, however, still have not, whilst others have older measures in need of revision to keep pace with new scientific knowledge and marketing practices. Although resolution WHA 34.22 [1981]¹¹ stresses that adoption and adherence to the Code is a minimum requirement, many national measures fail to meet this minimum standard and few national measures incorporate all subsequent WHA resolutions.

Health workers may sometimes find that their country's national measure is either silent on health workers' roles and responsibilities, or find that their prescribed duties and obligations fall far below those required by the Code and resolutions.

Regardless of the presence or absence of national measures, health workers can, as a matter of best practice, always ensure that their own professional conduct and the ethics of their workplaces are consistent with the provisions, aim and principles of the Code and resolutions. They can also influence their professional associations to endorse and support the Code and resolutions, as some professional health associations have indeed done.¹²

Understanding the Code

The Code promotes safe and adequate nutrition for infants and young children through the protection and promotion of breastfeeding. It also ensures the proper use of breastmilk substitutes and related products, when these are necessary. Since there are circumstances when these products are required, the Code prohibits promotion but not the sale and availability of products under its scope.

a. *What products are covered by the Code?*¹³

The Code applies to the marketing of the following products:

- breastmilk substitutes, including infant formula. This should be understood to include any milks (or products that could be used to replace milk) that are specifically marketed for feeding infants and young children up to the age of 3 years, including follow-up formula and growing-up milks;
- other foods and beverages promoted to be suitable for feeding a baby during the first six months of life when exclusive breastfeeding is recommended. This would include baby teas, juices and waters; and
- feeding bottles and teats.

A more detailed explanation on the scope of the Code appears in Part C on "Scope of the Code".

b. *What areas and activities are covered by the Code?*¹³

The Code sets out detailed provisions relating to:

- information and education on infant and young child feeding;
- promotion of breastmilk substitutes and related products to the general public and mothers;
- promotion of breastmilk substitutes and related products to health workers and in health care settings;
- labelling and quality of breastmilk substitutes and related products; and
- implementation and monitoring of the Code.

11. Retrieved from http://www.who.int/nutrition/topics/WHA34.22_jycn_en.pdf

12. The International Lactation Consultants Association (ILCA) upholds the Code and resolutions by ensuring that its educational programmes are Code compliant. To reflect an ethical environment, ILCA "does not invest in, nor accept funding, donations, advertising or sponsorship from corporate entities that do not meet their obligations under the Code". The International Board of Lactation Consultation Examiners (IBLCE) has a policy governing the conduct of International Board Certified Lactation Consultants (IBCLCs) which require them to adhere to the principles and aims of the Code and resolutions.

13. The International Code of Marketing of Breastmilk Substitutes: Frequently Asked Questions. 2017 Update, Geneva, Switzerland WHO, 2017.

How the Code affects health workers, health facilities and professional associations.

The bulk of the marketing of breastmilk substitutes is carried out through the health care system and targets health workers. Many health workers fail to realise that accepting free samples of products, equipment, supplies or services represents an ethical problem. Health workers must understand that such practices are aimed at penetrating the health care system in an attempt to get direct or indirect access to patients and obtain legitimacy for the use of commercial products which undermine or discourage breastfeeding. For example, if a health worker accepts free samples and uses, displays or gives them to mothers, the products will appear to be sanctioned or endorsed by the health care system. Any mother would likely think that the product has been given a medical professional's seal of approval.

One of the main principles of the Code is that health workers and health facilities should not be used for the purpose of promoting breastmilk substitutes, feeding bottles or teats. How the Code affects health workers and health care systems is summarised below. Each relevant Code provision and subsequent WHA resolution is explained in detail later in this booklet.

Article 3 of the Code

"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.

a. *What the Code means for health workers:*

- Health workers have the responsibility to encourage and protect breastfeeding.
- Health workers may only receive information on scientific and factual matters from manufacturers or distributors of breastmilk substitutes, feeding bottles and teats.
- To prevent conflicts of interest, health workers may not receive financial or material inducements from manufacturers and distributors (see position under the 2016 Guidance at p. 24).
- Health workers may receive free samples only when they are necessary for professional evaluation or for research at the institutional level. In no case should these samples be passed on to mothers.
- Health workers in both the public and private sector have the same responsibilities under Article 3 of the Code.

b. *What the Code means for health facilities:*

- Health facilities may not promote any product covered by the scope of the Code. This includes the display of products, placards and posters concerning such products and distribution of materials provided by manufacturers and distributors.
- Formula feeding should be demonstrated only to mothers or family members who need to use it; information given should include a clear explanation of risks of formula feeding and hazards of improper use.
- Donated equipment and materials should not refer to any brand names (see position under the 2016 Guidance at p. 26).
- Health facilities may not accept supplies of products under the scope for free or at low cost (read together with resolution WHA 47.5 [1994]).
- No programmes related to infant and young child nutrition may be sponsored by manufacturers or distributors as this will lead to conflicts of interest (read together with resolution WHA 58.32 [2005]). (See position under the 2016 Guidance at p. 28)

c. What about professional associations?

Articles 11.2 and 11.4 refer to "professional groups" and accord them the responsibility to monitor the application of the Code and to draw the attention of manufacturers and distributors to Code violations. This implies that the responsibilities imposed on health workers in their individual capacities apply also to their professional associations.

This interpretation is supported by paragraph 40 of the Global Strategy on Infant and Young Child Feeding,¹⁴ which states that health professional bodies should observe in their entirety their responsibilities under the Code and subsequent WHA resolutions, and national measures adopted to give effect to both.

d. How does the 2016 Guidance on ending the inappropriate promotion of foods for infants and young children (A69/7 Add.1) affect health workers?

The 2016 Guidance¹⁵ has a number of implications on the Code in so far as it relates to health workers. It recommends that health workers, health systems, health professional associations and non governmental organisations should avoid situations of conflicts of interest and be prohibited from engaging with manufacturers and distributors in a range of activities. This will be discussed in detail in Parts E and F on "Forbidden business in the health sector" and "Dangerous liaisons: The health worker-industry relationship".

14. Jointly formulated by WHO and UNICEF and 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. It lists the roles of all concerned parties, including professional associations, in achieving its targets.

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

B. Why breastfeeding is important¹⁶

“Breastfeeding is a natural “safety net” against the worst effects of poverty ... Exclusive breastfeeding goes a long way toward canceling out the health difference between being born into poverty and being born into affluence ... It is almost as if breastfeeding takes the infant out of poverty for those first few months in order to give the child a fairer start in life and compensate for the injustice of the world into which it was born.”

James Grant, former Executive Director, UNICEF

- Breastfeeding is important everywhere for best child health, growth and development. A millionaire's baby fed with formula has a poorer diet than the poorest family's baby who is breastfed.
- Exclusive breastfeeding for six months, followed by sustained breastfeeding and nutritious complementary feeding for two years or beyond, should be the norm. Exclusive breastfeeding means giving a baby no other food or drink, not even water, in addition to breastmilk (exceptions are medicines and vitamin drops when necessary).
- Breastmilk is superior to any other product fed to a baby. It contains the ideal balance of nutrients together with factors that protect against disease. Breastmilk is a dynamic substance which changes and adapts to the individual baby's needs.
- In both rich and poor societies, a baby who is not breastfed is at a far greater risk of having diarrhoea or pneumonia. In poor societies, this all too often leads to the baby's death.
- Early initiation of breastfeeding is important. One study found that the odds of neonatal death were more than doubled if the child only began breastfeeding on their second or third day, compared with those who started during the first hour of life.¹⁷
- Infants who receive any food or fluid other than breastmilk, even water, during the first six months have an increased risk of infection. Any other food or fluid will also reduce the mothers' milk production; breastmilk contains an inhibitor substance, and if the milk is not removed from the breast, the inhibitor shuts down the mother's milk-making system. Conversely, frequent removal of breastmilk keeps the system going. Thus, if any other food or fluid fills a baby's stomach, the baby will suckle less, the mother's breast will be less stimulated, and breastmilk production will reduce.
- Babies who are bottle-fed learn a different way of feeding, and this can lead them to suck the breast in a way which does not effectively remove milk. “Nipple sucking,” in contrast to “suckling” or “breastfeeding,” means the baby does not open its mouth widely and attach to the breast effectively. Mothers of babies who have been given bottles often get sore nipples and their milk supply is reduced because their babies are nursing ineffectively. Pacifiers can cause the same problems.
- Even one bottle feed can interfere with breastfeeding. The greater the proportion of substitute feeding, the greater the risk of interrupting breastfeeding.

“Breastfeeding gives babies the best possible start in life. Breastmilk works like a baby's first vaccine, protecting infants from potentially deadly diseases and giving them all the nourishment they need to survive and thrive.”

Dr Tedros Adhanom Ghebreyesus,
Director General
WHO 2017 Press Statement.

16. This first part of this write-up is adapted from teaching materials originally drafted by Gabrielle Palmer, Ellen Sokol, Dr. Lida Lhotska and other contributors.

17. Edmond, K. M., Zandoh, C., Quigley, M. A., Amenga-Etego, S., Owusu-Agyei, S., & Kirkwood, B. R. (2006). Delayed breastfeeding initiation increases risk of neonatal mortality. *Pediatrics*, 117(3), e380-e386.

Breastfeeding after the first six months

While it is important to emphasise exclusive breastfeeding during the first six months of life and improving the foods available for complementary feeding after six months, the benefits of continued breastfeeding during the post-six month period must not be overlooked.

Health workers should continue to protect, promote and support continued breastfeeding during the post-six month period so that babies continue to be provided with living cells and immuno-protective factors which breastmilk substitutes and complementary foods do not contain. Breastfeeding is also able to meet a higher proportion of children's energy needs than had previously been thought. Care should be taken to ensure that children are not given too much food or drink which reduces their desire to breastfeed thus displacing breastmilk rather than complementing it.¹⁸

Key messages from The Lancet Series on Breastfeeding

In 2016, The Lancet published a major new series on breastfeeding¹⁹ which represents the most in-depth analysis done to-date on the health and economic benefits of breastfeeding.

In the first of two papers in the Series, the authors reviewed the short-term and long-term health consequences of breastfeeding for the child and the mother, and confirmed that breastfeeding improves the survival, health, and development of all children. The paper concludes that:

- The scaling up of breastfeeding could prevent an estimated 823 000 child deaths.
- Breastfeeding is associated with lower mortality in both high- and low-income countries.
- Breastfeeding protects against diarrhoea, respiratory infections, otitis media and dental malocclusions.
- Breastfeeding has a beneficial impact on non-communicable diseases; it may protect against obesity and diabetes later in life.
- Breastfeeding is associated with higher intelligence in children and adolescents.
- Breastfeeding benefits mothers. It can prevent breast cancer (the scale up of breastfeeding could prevent 20 000 breast cancer deaths annually), improve birth spacing, and might reduce a woman's risk of diabetes and ovarian cancer.
- High-income countries have shorter breastfeeding duration than do low- and middle-income countries. However, even in low- and middle-income countries, only 37% of infants younger than 6 months are exclusively breastfed.
- Breastmilk is not just an ideal nutritional supply, but is also potentially a personalised medicine. Crucial health imprinting events that have a lifelong effect might be brought about during breastfeeding, mediated directly or indirectly through effects on the infant microbiome.
- Breastfeeding promotion is important in both rich and poor countries alike, and might contribute to achievement of the Sustainable Development Goals.

"WHO and UNICEF recommend that breastfeeding be initiated within one hour of birth, that it continue with no other foods or liquids for the first six months of life, and that it be continued with complementary feeding (breastfeeding with other age-appropriate foods) until at least 24 months of age".

"EXCLUSIVE BREASTFEEDING up to six months of age means that the infant receives only breastmilk. No other liquids or solids are given—not even water—with the exception of oral rehydration solution, or drops/syrups of vitamins, minerals, or medicines".

UNICEF/WHO (2017). The Investment Case for Breastfeeding: Nurturing the Health and Wealth of Nations.

18. Excerpted from Statement on protecting, promoting and supporting continued breastfeeding from 6-24 +months, WABA, 2008. Retrieved from http://www.waba.org.my/pdf/gbpm_statement_June09.pdf

19. The Lancet Breastfeeding Series (2016) comprises 1) Victora C.G. et al. (2016). Breastfeeding in the 21st century: epidemiology, mechanisms, and lifelong effect. Lancet 2016; 387: 475–90 and 2) Rollins; N.C. et al. (2016) Why invest, and what it will take to improve breastfeeding practices? Lancet; 387:491–504.

In 2015, before the release of The Lancet Breastfeeding series, a special issue supplement to the **Acta Paediatrica** journal presented a series of meta-analyses and systematic literature reviews that examined a variety of health effects related to breastfeeding.²⁰ Like The Lancet, the key message that emerged from the analyses is that the health benefits of breastfeeding are substantial.

If traditionally the importance of breastfeeding has been thought of in terms of protection from infectious diseases or malnutrition caused by contaminated water or over-dilution of breastmilk substitutes, the papers presented in *Acta Paediatrica* show that breastfeeding protects against a spectrum of adverse health outcomes, over and above these traditional perspectives.

The multiple benefits of breastfeeding demonstrate that it is a global public health issue of relevance for both low- and high-income populations alike.

Reduced healthcare costs from increased breastfeeding

The surge in scientific evidence shows just how critical breastfeeding is to human health and development and how healthcare costs for newborns could be drastically lowered with fewer hospitalisations and insurance claims. The United States could save \$13 billion per year if 90 percent of families were meeting the recommendation to exclusively breastfeed up to six months of age²¹; while in the United Kingdom, calculations from a mere handful of illnesses, where the evidence is strongest, show that moderate increases in breastfeeding could see potential annual savings of approximately £40 million per year. In South East Asia, a seven-country study shows that there could be a potential savings in health care treatment costs (\$0.3 billion annually) from reducing the incidence of diarrhoea and pneumonia by 50% through breastfeeding.²²

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20. *Acta Paediatrica* Special Issue: Impact of Breastfeeding on Maternal and Child Health. 2015. Volume 104, Issue Supplement S467 p.1-134. Includes: Grummer-Strawn, L. M.; Rollins, N. (2015). Summarising the health effects of breastfeeding. *Acta Paediatr.* 104; 1651-2227. <http://dx.doi.org/10.1111/apa.13136>.
 21. UNICEF/WHO (2017). The investment case for breastfeeding: Nurturing the health and wealth of nations. Retrieved from <http://www.who.int/nutrition/publications/infantfeeding/global-bf-collective-investmentcase.pdf>.
 22. Walters, D., Horton, S., Siregar, A. Y. M., Pitriyan, P., Hajeerhoy, N., Mathisen, R., ... & Rudert, C. (2016). The cost of not breastfeeding in Southeast Asia. *Health policy and planning*, 31(8), 1107-1116.

C. Scope of the Code

Article 2: Scope of the Code

The Code applies to the marketing, and practices related thereto, of the following products: breastmilk substitutes, including infant formula; other milk products, foods and beverages, including 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.

The following resolutions clarify Article 2 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.*

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.

The Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children (A 69/7 Add.1) (the 2016 Guidance)

This Guidance welcomed in Resolution WHA 69.9 [2016] confirms that a breastmilk substitute should be understood to include any milks (or products that could be used to replace milk, such as fortified soy milk), in either liquid or powdered form, that are specifically marketed for feeding infants and young children up to the age of 3 years including follow-up formula and growing-up milks (Recommendation 2).

Interpreting Article 2

The term “breastmilk substitute” in Article 2 is awkward and vague, but this article is important because it determines whether or not a particular product is covered by the Code. Manufacturers and distributors advance the argument that the Code covers only infant formula. The wording in Article 2 clearly does not support this narrow interpretation. Reading the Code and resolutions together, the term “breastmilk substitute” must necessarily cover any product marketed or represented as suitable to replace either partially or totally the breastmilk part of the baby’s diet.

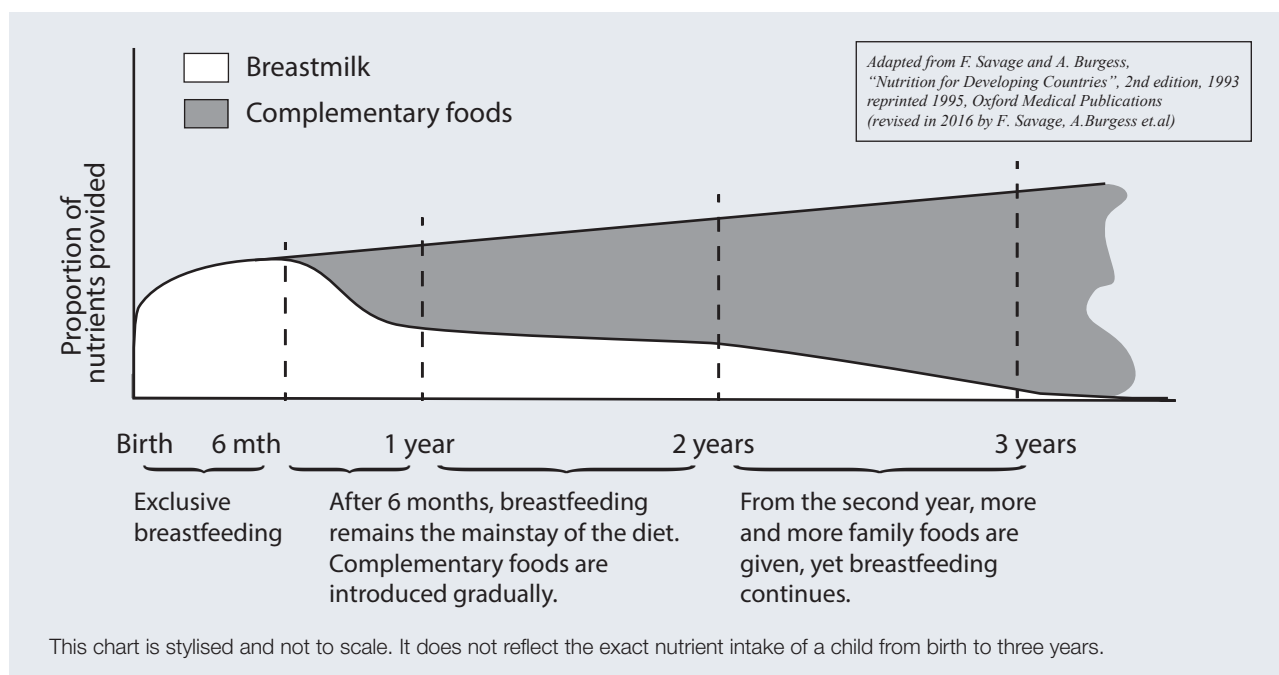
In May 2016, the WHO published a report recommending that countries should broaden the range of designated products under the scope of their legislation to include all milk products intended and marketed as suitable for feeding young children up to the age of 36 months.²³

In the same month, resolution WHA 69.9 [2016] welcomed the 2016 Guidance²⁴ which confirms that breastmilk substitutes should be understood to include any milks, 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. With these affirmative recommendations, it becomes clear that follow-up formula and growing-up milks are covered by the scope of the Code; something the industry has been disputing.

The scope of the Code can be summarised to cover the following products, and health workers should be on the alert for their promotion:

- Infant formula.
- Follow-up formula (also referred to as ‘follow-on milk’).
- Growing-up milk (also referred to as young child formula, growing-up formula, toddler milk or formulated milk).
- Any other milk for children 0 to < 36 months.
- Any other food or liquid targeted for infants under 6 months of age.
- Feeding bottles and teats.

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.



23. WHO. UNICEF. IBFAN. "Marketing of Breastmilk Substitutes: National Implementation of the International Code." Geneva: World Health Organization; 2016 WHO.

24. Retrieved from http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_7Add1-en.pdf

Complementary Foods

Complementary foods marketed for use after the age of six months generally fall outside the scope of the Code. Despite clear recommendations on the optimal duration of exclusive breastfeeding, many commercial complementary foods are still being promoted in many countries as suitable for babies below six months. Health workers should understand that this could lead to a reduction and shorter duration of breastfeeding. Babies and their mothers will also be deprived from the consequent benefits of breastfeeding. Promotional activities for commercial complementary foods marketed for use below six months are clear violations of the International Code.

Article 3 of the Code

"Complementary food" is defined by the Code to mean 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.

For complementary foods marketed for infants and young children above six months, the 2016 Guidance stipulates that they should not be promoted in any way that will **cross-promote** breastmilk substitutes, recommend or promote bottle feeding. Messages for this range of products should state the importance of continued breastfeeding for up to two years or beyond, and should not discourage breastfeeding. Under Recommendation 6 of the Guidance, there is a list of activities that health workers are prohibited from engaging in to avoid conflicts of interest. This is discussed in Parts E and F on "Forbidden business in the health sector" and "Dangerous liaisons: The health worker-industry relationship".

Health workers should encourage the integration of all elements of the Code with the 2016 Guidance to prevent unethical promotion of breastmilk substitutes and foods for infants and young children in health facilities. Health workers can also deter the promotion of complementary foods in health facilities by relying on resolution WHA 39.28 [1986], which warns that any food or drink given before complementary feeding is nutritionally required may interfere with the initiation or maintenance of breastfeeding. In addition, it is useful to cite Resolution WHA 49.15 [1996], which urges countries to ensure that complementary foods are not marketed for or used in ways that undermine exclusive and sustained breastfeeding.

Resolution WHA 54.2 [2001], which urges improvement in complementary feeding by, among other interventions, recommending the "widest possible use of indigenous nutrient-rich foodstuff", can also be relied upon to prevent the promotion of complementary foods in health facilities.

What is meant by "foods for infants and young children" in the 2016 Guidance

- Foods for infants and young children are defined as commercially produced food or beverage products that are specifically marketed as suitable for feeding children up to 36 months of age (paragraph 6).
- The term "foods" refers to both foods and beverages (including complementary foods).

The 2016 Guidance applies to all commercially produced foods that are marketed as being suitable for infants and young children from the age of **six months to 36 months**.

Products are considered to be marketed as being suitable for this age group if they

- (a) are labelled with the words "baby", "infant", "toddler" or "young child";
- (b) are recommended for introduction at an age of less than three years;
- (c) have a label with an image of a child who appears to be younger than three years of age or feeding with a bottle; or
- (d) are in any other way presented as being suitable for children under the age of three years.

D. Handling information and educational materials

Article 4. Information and education

Article 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;²⁵
- c. the negative effect on breastfeeding of introducing partial bottle feeding;
- d. the difficulty of reversing the decision not to breastfeed; and
- e. where needed, the proper use of infant formula, whether manufactured industrially or home-prepared.

When such materials contain information about the use of infant formula, they should include the social and financial implications of its use; the health hazards of inappropriate foods or feeding methods; and, in particular, the health hazards of unnecessary or improper use of infant formula and other breastmilk substitutes. Such materials should not use any pictures or text which may idealise the use of breastmilk substitutes.²⁶

Article 4.3 Donations of informational or educational equipment or materials by manufacturers or distributors should be made only at the request and with the written approval of the appropriate government authority or within guidelines given by governments for this purpose. Such equipment or materials may bear the donating company's name or logo, but should not refer to a proprietary product that is within the scope of this Code, and should be distributed only through the health care system.

Article 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.

Article 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.

The following resolutions expand on the Code provisions on information and education.

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; are informed that powdered infant formula may contain pathogenic microorganisms and must be prepared and used appropriately; and, where applicable, that this information is conveyed through an explicit warning on packaging.

25. See discussion in the part on "Recasting benefits and superiority of breastfeeding in Article 4.2".

26. See discussion in the part on "Manipulating information".

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 WHA 58.32.

The following excerpts regarding **conflicts of interest** are relevant when implementing information and education programmes.

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.

Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children (A 69/7 Add.1) (the 2016 Guidance)

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.

Need for unbiased information free of commercial influence

Health workers are often overworked and under-resourced. When they are also charged with the responsibility of providing information to pregnant women and mothers, it may seem helpful if manufacturers and distributors step in to offer information and education materials free of charge. Health workers must, however, be mindful of the inherent dangers in using company-produced materials. Invariably, they contain elements which promote breastmilk substitutes

Even when company materials are devoted solely to the topic of breastfeeding, they usually undermine breastfeeding in subtle ways. Rarely do company materials meet all the criteria required by Article 4.2 of the Code which is aimed at ensuring that objective and consistent information on breastfeeding is available to health workers, pregnant women and mothers. In particular, the clause in Article 4.2 which prohibits the use of pictures or text which idealise the use of breastmilk substitutes is seldom fulfilled.

Health workers must be conscious of the fact that pregnant women and mothers are not supported to breastfeed unless they receive unbiased information that is free from commercial influence. The confidence of women wanting to breastfeed will be undermined, and for women who are less intent on breastfeeding, the result will be that they slip into formula feeding. One study shows how mothers who recall exposure to formula information from print or websites are more likely to intend to use formula or to use formula earlier and are less likely to initiate breastfeeding than mothers who do not recall seeing such information.²⁷

A randomised controlled trial of 547 women demonstrated that educational materials on breastfeeding produced by manufacturers of infant formula and distributed to pregnant women intending to breastfeed had a substantially negative effect on the exclusivity and duration of breastfeeding. This impact was much greater on women with uncertain or short breastfeeding goals.

Howard, C., Howard, F., Lawrence, R., Andresen, E., DeBlieck, E., & Weitzman, M. (2000). Office prenatal formula advertising and its effect on breastfeeding patterns¹. *Obstetrics & Gynecology*, 95(2), 296-303.

27. Zhang, Y., Carlton, E., & Fein, S. B. (2013). The association of prenatal media marketing exposure recall with breastfeeding intentions, initiation, and duration. *Journal of Human Lactation*, 29(4), 500-509.

Manipulated information

Company materials often contain aspects that are discouraging or even damaging to breastfeeding. They use language and illustrations which may at first appear innocuous, even breastfeeding-friendly, but often within the counselling, tips and recommendations lie subtexts and subliminal messages intended to plant seeds of doubt in mothers. Formula feeding is often presented as an easy and equal alternative. Such discouraging tactics come in various guises.²⁸

Some examples:

- Praising something so apathetically that the final effect is denouncement. The sentence, “it is no longer considered in poor taste to breastfeed in public” gives one a nagging feeling that breastfeeding in public may still be in poor taste.
- Praising the ease and modelling the desirability of the product by showing happy bottle-feeding mothers against emotionally neutral or partially undressed breastfeeding mothers. This operates to discourage breastfeeding in conservative societies.
- Allying their product with the superior option (breastfeeding) by stressing the product’s similarities with breastmilk.
- Over-emphasising the difficulties of breastfeeding and the situations where a mother should not breastfeed. This is normally done under the guise of helping women prevent problems.
- “Damning with faint praise” by offering a short list of minor health differences between breastmilk and breastmilk substitutes, to distract the consumer from the more serious differences between the two.
- Expounding the modernity of formula feeding products and promoting formula feeding as an elite method of feeding infants.
- Associating the use of breastmilk substitutes with scientific progress and quality parenting.
- Implying that breastfeeding, although best, is difficult and not conducive to contemporary lifestyles.
- Entrenching the belief of insufficient breastmilk.

How to evaluate company materials

Health workers should reject any materials from their workplace and the institutions over which they have influence if the criteria of Articles 4.2. and 4.3 are not met.

Firstly, determine if there is some form of central control. If so, inquire whether company materials have been requested for and approved by the appropriate government authority or are in compliance with government guidelines, as required by Article 4.3. Proof is important and can be requested.

The next question to ask is whether there are “pictures or text which may idealise the use of breastmilk substitutes,” as they are prohibited under Article 4.2. Check if all the other requirements set out under Article 4.2 have been complied with. In particular, evaluate company materials for promotional content and any potential negative impact of the messages they contain on the target audience. Look out for manipulation of information. The evaluation should be strict, since the presence of any company materials in health facilities is often perceived as tacit endorsements of products.

While Article 4.3 does not allow company materials to refer to brand names, company names and logos are allowed and the link can easily be made to company products. Manufacturers and distributors also use information materials as vehicles to advertise other products which they claim fall outside the scope of the Code such as growing-up milks (toddler milks), complementary foods or supplements for mothers. Since these products intentionally carry similar brand names and logos as infant formula and follow-up formula belonging to the same company, there is indirect promotion (also known as **cross-promotion**, brand-crossover or brand stretching).

28. Modified from Auerbach, K. G. (1988). Beyond the issue of accuracy: Evaluating patient education materials for breastfeeding mothers. *Journal of Human Lactation*, 4(3), 108-110 and Foss, K. A., & Southwell, B. G. (2006). Infant feeding and the media: the relationship between Parents' Magazine content and breastfeeding, 1972–2000. *International Breastfeeding Journal*, 1(1), 10.

Health workers should also realise that there is a conflict of interest if manufacturers and distributors provide information materials on breastfeeding. They have a vested interest in shorter or non-exclusive breastfeeding. Their profits can only be maintained or grow if babies stop breastfeeding as early as possible or not start at all.

In the light of resolution WHA 58.32 [2005] which requires governments and health professionals to avoid conflicts of interest in infant and young child feeding programmes, health workers and their professional associations should refrain from receiving company sponsorship to produce information and educational materials for infant and young child feeding programmes. The better option would be for health workers to obtain materials from their own health authorities and international agencies like WHO and UNICEF. Most of these entities have their own websites from which up-to-date, consistent and objective information and educational materials can be downloaded free of charge.

Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children (A 69/7 Add. 1) (The 2016 Guidance)

With the issuance of the 2016 Guidance by WHO, it is now clear that any milks or products that are specifically marketed for feeding infants and young children up to the age of three years, including follow-up formula and growing-up milks, are breastmilk substitutes and their promotion is not allowed (Recommendation 2). For complementary foods, the 2016 Guidance specifies the type of messages that should be used if these products are promoted and the types of messages that are forbidden.

Health workers should ensure that the information materials they receive for complementary foods always -

- include a statement on the **importance of continued breastfeeding for up to two years or beyond** and **the importance of not introducing complementary feeding before six months of age**;
- include the appropriate age of introduction of the food (this must not be less than six months); and
- be easily understood by parents and other caregivers, with all required label information being visible and legible.

Materials 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)**;
- include any image, text or other representation that is likely to undermine or discourage breastfeeding, that makes a comparison to breastmilk, or that suggests that the product is nearly equivalent or superior to breastmilk;
- recommend or promote bottle feeding;
- convey an endorsement or anything that may be construed as an **endorsement by a professional or other body**, unless this has been specifically approved by relevant national, regional or international regulatory authorities (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).

Editorial Note: The 2016 Guidance is silent on supplements for pregnant women and mothers, but materials for these products should be rejected by health facilities as they discourage breastfeeding. Women and their families are led into thinking they need a special diet which would be fulfilled by these supplements. Such messages are far from the truth and compete unfairly with breastfeeding campaigns that work hard to show women that breastfeeding comes naturally, and given the right support, that every woman can breastfeed.

Information to health professionals

Although Article 7.2 of the Code allows manufacturers and distributors to provide information regarding their products to health professionals (and not health workers at large), such information must be restricted to matters that are factual and scientific, and may not imply or create a belief that bottle feeding is equivalent or superior to breastfeeding.

Companies use various means to undermine breastfeeding in their information materials for health professionals. Few are truly scientific and factual. Instead, doctors, nurses and midwives receive attractive brochures that imply products are almost equivalent to breastmilk, or that distort, gloss over or omit the negative impacts of using the products. By giving such informational materials to health workers for redistribution to mothers, companies earn valuable professional endorsement for the products in question.

Lots of company materials contain 'claims' which suggest enhanced nutrition and health benefits from additives contained in products. The materials show scientific-looking charts and diagrams that claim that the product is "higher" in a certain ingredient or effect, "improved" through compositional tinkering, "superior" to another product, "closer to breastmilk" or "easier to digest and absorb," etc. Crucially, the comparison is not made to the norm of a breastfed baby, but to babies who are fed on other formulas.

The claims are not only promotional but also misleading, and often lack reliable scientific evidence. Where published studies are cited, they are rarely independent, free from conflicts of interest or peer-reviewed.

Health and nutrition claims are prohibited by resolutions WHA 58.32 [2005] and WHA 63.23 [2010] unless specifically allowed by national legislation. Health workers receiving such materials in their workplaces should prevent them from being distributed further and should consider lodging a complaint to the relevant authorities.

Shifting the perspective on the "benefits and superiority of breastfeeding."

Article 4.2 of the Code provides that information and education materials on infant and young child feeding should emphasise the benefits and superiority of breastfeeding. On that basis, breastfeeding promotion programmes for many years have accentuated that "breast is best."

However, the use of the "breast is best" message may have a paradoxical, undermining effect on the success of breastfeeding promotion. Growing evidence demonstrates that such "breast is best" and "benefits of breastfeeding" messages not only fail to communicate the pivotal role of breastfeeding in the growth and development of infants and young children, but actually obscure the importance of breastfeeding.²⁹

This is because focus is placed on breastfeeding as an intervention, rather than the biological standard. By treating breastfeeding as the optimal, rather than the normal, a societal perception is reinforced that formula feeding is the standard way of feeding babies. Anything extra provided by breastfeeding is superfluous. The entrenchment of this idea is even evident in some scientific research, with many studies using partially breastfed or not-breastfed infants as the control group (i.e., treating breastfeeding as a health intervention, much like the use of a pharmaceutical). The "breast is best" message is also appropriated as a marketing tool by baby food companies who are happy to describe breastfeeding as best while positioning their products as "like breastmilk" or "inspired by nature."

A detailed study of 75 (post-Code) advertisements for breastmilk substitutes in two paediatric journals revealed that only 2.7% had scientific references and only 24% were clearly targeted at professionals while 20% were directly addressed to mothers. Three quarters of the ads did not comply with all Code requirements.

Vallone, F. (2009). Pequeños grandes clientes. La publicidad de sucedáneos de la leche materna en dos revistas pediátricas de Argentina entre 1977 y 2006. *Salud Colectiva*, 5(1), 87-105.

29. Berry, N. J., & Gribble, K. D. (2008). Breast is no longer best: promoting normal infant feeding. *Maternal & Child Nutrition*, 4(1), 74-79.

There is an increasing movement among researchers and public health advocates to “establish the breastfed child as the normative model for growth and development.”³⁰ The WHO legitimised this shift in 2006 by taking the decision to develop infant growth standards based only on the growth of children fed as recommended by health authorities (i.e. exclusively breastfed for around six months, followed by introduction of complementary foods and continued breastfeeding for up to two years or beyond). This was after the Multicenter Growth Reference Study (MGRS, 1997-2003) showed that previous growth charts based on infants rarely breastfed beyond three months and formula-fed were inaccurate, and did not describe normal infant growth.³¹

“The potential for this interpretation of the “breast is best” message has been demonstrated empirically by Hannan et al. (2005),³² who found that while most of their respondents agreed with the statement “Breastfeeding is healthier for babies,” half to three-quarters of the same people did not agree that “Feeding a baby formula instead of breastmilk increases the chances the baby will get sick.” That is, respondents agreed with a statement indicating that breastfeeding had health benefits, while simultaneously disagreeing with a similar statement framed negatively, ascribing adverse health consequences to feeding babies with infant formula.”

Berry, N. J., & Gribble, K. D. (2008). Breast is no longer best: promoting normal infant feeding. *Maternal & Child Nutrition*, 4(1), 74-79.

The focus should not be on the fact that breastfeeding “reduces” mortality and morbidity or “enhances” development, rather, it should be on the fact that formula feeding “increases” mortality and morbidity and “undermines” development. Health workers have an important role to play in communicating this message to mothers. They should remember at all times that breastfeeding is not an intervention, but the physiologically normal way to feed babies.

In order to meet the intent of Article 4.2 of the Code, breastfeeding educational materials should emphasise the fundamental importance of breastfeeding to the normal health, growth and development of infants while also describing the ways in which formula feeding undermines the health of infants, i.e. associated risks.

Concerns about making mothers feel guilty have been used to exempt health workers from promoting breastfeeding and informing mothers about the risks associated with the use of formula. This approach is flawed considering that in other health arenas, the ability of an individual to make an informed decisions is paramount. Mothers are capable of making good decisions, and it is patronising and unethical to protect mothers from the information they need to make fully informed decisions about infant feeding.

When formula is necessary

Article 6.5 requires health workers to demonstrate the use of infant formula to mothers who need to use the product. Manufacturers and distributors deliberately misinterpret Article 6.5 implying that it allows them to provide information and educational materials or instructions so as to assist health workers in guiding mothers. There is no requirement or necessity to do so. Health workers can obtain preparation instructions from product labels without referring to additional company materials which are inherently promotional. There are WHO/FAO guidelines on how to prepare formula safely in care settings³³ and at home,³⁴ rendering obsolete any argument that company materials are required.

In principle, infant formula should be used only when medically indicated. A list of acceptable medical reasons for temporary or long-term use of breastmilk substitutes is available for health workers working with mothers and newborn infants.³⁵

30. De Onis, M. (2006) Foreword. *Acta Paediatrica* 95 (Suppl. 450), 5–6.

31. Onis, M. (2006). WHO Child Growth Standards based on length/height, weight and age. *Acta paediatrica*, 95(S450), 76-85.

32. Hannan, A., Li, R., Benton-Davis, S., & Grummer-Strawn, L. (2005). Regional variation in public opinion about breastfeeding in the United States. *Journal of human lactation*, 21(3), 284-288.

33. WHO/FAO (2007) How to Prepare Powdered Infant Formula in Care Settings. World Health Organisation, Geneva, Switzerland. Retrieved from http://www.who.int/foodsafety/publications/micro/PIF_Care_en.pdf.

34. WHO/FAO (2007) How to Prepare Formula for Bottle-Feeding at Home. World Health Organisation, Geneva, Switzerland. Retrieved from http://www.who.int/foodsafety/publications/micro/PIF_Bottle_en.pdf.

35. WHO/UNICEF (2009) Acceptable Medical Reasons for Use of Breastmilk Substitutes", World Health Organization, Geneva, Switzerland. Retrieved from http://www.who.int/nutrition/publications/infantfeeding/WHO_NMH_NHD_09.01/en/

Rare instances where breastmilk is not available or where breastfeeding is not recommended include:

- when the mother is taking medication that is contraindicated for breastfeeding;
- when the infant has a health condition that precludes breastfeeding (e.g., galactosemia);
- when the mother, following good-quality counselling, has made an informed decision not to breastfeed (such as a HIV-positive mother);
- very low-birth-weight babies who may not be able to breastfeed directly; and
- where expressed breastmilk may not be available at all, or available in insufficient quantities.

Dealing with the problem of intrinsic contamination of powdered infant formula

Infants who are not breastfed require a suitable breastmilk substitute such as an infant formula, prepared in accordance with the WHO/FAO Guidelines. Health workers should be aware that powdered infant formula (PIF) is not a sterile product, even if it has been manufactured to meet current hygiene standards. During production, PIF can become contaminated with harmful bacteria such as **Enterobacter sakazakii** and **Salmonella enterica**. This means that it may occasionally contain pathogens that can cause serious illness. Inappropriate handling practices during preparation can exacerbate the problem. PIF has been associated with serious illness and death in infants due to infections with *Enterobacter sakazakii*.

Pursuant to resolution WHA 58.32 [2005], the WHO's Food Safety Department issued Guidelines on safe preparation of PIF³⁶ in collaboration with FAO, which recommend that the product be prepared one feed at a time with water first boiled and then cooled to no less than 70°C in order to reduce the risk of infection. Minimising the time from preparation to consumption and discarding of the unused reconstituted formula also reduces the risk, as does storage of prepared feed at temperatures no higher than 5°C.

Editorial Note: All of the above-mentioned guidelines are considered to be generic documents that provide guidance and support for countries and governments. Health workers should check if there are national guidelines which reflect conditions (i.e, climatic and socioeconomic differences) within the country.

36. WHO/FAO (2007) Safe preparation, storage and handling of powdered infant formula: Guidelines. World Health Organisation, Geneva, Switzerland. 2007. Retrieved from http://www.who.int/foodsafety/publications/micro/pif_guidelines.pdf.

"Health facilities and health workers are responsible for protecting optimal infant and young child feeding, and should minimise the potential for companies to influence parents, caregivers and families in the health setting. If health facilities are used to allow companies to access families directly, this will put the facility in situation of promoting products rather than promoting health."

Guidance on ending the inappropriate promotion of foods for infants and young children: implementation manual.
Geneva: World Health Organization; 2017

E. Forbidden business in the health sector

Article 6. Health care systems

- 6.1 The health authorities in Member States should take appropriate measures to encourage and protect breastfeeding and promote the principles of this Code, and should give appropriate information and advice to health workers in regard to their responsibilities, including the information specified in Article 4.2.
- 6.2 No facility of a health care system should be used for the purpose of promoting infant formula or other products within the scope of this Code. This Code does not, however, preclude the dissemination of information to health professionals as provided in Article 7.2.
- 6.3 Facilities of health care systems should not be used for the display of products within the scope of this Code, for placards or posters concerning such products, or for the distribution of material provided by a manufacturer or distributor other than that specified in Article 4.3.
- 6.4 The use by the health care system of "professional service representatives", "mothercraft nurses" or similar personnel, provided or paid for by manufacturers or distributors, should not be permitted.
- 6.5 Feeding with infant formula, whether manufactured or home-prepared, should be demonstrated only by health workers, or other community workers if necessary; and only to the mothers or family members who need to use it; and the information given should include a clear explanation of the hazards of improper use.³⁷
- 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.³⁸ 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.
- 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 serious 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.

37. Article 6.5 is discussed in the part on "When formula is necessary."

38. Free supplies are no longer allowed under resolution WHA 47.5 [1994].

The following resolutions clarify Articles 6.5, 6.6 and 6.7.

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 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.”

Resolution WHA 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.”

Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children (A 69/7 Add. 1) (The 2016 Guidance)

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. Such companies, or their representatives, should not:

- provide free products, samples or reduced-price foods for infants or young children to families through health workers or health facilities, except as supplies distributed through officially sanctioned health programmes. Products distributed in such programmes should not display company brands;
- donate or distribute equipment or services to health facilities;
- give gifts or incentives to health care staff;
- use health facilities to host events, contests or campaigns;
- give any gifts or coupons to parents, caregivers and families;
- directly or indirectly provide education to parents and other caregivers on infant and young child feeding in health facilities;
- provide any information for health workers other than that which is scientific and factual;
- sponsor meetings of health professionals and scientific meetings.

(Recommendation 6)

The 2016 Guidance applies to all commercially produced foods that are marketed as being suitable for infants and young children from the age of six months to 36 months.

How promotion is channelled through the health care system

Without their influence over health workers and others in the health care system, companies would find it much harder to promote their products. In order to compete with breastmilk, a product far superior to any commercial product, companies need to gently **mould health workers into willing partners**. Listed below are some of the **highly successful marketing tactics** companies use to court health workers.³⁹

- free supplies to hospitals and to individual health professionals (donated formula, feeding bottles, etc.);
- free samples of products under the scope of the Code;
- posters, calendars, diaries;
- small gifts such as pens, prescription pads, or other inexpensive items;
- large gifts such as incubators, refrigerators, air conditioners, computers and software;
- gifts of professional services such as architectural design of hospitals or organisation of events for the public;

Manufacturers and distributors employ marketing personnel whose main job is to build relationships with health workers in a marketing tactic known as medical detailing. This is a practice of contacting health workers and hospitals directly and providing them with free or discounted products and encouraging them to recommend a particular brand of product to their patients. Medical detailing also includes the practice of providing hospitals with discharge packs containing samples or products, coupons and other types of company promotion. Such activities serve as an implicit endorsement of a particular brand of product by the hospital. This is extremely important to manufacturers and distributors as it builds brand loyalty.

Walker, M. (2001). Selling Out Mothers and Babies: Marketing Breastmilk Substitutes in the USA. MA, USA: NABA REAL.

- close relationships with government agencies and their employees;
- visits by representatives to doctors in private practice, health institutions and ministries;
- friendly relations to make health workers feel well-disposed to the company: birthday cards, parties;*
- personal gifts such as holiday trips, mobile phones or other appliances, meals and entertainment;*
- sponsorship of hospitals, clinics or projects;*
- funding of research grants and salaries;*
- support to attend professional events;*
- support for professional associations;*
- financial sponsorship of students and presence in health training establishments, which may include actual teaching in infant feeding courses;*
- sponsorship of conferences, seminars and publications;* and
- advertisements and advertorials in journals and similar publications.*

Health workers must realise that company representatives are not members of the health care system and are not their friends. Company representatives are required to meet specific sale quotas and maintain a specific market share of infants discharged from particular hospitals, add a number of new-borns receiving the company's products, establish promotional programmes in paediatric and obstetric offices and add a specific number of mothers to the company's mother and baby club through sign-up materials placed in doctor's offices.⁴⁰ To achieve these goals, companies lavish incentives and gifts on health workers in an attempt to influence them and to compromise their objectivity. In return, health workers (usually unknowingly) confer **"endorsement by association"** to the companies in question by acting as emotional and subconscious levers for company promotion.

39. Practices marked with an asterisk (*) are also relevant in the context of promotion to health workers under Article 7.

40. Walker, M. (2007). Still selling out mothers and babies: marketing of breastmilk substitutes in the USA. MA, USA: NABA REAL.,

Article 6.1 thus requires health authorities to take appropriate measures to encourage and protect breastfeeding and to promote the principles of the Code. The success of such measures, depends on whether health workers act to give effect to the other provisions in Article 6. Article 6.2 states that promotion of all products within the scope of the Code is forbidden in any part of a health care system. Article 6.3 adds other specific types of promotional activities that are not allowed. These two articles provide the basis for health workers to turn away any overtures from company representatives to infiltrate their workplace.

Materials such as posters, clocks, calendars, desk pads, stickers, note pads, pen holders, letter openers, sample packets, hats, t-shirts, plates or cups, bibs, discharge gift packs, growth charts, health monitoring cards (baby passports), cot identification cards and birth certificates must all be rejected because they are designed to associate companies and their products with infant and young child feeding or care. Careful adherence to Articles 6.2 and 6.3 will effectively remove any perceived association between the health care system and manufacturers and distributors. These articles do not interfere with the donation of educational or information materials regulated by Articles 4.3 and 7.2, or with materials and equipment allowed under Article 6.8, but can stop promotional elements from appearing on donated materials. See discussion under these three sub-articles on pp. 16, 18 and 26 respectively for the considerations and criteria to apply to minimise the impact of company promotion.

Recommendation 6 of the 2016 Guidance is couched in the context of avoidance of conflicts of interest. In many ways, it reinforces the provisions, aim and spirit of Articles 6.2 and 6.3. The ban on promotion in health facilities is extended to cover activities such as donation or distribution of equipment or services to health facilities, gifts or incentives to health care staff, hosting of events, contests or campaigns and sponsoring meetings of health professionals and scientific meetings. This is to prevent health professionals and health facilities from being targeted and influenced by manufacturers and distributors through relationships and incentives that can result in the loss of independence, integrity and public credibility.⁴¹ For a full listing of prohibited activities in the promotion of foods for infants and young children, see p.22.

'Educating' mothers

The use of so-called "mothercraft services," whereby salespeople dressed in nurses' uniforms promote products, led to the adoption of Article 6.4. This practice is increasingly rare, but violations of Article 6.4 do occur in other forms, for example, when companies conduct classes on infant and young child feeding at "educational" events. Resolution WHA 58.32 [2005] calls for scrutiny of such programmes to ensure there are no conflicts of interest, and the 2016 Guidance recommends that companies should not "directly or indirectly provide education to parents and caregivers."

In cases where breastfeeding is not an option,⁴² feeding with infant formula may be demonstrated. Pursuant to Article 6.5, such demonstrations should only be held in private to the mother and family members. In the light of resolution WHA 58.32 [2005], information regarding risks of intrinsic contamination of powdered infant formula should also be provided.

Reflections of a pioneer

"We allowed the companies to touch the lives of our babies, not because we did not care, but because we did not realise the consequences of granting such a privilege ... How to break the 'friendly' stranglehold that we had allowed milk companies to have on our hospital? I closed the door of the nursery to the milk companies. We stopped giving our babies the starter dose of infant formula. Down came the colourful posters and calendars... Everything that was conducive to bottle feeding was removed not only from the nursery, but from everywhere else in the hospital. I myself rejected samples and donations from the milk companies. How else could we be credible."

Dr Natividad Clavano, excerpted from Clavano, N. "The results of a change in hospital practices— a paediatrician's campaign for breastfeeding in the Philippines", *Assignment Children* 55/56:2/1981 UNICEF.

41. Guidance on ending the inappropriate promotion of foods for infants and young children: implementation manual. Geneva: World Health Organization; 2017. Retrieved from: <http://www.who.int/nutrition/publications/infantfeeding/manual-ending-inappropriate-promotion-food/en/>.

42. See WHO/UNICEF (2009) *Acceptable Medical Reasons for Use of Breastmilk Substitutes*, World Health Organization, Geneva, Switzerland. Retrieved from http://www.who.int/nutrition/publications/infantfeeding/WHO_NMH_NHD_09.01/en/

This restriction is to prevent contacts between manufacturers and distributors and mothers.

Some companies have taken to producing information and educational materials which they claim are to assist health workers in carrying out the tasks they are required to perform under Article 6.5. There is neither a requirement nor an obligation on their part to do so under the Code. Company assistance in this regard should be avoided to prevent undue commercial influence in health facilities. It could be perceived to be some form of endorsement by association.

Supplies - Free now, pay later

Donation of free supplies is a time-tested technique to encourage formula feeding. Mothers tend to continue with the brand they were given at the hospital because of implied medical endorsement. Supplies are normally unsolicited by health facilities but are delivered at such regular intervals that many hospitals become dependent on them. For manufacturers and distributors, free supplies are an investment that will be recovered through future sales. The potential for brand loyalty and its impact on sales are so great that companies are known to enter into contracts with hospitals to be their exclusive supplier of free infant formula. On top of that, they give cash rewards to hospitals for every infant fed on their formula. In some countries companies take turns supplying formula, as hospitals do not want to be seen to be favouring any particular brand. In the process, they get rewarded equally by every manufacturer on their panel.

During consultations to draft the Code, free supplies had been discussed extensively because there was a perceived need for donated formula. The health professionals consulted had trouble believing that hospitals could afford the required amount of formula.

Those concerns were seemingly solved by Articles 6.6 and 6.7 which allow donations of supplies of products (defined as quantities provided for an extended time, free or at low price⁴³, for social purposes) to institutions or organisations to be used only for “infants who have to be fed on breastmilk substitutes”. The phrase “**infants who have to be fed on breastmilk substitutes**” 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 critical illness or death of the mother, abandonment of the child, separation of mother and child due to natural or man-made disasters, inborn errors of metabolism and certain maternal illnesses.⁴⁴

The term “**institutions or organisations**” in Article 6.6 was subsequently clarified to mean orphanages and organisations caring for abandoned babies.⁴⁵ Companies chose to read the word “institutions” in Article 6.6 as hospitals and continued to offer free and low-cost supplies to maternity wards. Because the majority of health workers are poorly trained in breastfeeding management, these supplies led to routine use of pre-lacteals and supplementary feeds which undermine the establishment of breastfeeding.

The World Health Assembly attempted to stop the companies’ misinterpretation of the Code through resolution WHA 39.28 [1986]. This resolution calls for the “small amount of breastmilk substitutes needed for the minority of infants who require them in maternity wards and hospitals” to be made available through “**normal procurement channels** and not through free or subsidised supplies.”

It was very difficult to stop free supplies. Companies insisted they were charitable, that health workers requested them and maternities needed them. Hospitals were persuaded to accept free supplies by huge cash grants and other programmes. One company manager was reported to have said that giving up supplies was commercial suicide. Yet the adverse effect on breastfeeding initiation became more and more clear, and finally the World Health Assembly adopted very clear wording in 1994 to dispel any remaining confusion over this issue.

43. 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.”

44. 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>;

45. Dr. H. Mahler, Director-General of WHO, Letter to Finnish Minister of Health, 9 August 1985.

Resolution WHA 47.5 [1994] urges Member States: “to ensure that there are **no donations of free or subsidised supplies of breastmilk substitutes** and other products covered by the International Code of Marketing of Breastmilk Substitutes in any part of the health care system.”

Article 6.6 as it applies to health facilities is clearly superseded by resolution WHA 47.5 [1994]. Health workers should therefore ensure that companies do not distribute free or low-cost supplies in any part of the health care system.

Donations of equipment and materials

Under Article 6.8, the name and logo of the donor company may appear on donated equipment or material but there should be no reference to brand names. This is not a sufficient safeguard against promotion since the name and logo of some manufacturers and distributors are the same or indistinguishable from the name and logo of their products. The issue of donations of equipment is another weakness in the Code, as such donations may lead to the promotion of formula products. It does not consider the possibility of conflicts of interest which may arise when health facilities receive expensive equipment and materials from companies. Health facilities may feel obligated to these companies for the material assistance provided and reciprocate in a way that adversely affects the promotion of breastfeeding.

This weakness in the Code is addressed by Recommendation 6 of the 2016 Guidance which specifically prohibits companies that market foods for infants and young children from donating or distributing equipment or services to health facilities. There are no qualifications to this recommendation. In the absence of regulation restricting donations of equipment and materials, health workers can advocate for the implementation of the 2016 Guidance in their work places as a matter of best practice.

The prohibitions in Recommendation 6 should be extended to further restrict the promotion of breastmilk substitutes in health facilities.

Breastmilk substitute marketing impacts breastfeeding behaviours via multiple channels, including marketing to and through health facilities and providers, consumers, and policy makers. Such marketing influences health system practices and community norms around the social acceptability and desirability of milk formula use. It undermines breastfeeding confidence among women, and it affects implementation of local policies and regulations.

Piwoz, E. G., & Huffman, S. L. (2015). The impact of marketing of breast-milk substitutes on WHO-recommended breastfeeding practices. Food and nutrition bulletin, 36(4), 373-386

"If breastfeeding, with all its benefits, is to be established as a majority activity, we paediatricians must learn to recognise the elaborate web woven around us by formula manufacturers, which currently ensures our goodwill and support for a product that we may acknowledge, but would mostly not wish to actively promote."

Wright, C. M., & Waterston, A. J. R. (2006). Relationships between paediatricians and infant formula milk companies. Archives of disease in childhood, 91(5), 383-385

F. Dangerous liaisons: The health worker-industry relationship

Article 7. Health Workers

- 7.1 Health workers should encourage and protect breastfeeding; and those who are concerned in particular with maternal and infant nutrition should make themselves familiar with their responsibilities under this Code, including the information specified in Article 4.2.
- 7.2 Information provided by manufacturers and distributors to health professionals regarding products within the scope of this Code should be restricted to scientific and factual matters, and such information should not imply or create a belief that bottle-feeding is equivalent or superior to breastfeeding. It should also include the information specified in Article 4.2.
- 7.3 No financial or material inducements to promote products within the scope of this Code should be offered by manufacturers or distributors to health workers or members of their families, nor should these be accepted by health workers or members of their families.
- 7.4 Samples of infant formula or other products within the scope of this Code, or of equipment or utensils for their preparation or use, should not be provided to health workers except when necessary for the purpose of professional evaluation or research at the institutional level. Health workers should not give samples of infant formula to pregnant women, mothers of infants and young children, or members of their families.
- 7.5 Manufacturers and distributors of products within the scope of this Code should disclose to the institution to which a recipient health worker is affiliated any contribution made to him or on his behalf for fellowships, study tours, research grants, attendance at professional conferences, or the like. Similar disclosures should be made by the recipient.

The following resolutions clarify Article 7, in particular the issue of sponsorship and conflicts of interest.

Resolution WHA 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.

Resolution WHA 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.

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.

Resolution WHA 61.20 [2008]

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

Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children (A 69/7 Add. 1) (The 2016 Guidance)

Companies that market foods for infants and young children should not create conflicts of interest in health facilities or throughout health systems. Likewise, health workers, health systems, health professional associations and nongovernmental organisations should not:

- accept free products, samples or reduced-price foods for infants or young children from companies, except as supplies distributed through officially sanctioned health programmes. Products distributed in such programmes should not display company brands.
- accept equipment or services from companies that market foods for infants and young children;
- accept gifts or incentives from such companies;
- allow health facilities to be used for commercial events, contests or campaigns;
- allow companies that market foods for infants and young children to distribute any gifts or coupons to parents, caregivers and families through health facilities;
- allow such companies to directly or indirectly provide education in health facilities to parents and other caregivers;
- allow such companies to sponsor meetings of health professionals and scientific meetings.

(Recommendation 6)

The 2016 Guidance applies to all commercially produced foods that are marketed as being suitable for infants and young children from the age of six months to 36 months.

Minimising the impact of commercial promotion

Article 7.1 makes health workers responsible for the encouragement and protection of breastfeeding. Many health workers, however, inadvertently assist manufacturers and distributors in their marketing in ways which undermine breastfeeding. The situation is compounded by the low level of awareness amongst health workers regarding the real risks of formula feeding.

While the Baby-friendly Hospital Initiative (BFHI)⁴⁶ has made major inroads in educating health workers, there are still many doctors, nurses and other health workers who believe that formula feeding, mostly administered by feeding bottle, is a good alternative to breastfeeding. In the long run, this should be addressed by improving the pre-service curriculum and training of health workers to include breastfeeding and lactation management, in line with resolution WHA 47.5 [1994]. In the meantime, the Code and resolutions must be introduced into the work policies of all health settings to ensure that misleading information and promotion is not allowed to distort health workers' perceptions.

Companies sometimes offer educational materials (videos, brochures and posters) for health workers to promote breastfeeding. Nothing in Article 7 requires companies to do this. In fact, paragraph 44 of the Global Strategy on Infant and Young Child Feeding confines the role of companies to ensuring quality of their products and compliance with the Code and resolutions.⁴⁷

46. BFHI is a designation awarded by WHO and UNICEF to hospitals that foster the implementation of evidence-based strategies concerning infant feeding. The revised 2018 BFHI operational guidance encompasses the Code as a distinct step within the Ten Steps to Successful Breastfeeding, a summary of practices necessary to support breastfeeding.

47. Retrieved from <http://www.who.int/nutrition/publications/infantfeeding/9241562218/en/>. The Global Strategy is a guide jointly 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].

Studies show that due to a variety of reasons, health professionals are often a source of advice that undermines breastfeeding. One such reason is company influences such as promotional materials or incentives.⁴⁸ In the Philippines, one study showed that mothers who received a formula recommendation from a doctor are four times more likely to use formula than those who did not receive a doctor's recommendation.⁴⁹

Resolution WHA 49.15 [1996] urges Member States to ensure that financial support for health professionals does not create conflicts of interest. This call was extended by resolution WHA 58.32 [2005] to other incentives for programmes and health professionals working in infant and young child health. Likewise, Recommendation 6 of the 2016 Guidance requires health workers, health systems, health professional associations and nongovernmental organisations to avoid conflicts of interest and lists things that should be avoided in the promotion of foods for infant and young child feeding (see p. 28).

Article 7.2 allows manufacturers and distributors to provide information to health professionals regarding products covered by the Code. This type of information is only for health professionals, not for the wider class of health workers and should be scrutinised carefully. Anything that is not restricted to matters that are factual and scientific, and anything that implies or creates a belief that formula feeding is equivalent or superior to breastfeeding, should be rejected, as detailed in Part D on "Manipulated information"(p.16) and "Information to health professionals"(p.18).

Myths of small gifts

One way for manufacturers and distributors to forge links with health workers is by offering them personal benefits and gifts, a practice forbidden by Article 7.3. The financial and material inducements referred to under Article 7.3 can take many forms. Gifts, regardless of value, create brand awareness and corporate goodwill. They act as inducements for health workers to recommend the company's products. Despite the clear provisions of Article 7.3, some manufacturers and distributors allow their marketing personnel to offer to health workers "inexpensive gifts unrelated to the health worker's practice in acknowledgment of significant national, cultural or religious events,"⁵⁰ "low-cost items of professional utility" or "culturally appropriate' gifts."⁵¹

There is a widely accepted assumption among health workers that small gifts do not significantly influence professional behaviour, but research calls into question the validity of this assumption.⁵² For example, **the impulse to reciprocate for even small gifts has been demonstrated by social science research to be a driving force behind people's behaviour.** Individuals receiving gifts are often unable to remain objective and they reweigh information and choices in light of the gift or the gratitude they feel for it.

Even when gifts are offered with no explicit "strings attached," there is still an **implicit expectation of some kind of reciprocity.** Since even gifts of minimal value carry influence, health workers should subscribe to a "no gift" ethos and extend the same principle to family members in line with Article 7.3. Gifts and incentives to health care staff are prohibited under Recommendation 6 of the 2016 Guidance to avoid conflicts of interest.

Me? No! Others? Yes!

While most doctors consider themselves immune to manipulation by drug representatives and their gifts, they consider that such activities will influence other doctors.

van Mil, J.F. (2006). "Influences of prescribing," *Pharmacy World & Science*, 28 (1), 1-2.

48. Piwoz, E. G., & Huffman, S. L. (2015). The impact of marketing of breast-milk substitutes on WHO-recommended breastfeeding practices. *Food and nutrition bulletin*, 36(4), 373-386.

49. Sobel, H. L., Iellamo, A., Raya, R. R., Padilla, A. A., Olivé, J. M., & Nyunt-U, S. (2011). Is unimpeded marketing for breast milk substitutes responsible for the decline in breastfeeding in the Philippines? An exploratory survey and focus group analysis. *Social science & medicine*, 73(10), 1445-1448.

50. Danone's Policy for the Marketing of Breastmilk Substitutes. Version 4: 30 May 2016. Retrieved from http://danone-danonecom-prod.s3.amazonaws.com/PUBLICATIONS/Danone_Policy_for_the_Marketing_of_BMS.pdf.

51. The Nestlé Policy and Procedures for the Implementation of the WHO International Code of Marketing of Breast Milk Substitutes (September 2017). Retrieved from https://www.nestle.com/asset-library/documents/creating%20shared%20value/nutrition/nestle_policy_who_code_en.pdf.

52. Brennan, T. A. et al. (2006). Health industry practices that create conflicts of interest: a policy proposal for academic medical centers. *Jama*, 295(4), 429-433.

Samples for professional evaluation or research

The provision of free formula samples and other gifts in hospital discharge packs is still common and negatively impacts on breastfeeding.⁵³ Of 11 studies selected for review by the US Government Accountability Office, seven found that for at least one point in time, breastfeeding rates were lower among women who received company-produced discharge packs and/or formula, or formula coupons from hospitals, as compared to women who received non-commercial packs or no packs at all.⁵⁴ Conversely, inclusion of items useful for breastfeeding in discharge materials may significantly prolong breastfeeding compared to the effect of company-produced discharge packs.⁵⁵

Article 7.4 prohibits distribution of samples of infant formula to pregnant women, mothers or members of their families. There is only one exception to the ban on samples, which is in cases of **professional evaluation or research at the institutional level**. In most health care settings, this would require protocols and approval by ethics committees. Ideally, products used in professional evaluation and research should be purchased, not acquired as free samples, as company-supported research is known to produce results favourable to company products. When results are not favourable, companies restrict their dissemination.⁵²

Some manufacturers and distributors interpret Article 7.4 to mean that they are able to provide samples to individual health workers to introduce a new product, a new formulation of an existing product or a range of products to newly qualified health professionals.^{50,51} This is a ruse for promotion, which cannot be supported by the plain wording of Article 7.4. Furthermore these samples are usually provided in bulk and passed on to mothers. Health workers should also bear in mind that the very notion of using free samples to conduct professional evaluation and research gives rise to ethical concerns. The use of free samples will encourage formula feeding and lead mothers to cease breastfeeding. Any professional evaluation or research involving infants should require mothers' written consent, after they have been properly counselled on the risks of formula feeding.

To avoid conflicts of interest, health workers or health facilities are forbidden from accepting free products, samples or reduced-price foods from companies under Recommendation 6 of the 2016 Guidance. The only exception is supplies distributed through officially sanctioned health programmes. To avoid inappropriate promotion, products distributed in such programmes should not display company brands.

Profiting from failure of breastfeeding

Infant formula manufacturers have a duty to their shareholders to maximise sales of their products, which by definition means minimising exposure of infants to breastmilk. Hence while publicly stating their commitment to breastfeeding, ...infant formula milk companies are in fact profiting from the failure of breastfeeding.

Wright C.M., & Waterston A.J.R. (2006) "Relationships between paediatricians and infant formula milk companies." Archives of disease in childhood, 91 (5): 383-385.

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53. Rosenberg, K. D., Eastham, C. A., Kasehagen, L. J., & Sandoval, A. P. (2008). Marketing infant formula through hospitals: the impact of commercial hospital discharge packs on breastfeeding. American Journal of Public Health, 98(2), 290-295.
54. United States Government Accountability Office (GAO). Breastfeeding: Some Strategies Used to Market Infant Formula May Discourage Breastfeeding; State Contracts Should Better Protect Against Misuse of WIC Name. Report to Congressional Addresses. GAO-06-282, February 2006. Available at: <http://www.gao.gov/new.items/d06282.pdf>.
55. Frank, D. A., Wirtz, S. J., Sorenson, J. R., & Heeren, T. (1987). Commercial discharge packs and breast-feeding counseling: effects on infant-feeding practices in a randomized trial. Pediatrics, 80(6), 845-854

Problems with sponsorship and disclosures

The most effective and insidious way in which manufacturers and distributors forge links with health workers is by providing them with contributions for their professional development, whether it be fellowships, study tours, research grants or attendance at professional conferences, etc. Manufacturers and distributors use sponsorship to spread the idea that they are responsible corporate citizens and to link their name to health professionals and prestigious organisations.

Article 7.5 allows this kind of sponsorship, even though it can create conflicts of interest. The only safeguard provided by Article 7.5 is the need for manufacturers and distributors and recipients to disclose the contribution to the institution to which a recipient is affiliated. The assumption that disclosure is sufficient to avoid conflicts of interest is unfounded, because:

- Health workers may have a different understanding of a conflict of interest, and therefore not disclose all conflicts of interest.
- Declarations of conflict of interest are usually unverified, casting doubts on accuracy.
- Disclosure may be used to “sanitise” a problematic situation, suggesting that no ill effects will follow from the disclosed relationship.

Article 7.5 is a weakness in the Code. Companies spend considerable sums on sponsorship, with the intention of obtaining a proportionate return for the money invested.

To overcome some of the shortcomings of the Code on this topic, three WHA resolutions caution against conflicts of interest, namely resolution WHA 49.15 [1996]; resolution WHA 58.32 [2005] and resolution WHA 61.20 [2008]. The 1996 resolution calls for caution in accepting financial support for health professionals working in infant and young child health which 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, projects implemented within schools and colleges, medical or health education. The need to avoid conflicts of interest was reiterated in the 2008 resolution in the call for Code implementation by scaling up of efforts to monitor and enforce national measures to protect breastfeeding. See also discussion on Recommendation 6 of the 2016 Guidance at p.24.

Understanding conflicts of interest

The concept of a conflict of interest has its origins in the law used to regulate fiduciaries— individuals entrusted to serve the interest of another party or to serve a designated mission— who are held to the highest legal standards of conduct. The law does not permit fiduciaries to promote their own interests, or the interests of third parties. It requires fiduciaries to be loyal to the party they serve, to act prudently and diligently, and to account for their conduct.⁵⁶ Health professionals have specialised knowledge and hold the trust of their patients. As patients are in no position to check whether health professionals are acting solely for their benefit or have been influenced by some personal interest, a duty to avoid conflicts of interest is implied.

Acceptance of funding or other incentives, however conditional, creates a sense of obligation and loyalty to the company in question. This is exactly what health professional associations ... should avoid. They have a moral obligation to protect themselves and their members from inappropriate promotion of BMS in all forms, however indirect, and from resulting competing interests in healthcare settings. Furthermore, health professional associations have a moral obligation to respect and protect women's and children's rights to be free from all forms of inappropriate marketing practices.

Costello, A., Branca, F., Rollins, N., Stahlhofer, M., & Grummer-Strawn, L. (2017). Health professional associations and industry funding. *The Lancet*, 389(10069), 597-598.

56. Rodwin, Marc A., Attempts to Redefine Conflicts of Interest (2017). Accountability in Research: Policies in Quality Assurance (December 6). In this paper, Rodwin posits that the traditional legal concept of conflict of interest is a practical tool to regulate conduct and warns that attempts to redefine conflicts of interest will result in policies that cannot be implemented effectively and the de-regulation of financial conflicts and overregulation of so-called intellectual conflicts.

A conflict of interest arises every time anyone (including a non-professional health worker or health educator) whose duty it is to promote breastfeeding accepts some kind of gift or benefit from a company. The term 'conflict of interest' also covers any situation in which an individual or an organisation, is in a position to exploit a professional or official capacity in some way that results in their personal or organisational benefit.

A non-exhaustive list of actions that would give rise to a conflict of interests includes:⁵⁷

- acceptance of gifts, even of relatively small items, including meals;
- acceptance of payment for attendance at lectures and conferences, including online activities;
- acceptance of fellowship for continuing medical education;
- acceptance of fees for time while attending meetings;
- acceptance of funding for travel to meetings or fellowships to attend meetings;
- acceptance of samples;
- acceptance of grants for research projects;
- acceptance of payment for consulting relationships; and
- the provision of ghost-writing services.

See also p.28 for a list of activities that are prohibited under the 2016 Guidance to prevent conflicts of interest among health workers, health professional associations and nongovernmental organisations. Resolution WHA 69.9 [2016] **"welcomes with appreciation"** the 2016 Guidance.

What does the phrase "welcomes with appreciation" in WHA 69.9 [2016] mean?

At the 39th session of the Codex Committee on Nutrition and Foods for Special Dietary Uses, the delegations of France and US advanced the argument that the World Health Assembly did not "approve" or "endorse" the **2016 Guidance** because the words "welcomes with appreciation" are used in resolution WHA 69.9.

In response, the Representative of WHO stated that resolutions and decisions of the WHO Governing Bodies (i.e., Executive Board, WHA) use various operative phrases to express their views regarding the substantive content contained in or annexed to the resolutions or decisions.

Commonly used phrases are: adopts, approves, endorses, welcomes, noted with appreciation and notes and they lie on **a spectrum expressing approval**- with greater or less strength on one side and general recognition on the other. The terms "welcomes", "welcomes with appreciation" and "notes with appreciation" express approval as well, although somewhat less strongly.

The Representative highlighted that regardless of different operative phrases used by various resolutions and decisions, there is one thing which is common to all these resolutions and decisions - they are the resolutions and decisions of the WHA which is the highest Governing Body of WHO.

- Report Of The Thirty-Ninth Session Of The Codex Committee On Nutrition And Foods For Special Dietary Uses Berlin, Germany 4 – 8 December 2017

Editorial Note: The introduction to **the Guidance on ending the inappropriate promotion of foods for infants and young children: implementation manual** stated that the 2016 Guidance was "approved" by the WHA.

57. Adapted from Brennan, T. A. et. al (2006). Health industry practices that create conflicts of interest: a policy proposal for academic medical centers. *Jama*, 295(4), 429-433.

Drawing the line between the unacceptable and the permissible

The best way to deal with conflicts of interests is to avoid them completely. However, unless national laws which implement the Code include a specific ban on sponsorship and other interactions with industry, it will not always be possible to avoid every conflict of interest situation. Moreover, not all conflicts of interest are the same. Some may be very serious and should be prohibited at all costs, others may be minor and could be permitted with appropriate management.

Questions for assessing the seriousness of a conflict of interest include:⁵⁸

- What is the probability that professional judgment will be influenced by financial interest and ties?
- What kinds of risks are posed?
- How serious might the consequences be?

Serious consequences include not just avoidable harm to infants and young children or to society, but also the insidious damage associated with the loss of public confidence. To draw the line between the unacceptable and the permissible, there must be an evaluation of the value of an activity to society.

Table 1* Which types of businesses should be avoided

Definitely	Any manufacturer and distributor whose main products are breastmilk substitutes, bottles or teats.
Arguably	Any manufacturer and distributor who markets other clinical products using a name clearly identified with breastmilk substitutes and feeding bottles and teats.
Not usually	Any company that sells, among other products, infant formulas, e.g. a supermarket might generally be an acceptable sponsor, but not if this was linked to their promotion of breastmilk substitutes, feeding bottles and teats.

Table 2* What sort of sponsorship should be avoided

Within an organisation or association	Reason to be avoided
The use of leaflets or posters displaying name and logo of manufacturer and distributor.	Promotes company to public in trusted environment.
Development of publications, brochures etc. on infant and young child feeding.	Link of company name to organisation enhances the credibility of company products.
Support from manufacturers and distributors for teaching sessions or meetings	Publicity will associate organisation with the company.
Support for staff salaries, equipment, or research.	Organisation will be indebted to the company, tending to stifle expressions of doubt about their products or practices.
Support for programmes.	Conveys impression that company is health-giving even if products may cause harm to children's health.
As an individual	Reason to be avoided
Accepting gifts of stationery, pens, clinical equipment.	By using them, you promote the company to your patients
Speaking at meetings sponsored by companies.	Publicity will be used to promote the company and link your name to it.
Support for attending a conference or course.	You will feel indebted to the company and be inclined to expect such support in future.

* Adapted from Wright, C. M., & Waterston, A. J. R. (2006). Relationships between paediatricians and infant formula milk companies. Archives of disease in childhood, 91(5), 383-385.

58. Richter, J. (2005) "Conflicts of Interest and Young Child Feeding". Geneva, Switzerland: IBFAN-GIFA.

Some conflicts of interest may stem from an action or relationship that is considered socially desirable. Looking at the value of an activity to society should not be interpreted as an invitation to disregard the problem of conflicts of interest.

There may be alternatives which may create fewer or less serious conflicts of interest and one should investigate how best to mitigate predictable ill effects from unavoidable conflicts of interest. **Tables 1 and 2** above may help to decide whether a conflict of interest situation is unacceptable or permissible.

It should be noted that the International Baby Food Action Network (IBFAN) is against sponsorship of any sort. In addition to IBFAN, various other organisations have resolved not to accept sponsorship from any manufacturers and distributors of products under the scope of the Code. However, some of those organisations state that they will not accept sponsorship from companies that do not comply with the Code and resolutions. The organisations include the Academy of Breastfeeding Medicine (ABM),⁵⁹ the International Society for Social Pediatrics and Child Health (ISSOP),⁶⁰ the International Lactation Consultant Association (ILCA),⁶¹ the World Alliance for Breastfeeding Action (WABA),⁶² the International Paediatric Association (IPA)⁶³ and the National WIC Association (NWA), a non-profit association that advocates for the Special Supplemental Nutrition Programme for Women, Infants and Children (WIC).⁶⁴

Taking a stand against sponsorship of events

Individual health workers are increasingly faced with the question of whether to participate in industry sponsored events such as seminars, exhibitions and conferences.

In considering whether to attend any such event, it helps to go through the following checklist:⁶⁵

- Have the event's organisers been told why sponsorship of the event is objectionable?
- Have suggestions been provided for alternative sources to fund the event?
- Is the sponsorship in any way directly "benefiting" the participant? (meals, gifts etc.)
- Will health workers compromise their ability to be a critical voice for breastfeeding protection?

If the decision has been made to participate in the event, health workers should consider whether:

- participation is tantamount to endorsing company practices?
- there could be transference of their good image onto the company and/or the event itself?
- participation might be used against them in the future?
- participation would send out mixed messages about their expressed principles?
- the meeting is likely to provide information, contacts, opportunities for learning and interaction with key actors not available elsewhere or in other ways?
- any difference would be made through their technical/strategic presentations?
- any interventions could be made to raise awareness of the sponsorship and conflicts of interest?

59. ABM Position on Breastfeeding (revised 2015) specifies that medical professionals and health care systems should have an ethical responsibility to avoid conflict of interest and to avoid support from companies that do not adhere to the Code. Retrieved from <http://www.bfmed.org/statements>.

60. ISSOP in a 2014 Position Statement on sponsorship of paediatricians/paediatric societies by manufacturers and distributors pointed out that sponsorship of medical conferences and meetings, along with gifts to health workers is "damaging to the reputation of paediatricians, to the health of mothers and infants, and to the status of breastfeeding. Retrieved from <https://www.issop.org/cmdownloads/issop-position-statement-4-sponsoring-baby-feeding-industry/#>

61. As an organisation, ILCA and its affiliates will not endorse any literature or products, or accept direct funding from manufacturers that are not meeting their obligations under the Code and resolutions. (Article 2.2 of ILCA's Organisational Bylaws). Retrieved from <http://www.ilca.org/main/about/people/board/interiorpage/organizational-documents>.

62. All WABA materials are not to be used in conjunction with or by business interests associated with the production or sale of breastmilk substitutes, related equipment, breast pumps and complementary foods. WABA does not accept sponsorship of any kind from such companies and encourages all participants of World Breastfeeding Week to respect and follow this ethical stance. Retrieved from <http://www.waba.org.my/resources/otherlanguages/guideli.htm>.

63. The IPA's guidelines for relationships with industry prohibits grants and donations from organisations or industries engaged in negative practices including violations of the International Code and other unethical marketing practices. Retrieved from http://ipa-world.org/uploadedbyfck/IPA%20Guidelines%20for%20relationships%20with%20Industry_updated%20May'14.pdf

64. Following a resolution passed in May 2015 and reaffirmed in May 2016 by voting members of the NWA that formula manufacturers are no longer invited to be members, exhibitors at conferences, advertisers or sponsors of events and activities. Retrieved from <https://www.nwica.org/statement-on-progress-towards-the-gold-standards>. WIC is a federal public nutrition programme governed by the US Department of Agriculture and the Food and Nutrition Service. The National WIC Association is not an administrative part of WIC and does not make policy for WIC programmes.

65. Modified from "Guidance for IBFAN groups and members on participation in events sponsored fully or partially by companies with commercial interest in infant and young child feeding", IBFAN-GIFA, 2006.

- if going as speakers, whether there will be an opportunity to publicly express discontent about the sponsorship in a noticeable manner e.g. in a keynote speech or on a panel?
- speeches/abstracts will be used/published in company materials or in conference announcements or reports, which also contain advertisements for breastmilk substitutes or feeding bottles and teats?
- the sponsoring company is subject to any campaign or boycott for abuses regarding labour, environment or human rights either in the country where the event is taking place or elsewhere in the world?

If the final decision is not to attend the event, the ethical reasons behind the decision should be made known to the organisers.

If the decision is made to attend, there should be an explanation of that decision to the institution the health worker is affiliated to, for accountability and consistency.

Professional associations have to act responsibly on behalf of members. The points which individual health workers must consider apply equally to associations, so the office bearers have a primary duty to question offers of sponsorship. Pressure to accept may be high. Where sponsorship is offered for events that professional associations are themselves organising, alternatives should include the option to scale down the luxury of the event such as using college or hospital auditoriums instead of five-star hotels.

Conflicts of interest principles are aimed at minimising conditions that would cause reasonable persons (patients, colleagues and citizens) to believe that professional judgement has been influenced and loyalties have been divided, whether or not that is true. Health workers and professional associations whose duties under the Code are to promote breastfeeding should steer away from any interaction with companies whose practices might be detrimental to infant and young child health.

In addition to concerns about company sponsorship, health workers must be sensitive to the changing landscape of multi-stakeholder initiatives that, by the nature of their configuration, have built-in conflicts of interest. In resolution WHA 65.6 [2012], the Director-General of WHO was requested to “develop risk assessment, disclosure and management tools to safeguard against possible conflicts of interest in policy development and implementation of nutrition programmes consistent with WHO’s overall policy and practice.”

In a technical consultation convened in response to this request, it was stressed that interactions with manufacturers and distributors could lead to the loss of independence, integrity, trustworthiness and credibility. The Code as clarified and extended by resolutions WHA 49.15, WHA 58.32, WHA 61.20 and the Global Strategy for Infant and Young Child Feeding (paragraphs 35 and 44) were identified as key tools for preventing conflicts of interest.⁶⁶

66. Chapter 3.2 External Expert Presentation (Lhotska, L). Addressing and managing conflicts of interest in the planning and delivery of nutrition programmes at country level - Report of a technical consultation convened in Geneva, Switzerland, on 8–9 October 2015. World Health Organization (2016).

"Aggressive and inappropriate marketing of breastmilk substitutes, and other food products that compete with breastfeeding, continue to undermine efforts to improve breastfeeding rates. As such, Code implementation, monitoring and enforcement remains a vital tool to ensure mothers are able to make infant feeding decisions free of market influences."

The Netcode Monitoring and Assessment Toolkit: Protocol for Ongoing Monitoring Systems. Geneva: World Health Organization; 2017.

G. Code watch by health workers

Article 11. Implementation and monitoring

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

The following resolutions explain Article 11 on Code implementation and monitoring.

Resolution WHA 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.

Resolution WHA 61.20 [2008]

Member States are urged to strengthen implementation of the International Code of Marketing of Breastmilk Substitutes and subsequent 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.

Why monitor

Monitoring is centred on fact-gathering with a view to punishing, admonishing, cautioning or reminding manufacturers and distributors about their responsibilities relating to the marketing of products under the scope of the Code. It is a whistle-blowing mechanism which has proven effective in shaming companies into behaving. Article 11.4 of the Code makes it everyone's responsibility to monitor the activities of manufacturers and distributors for compliance with the Code and resolutions. Health workers have a central role to play in monitoring because they work in settings where manufacturers and distributors focus their marketing activities. Monitoring by health workers provides important information for policy makers about marketing practices in health care settings and how these practices affect breastfeeding. The information can be the catalyst for change in the policies of health facilities in relation to their dealings with manufacturers and distributors. Where there are policies already in place, monitoring ensures that they are being observed and achievements are not eroded over time.

Monitoring may even bring about change at the national and international level through legislative reform or the power of shaming. Health workers can link with local, national and international groups so that information they collect can be systematically collated, analysed and published. The reports can in turn be adapted as advocacy tools to bring about positive changes in policies for the protection of infants and young children at all levels.

How monitoring is carried out within health care settings depends on whether or not there are provisions on monitoring in national measures. Where such provisions exist, they need to be followed. Not many national measures have monitoring provisions and they are often restricted to structures and procedures and not the practical aspects of monitoring such as where, what, who and how.

Available monitoring tools

The '**Quick and Easy Monitoring Form**' provided in **Annex 3** is a simple format devised to help in the collection of monitoring data. Health workers who are keen to report on an adhoc basis on company activities which contravene the Code will find this form useful. The form, is available in English, French, Spanish, and Chinese.

With the aim of providing easy, on-the-go access for groups and individuals wishing to participate in Code monitoring, IBFAN-ICDC has developed two new monitoring tools: the **online monitoring forms** and the **smartphone app**, both built on KoBoCollect.⁶⁷ All data submitted through these tools will instantly be transmitted to IBFAN-ICDC's KoBoCollect database.

A full set of online **monitoring forms** (the Quick & Easy, plus 7 detailed forms) adapted from ICDC's Code Monitoring Kit (revised 2015)⁶⁸ can be accessed for free on the IBFAN-ICDC website: <https://www.ibfan-icdc.org/report/>. Monitoring forms devised by IBFAN are meant for borderless community monitoring. Some groups and a few governments have adapted them for their national monitoring exercises.

The KoBoCollect **smartphone app**, available for free on all Android smartphones, allows monitoring forms to be downloaded. A set of "10 Easy Steps" instructions for monitoring with the app is available from <http://www.ibfan-icdc.org/wp-content/uploads/2017/03/KoboCollect-steps.pdf>. Monitors using iPhone can access monitoring forms on IBFAN-ICDC's website through their web browser.

In 2017, the **Network for Global Monitoring and Support for Implementation of the International Code of Marketing of Breastmilk Substitutes and subsequent relevant World Health Assembly Resolutions (NetCode)** developed a toolkit to reinvigorate and reinforce ongoing monitoring and periodic assessment of the Code and national laws. The protocols, guidance, and tools are available from <http://www.who.int/nutrition/netcode/toolkit/en/>. This toolkit is ideal for government-run monitoring but can also be used by civil society and other entities interested in establishing a monitoring system.

What to look for in health facilities

- **Free supplies:** Manufacturers and distributors are prohibited from providing any products to health facilities free or at low cost (less than 80% of the retail price). Remember: although the Code allowed free supplies under extremely limited circumstances, the provision was much abused. Consequently, the World Health Assembly passed two resolutions (WHA 39.28 [1986] & WHA 47.5 [1994]) which effectively called for an end to all free or low-cost supplies to any part of the health care system.
- **Company materials:** There should be no posters, literature, crib cards, equipment or other materials with a name, picture, logo or other reference to any product under the scope of the Code on display in a health facility. Company literature must be in accordance with Article 4.2 provisions.
- **Gifts:** Manufacturers should not distribute gifts such as pens, note pads, car stickers, bibs or toys, whether or not the item carries a product brand name.
- **Medical representatives, mother craft nurses, etc:** Company marketing personnel, no matter what they are called, should not have contact with new mothers or their families. If company personnel are in health facilities it is for the purpose of product promotion or for gathering information from the new mothers so as to contact them later, which is prohibited.

67. KoBoCollect is based on the Open Data Kit's 'ODK Collect,' and has been widely tested in extreme conditions for ease of use and reliability.

68. This kit contains a form designed specifically for monitoring in health facilities and is available for purchase from IBFAN-ICDC. Go to <https://www.ibfan-icdc.org/product/code-monitoring-kit-new/>

- **Programmes:** Any planned event or service relating to infant and young child feeding aimed at health workers or mothers.

What to look out for where health workers are concerned

- **Information materials for health professionals:** Information by manufacturers and distributors must only contain scientific and factual matters.
- **Financial or material inducements:** Manufacturers and distributors must not provide gifts in the form of money, goods, travel or services to health care workers.
- **Free samples:** Health workers can only receive free samples for professional evaluation or for research at institutional level. In no case should these samples be passed on to mothers.
- **Sponsorship:** Contributions by manufacturers and distributors for fellowships, study tours, research grants, attendance at professional conferences must be subject to disclosure to the health worker's institution and should not give rise to conflicts of interest.

Reporting on Code violations

How health workers handle Code violations they uncover depends on whether they are monitoring for the health care system as part of their duty or doing it in their personal capacity.

If monitoring is part of their duty, they need to:

- Set a time frame for analysing materials and prepare a brief report (if possible via committee). The report may be forwarded to IBFAN-ICDC for a legal check on validity and accuracy.
- Submit the report together with selected evidence as exhibits to relevant authorities.
- If there is support from relevant authorities, arrange for a dialogue with manufacturers and distributors with a view to correcting their conduct. Such meetings should have a clear agenda, and official minutes that record opinions. They should not allow any intimidation. Always ask for statements in writing and allow time for internal consultation and discussion before a decision is taken. This is particularly important if the monitoring report is being challenged.
- Where a particular practice is an offence under national law, lodge a complaint for the initiation of enforcement proceedings against errant companies.

If monitoring is carried out voluntarily by the health worker's, he or she may:

- Submit evidence of Code violations to IBFAN-ICDC which has a continuous global Code monitoring programme. IBFAN-ICDC publishes periodical reports to highlight practices of Code violators.
- Where a particular practice is an offence under national law, lodge a complaint for the initiation of enforcement proceedings against errant companies.

Monitoring under the 2016 Guidance on ending the inappropriate promotion of foods for infants and young children

Resolution WHA 69.9 [2016] calls on Member States to establish a system for monitoring and evaluation of the 2016 Guidance. No such system exists at the time of writing but the implementation manual⁶⁹ for the 2016 Guidance contains some useful suggestions on processes, mechanisms and desired outcomes. With the aim of promoting, protecting and supporting breastfeeding, health workers can extend their watch to activities prohibited under recommendations 4, 5 and 6 of the 2016 Guidance (see pp. 17,22 and 28). This is coherent with their existing responsibilities under the Code.

69. Chapter IV. Guidance on ending the inappropriate promotion of foods for infants and young children: implementation manual. Geneva: World Health Organization; 2017. Retrieved from <http://www.who.int/nutrition/publications/infantfeeding/manual-ending-inappropriate-promotion-food/en/>

H. HIV, breastfeeding and the Code

Risk of HIV infection in infants and young children

Breastfeeding is one of the most valuable interventions to improve the health and chances of survival for the majority of babies of HIV-positive mothers. Although there is the risk that HIV-positive women can transmit HIV to their child during pregnancy, childbirth or breastfeeding,⁷⁰ this should not be used to undermine breastfeeding.

When the WHO HIV and Infant Feeding Technical Consultation was held in Geneva in 2006, there was insufficient data to support the use of anti-retrovirals (ARVs) to prevent transmission through breastfeeding. However, evidence has since surfaced to support the efficacy of ARV drug treatments. When properly adhered to by HIV-positive mothers, HIV-exposed infants,⁷¹ or pregnant or breastfeeding women who are at risk of acquiring the virus,⁷² ARVs can significantly reduce the risk of HIV transmission through breastfeeding.

Important changes have been made to the 2006 WHO Guidelines on HIV and Infant Feeding in 2010,⁷³ 2012⁷⁴ and 2016.⁷¹ At the time of writing, the global recommendation is that mothers living with HIV should breastfeed for at least 12 months (early initiation and exclusive breastfeeding for the first six months) and may continue breastfeeding for up to 24 months or longer, while being fully supported for antiretroviral therapy (ART) adherence.⁷¹ This has significant implications on infant feeding in the context of HIV and on how health workers should counsel HIV-positive mothers.

The Code is of particular relevance in this context, as misinformation on the risks associated with paediatric HIV (such as the false idea that all breastfed babies of HIV-positive mothers get infected) can become an argument for companies to justify their promotional activities (e.g. unsolicited supplies, charitable donations or discounts).

New guidelines for HIV and infant feeding

This part of CE 3 offers an overview of WHO recommendations on HIV and infant feeding, and includes a discussion on the significance of the Code and relevant WHA resolutions in protecting breastfeeding in the context of HIV. CE 3's focus is Code-centric and is not aimed at providing medical recommendations on HIV and infant feeding. For specifics, readers should refer to the WHO documents cited.

a. *The 2010 Guidelines: Key principles and recommendations*

In 2010, WHO revised its previous guidelines in which women living with HIV were counselled on feeding options according to their household circumstances. This individualised approach was replaced by the recommendation of ARV treatment to prevent postnatal transmission of HIV through breastfeeding.⁷³ The key principles and recommendations of the 2010 Guidelines, all of which remain valid except where indicated, are:

- Infant feeding practices recommended to mothers should balance HIV prevention with protection from other causes of child mortality.
- National authorities should integrate HIV testing, care and treatment interventions for all women into maternal and child health services.

70. WHO. Mother-to-child transmission of HIV. Retrieved from <http://www.who.int/hiv/topics/mtct/about/en/>

71. WHO & UNICEF. Guideline: Updates on HIV and infant feeding: the duration of breastfeeding, and support from health services to improve feeding practices among mothers living with HIV. Geneva: World Health Organization; 2016. Retrieved from http://www.who.int/maternal_child_adolescent/documents/hiv-infant-feeding-2016/en/

72. WHO Technical brief: Preventing HIV during pregnancy and breastfeeding in the context of pre-exposure prophylaxis (PrEP). Geneva: World Health Organization; 2017. Retrieved from <http://www.who.int/hiv/pub/toolkits/prep-preventing-hiv-during-pregnancy/en/>

73. Guidelines on HIV and Infant Feeding: Principles and Recommendations for Infant Feeding in the Context of HIV and a Summary of Evidence. World Health Organization. 2010. Retrieved from http://www.who.int/maternal_child_adolescent/documents/9789241599535/en/

74. WHO Guidelines on HIV and Infant Feeding 2010: An Updated Framework for Priority Action. World Health Organization. 2012. Retrieved from http://www.who.int/maternal_child_adolescent/documents/9241590777/en/

- National (or subnational) authorities should decide which infant feeding practice should be promoted and supported as national policy– either breastfeeding with an ARV intervention OR avoidance of all breastfeeding⁷⁵- a paradigm shift from the previous individualised approach.
- When ARV drugs are not available, breastfeeding may still provide infants born to mothers living with HIV a greater chance of HIV-free survival. Mothers should be counselled to exclusively breastfeed for the first six months and continue breastfeeding thereafter unless environmental and social circumstances are safe for and supportive of replacement feeding. Meanwhile, every effort should be made to accelerate access to ARV drugs for both maternal health and preventing HIV transmission to infants.
- Counselling and support for mothers known to be living with HIV should be carefully delivered so as to avoid undermining optimal breastfeeding practices among the general population.

Recommendations:

- Mothers known to be living with HIV should be provided with lifelong ART or ARV drug prophylaxis interventions to reduce HIV transmission through breastfeeding.
- Where national authorities have adopted promoting breastfeeding and ARV drug interventions as the chosen strategy, mothers living with HIV should exclusively breastfeed their infants for the first six months of life,⁷⁶ introducing appropriate complementary foods thereafter and continuing to breastfeed for the first 12 months of life.
- If mothers living with HIV decide to stop breastfeeding they should do so gradually over one month. Those receiving ARV drug prophylaxis should continue this for one week after breastfeeding has fully stopped.⁷⁷
- When mothers stop breastfeeding, only commercial infant formula milk and heat-treated expressed breastmilk are alternatives for replacement feeding infants under six months. For infants over six months, commercial infant formula milk or animal milk (boiled for those under 12 months) is suitable.
- The AFASS acronym (acceptable, feasible, affordable, sustainable and safe) for conditions of replacement feeding used prior to 2010 is replaced with simpler and more explicit meanings of the concepts. Necessary conditions for replacement feeding are now:
 - i. safe water and sanitation at household level; ii. caregiver's ability to reliably provide sufficient infant formula to support infant's normal growth and development; iii. caregiver's ability to prepare it cleanly and frequently enough to ensure it does not pose risks of diarrhoea and malnutrition; iv. caregiver's ability to give infant formula exclusively for the first six months; v. family support; and vi. access to healthcare that provides comprehensive child health services.
- Mothers living with HIV may consider expressing and heat-treating breastmilk as an interim feeding strategy.
- If infants are known to be living with HIV, mothers are encouraged to exclusively breastfeed for the first six months and continue breastfeeding up to 2 years or beyond.

b. *Revised recommendations in the 2016 HIV and Infant Feeding Guideline*

The WHO consolidated guidelines on ARV use for treating and preventing HIV infection were updated in 2013 and 2016.⁷⁸ Lifelong ART for all adults (including pregnant and breastfeeding women) and children from the time when HIV is first diagnosed is now recommended.

75. Taking into consideration the socioeconomic and cultural contexts of the populations served, availability and quality of health services, the epidemiological prevalence, and main causes of maternal and child under-nutrition and infant and child mortality.

76. The recommended duration of breastfeeding and HIV treatment is revised in the 2016 Guideline (fn 71).

77. This recommendation remains valid but lifelong ART is now recommended instead of ARV drug prophylaxis.

78. WHO Consolidated Guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. Retrieved from <http://www.who.int/hiv/pub/arv/> pub/arv/arv-2016/en/ (See also "What's new in treatment monitoring viral load and CD4 testing" retrieved from <http://www.who.int/hiv/pub/arv/treatment-monitoring-info-2017/en/>)

As a result of these changes, the Guideline on HIV and Infant Feeding was reviewed and updated in 2016.⁷¹ The latest recommendations on HIV and infant feeding are:

- Mothers living with HIV should breastfeed for at least 12 months and may continue breastfeeding for up to 24 months or beyond (similar to the general population) while being fully supported for ART adherence.⁷⁹
- National and local health authorities should actively coordinate and implement health services or activities in workplaces, communities and homes to protect, promote and support breastfeeding among women living with HIV.

The 2016 HIV and Infant Feeding Guideline also prescribes some guiding practice statements:

- ARV treatment reduces the risk of postnatal HIV transmission in case of mixed feeding. Although exclusive breastfeeding is recommended, mixed feeding is not a reason to stop breastfeeding in the presence of ARV drugs.
- Duration of breastfeeding of less than 12 months is better than never initiating breastfeeding.

The Code, HIV and infant feeding

Although there was comparatively less awareness about HIV when the Code was adopted in 1981, the Code is relevant to mothers who are HIV-positive and fully covers their needs. The Code and resolutions aim to prevent manufacturers from donating supplies of breastmilk substitutes or providing them at a reduced price to any part of the health care system. Governments are not prevented from making breastmilk substitutes available to HIV-positive mothers for free or at a subsidised price when the products are procured through normal channels (resolution WHA 39.28 [1986]).

The WHO Updated Framework for Priority Action (2012)⁷⁴ highlights that implementation and enforcement of the Code and resolutions is one of the priority actions for governments in relation to the special circumstances created by HIV/AIDS. Implementation and enforcement should be done with the aim to:

- protect breastfeeding as the recommended infant feeding practice for mothers living with HIV (with lifelong ART);
- protect those who are formula fed by ensuring product labels contain necessary information for safe preparation and consumption, and the independence of choice that is free from commercial influence; and
- avoid spillover of breastmilk substitutes to the general population.

Role of health workers

Health workers must:

- make sure monitoring takes place to ensure Code compliance in healthcare facilities.
- ensure there is no donation of supplies of breastmilk substitutes or reduced-price offer to any part of the healthcare system.
- ensure proper procurement and distribution of supplies of breastmilk substitutes at health facilities.
- ensure the conduct of manufacturers and distributors conforms to the Code.
- ensure response to the HIV pandemic does not lead to Code violations, and the prevalence of HIV is not used to misinform and undermine Code compliance and importance of breastfeeding.
- not accept financial support and other incentives for programmes and health professionals that create conflicts of interest.
- Raise awareness on the importance of the Code in healthcare settings and its relevance in the context of HIV to prevent companies from capitalising on the fear of HIV transmission.

79. Recommended breastfeeding practice and condition for stopping breastfeeding remain unchanged from 2010: exclusively breastfeed infants for the first six months, introducing appropriate complementary food thereafter and continue breastfeeding. Breastfeeding should then only stop once a nutritionally adequate and safe diet without breastmilk can be provided.

I. BFHI and the Code

Foundation for breastfeeding in health facilities

The Baby-friendly Hospital Initiative (BFHI) was launched in 1991 by WHO and UNICEF as a global programme to improve breastfeeding support in maternity and newborn facilities. The basis of the BFHI is the adherence of the **Ten Steps to Successful Breastfeeding**⁸⁰ in the care of mothers and infants and compliance with the International Code of Marketing of Breastmilk Substitutes and resolutions in maternity hospitals.⁸¹

BFHI was updated in 2006 and after extensive user surveys, was re-launched in 2009. The revised BFHI implementation tools⁸² provided additional recommendations for expansion into other parts of health care and community settings. These included maternal care, paediatric units, community health clinics, etc. It took into consideration guidance provided by the Global Strategy for Infant and Young Child Feeding as well as the challenges posed by the HIV pandemic.

Importantly, the revised materials also expanded the component dealing with issues of compliance with the Code and resolutions. Facilities that documented their full adherence to the Ten Steps, as well as their compliance with the Code and resolutions could be designated “Baby-friendly” after an external audit.

In 2015, WHO and UNICEF began a process to re-evaluate and adapt the BFHI programme. A new guideline published in 2017⁸³ examines each of the practices in the Ten Steps in order to bring together evidence and considerations to inform practice.

This guideline provides global, evidence-informed recommendations on protection, promotion and support for breastfeeding in facilities that provide maternity and newborn services, as a public health intervention, to protect, promote and support optimal breastfeeding practices, and improve nutrition, health and development outcomes. It recognises that to create an enabling environment for breastfeeding, facilities providing maternity and newborn services should have a clearly written breastfeeding policy to underpin the quality standards for promoting, protecting and supporting breastfeeding and that must be routinely communicated to staff and parents. The policy should incorporate provisions of the Code and resolutions.

In 2018, an updated implementation guidance incorporating the first revision of the Ten Steps since 1989 was published.⁸⁴

This implementation guidance re-organises and rewords the Ten Steps while maintaining the basic theme of each step.

The requirement to comply fully with the Code and resolutions is incorporated into Step 1 which is separated into two sub-steps to address the management procedures necessary to ensure that care is delivered consistently and ethically. The other eight steps standards for clinical care of mothers and infants.

The updated Ten Steps is presented in Box 1.

"Step 1 on facility breastfeeding policy has been modified to include three components. Application of the Code has always been a major component of the BFHI but was not included as part of the original Ten Steps. This revision explicitly incorporates full compliance with the Code as a step."

Implementation guidance: protecting, promoting and supporting breastfeeding in facilities providing maternity and newborn services – the revised Baby-friendly Hospital Initiative. Geneva: World Health Organization; 2018 at p.14.

80. The Ten Steps, published two years before the launch of BFHI, summarises the practices and policies necessary to support breastfeeding and laid the foundation of BFHI.

81. National Implementation of the Baby-friendly Hospital Initiative, 2017. Geneva: World Health Organization; 2017. Retrieved from <http://www.who.int/nutrition/publications/infantfeeding/bfhi-national-implementation2017/en/>.

82. UNICEF/WHO. Baby-friendly Hospital Initiative, revised, updated and expanded for integrated care, Section 1, Background and implementation, January 2009.

83. Guideline: protecting, promoting and supporting breastfeeding in facilities providing maternity and newborn services. Geneva: World Health Organization; 2017. Retrieved from <http://www.who.int/nutrition/publications/guidelines/breastfeeding-facilities-maternity-newborn/en/>.

84. Implementation guidance: protecting, promoting and supporting breastfeeding in facilities providing maternity and newborn services – the revised Baby-friendly Hospital Initiative. Geneva: World Health Organization; 2018. Retrieved from: <http://www.who.int/nutrition/publications/infantfeeding/bfhi-implementation/en/>

Box 1

Ten Steps to Successful Breastfeeding (revised 2018)⁸⁴

Critical management procedures

1. a. Comply fully with the International Code of Marketing of Breast-milk Substitutes and relevant World Health Assembly resolutions.
b. Have a written infant feeding policy that is routinely communicated to staff and parents.
c. Establish ongoing monitoring and data-management systems.
2. Ensure that staff have sufficient knowledge, competence and skills to support breastfeeding.

Key clinical practices

3. Discuss the importance and management of breastfeeding with pregnant women and their families.
4. Facilitate immediate and uninterrupted skin-to-skin contact and support mothers to initiate breastfeeding as soon as possible after birth.
5. Support mothers to initiate and maintain breastfeeding and manage common difficulties.
6. Do not provide breastfed newborns any food or fluids other than breast milk, unless medically indicated.
7. Enable mothers and their infants to remain together and to practise rooming-in 24 hours a day.
8. Support mothers to recognize and respond to their infants' cues for feeding.
9. Counsel mothers on the use and risks of feeding bottles, teats and pacifiers.
10. Coordinate discharge so that parents and their infants have timely access to ongoing support and care.

Step 1 on management procedures has been modified to include three components. Application of the Code and resolutions has always been a major component of the BFHI but was not included as part of the original Ten Steps. This revision explicitly incorporates full compliance with the Code and resolutions as a step. In addition, the need for ongoing internal monitoring of adherence to the clinical practices has been incorporated into Step 1.

The Code and resolutions lay out clear responsibilities of health-care systems to not promote products under the scope of the Code and to not be used by manufacturers and distributors for this purpose. This means all facilities providing maternity and newborn services must acquire any breast-milk substitutes, feeding bottles or teats they require through normal procurement channels and not receive free or subsidised supplies. Furthermore, staff of facilities providing maternity and newborn services should not engage in any form of promotion or permit the display of any type of advertising of breast-milk substitutes, including the display or distribution of any equipment or materials bearing the brand of manufacturers of breastmilk substitutes, or discount coupons, and they should not give samples of infant formula and other products under the scope of the Code mothers to use in the facility or to take home.

In line with the 2016 WHO Guidance on ending the inappropriate promotion of foods for infants and young children, health workers and health systems should avoid conflicts of interest with companies that market foods for infants and young children.⁸⁵ This is coherent with their existing responsibilities under the Code. In practice, this means prohibition of sponsorship, educational materials for parents and health care workers, lunches, gifts, etc. from industries who manufacture and distribute products that come under the scope of the Code.

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

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. ^{^ 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.

¹ 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]

⁶ A69/7 Add.1

Relevant World Health Assembly resolutions summary

Year	Number	Resolutions
1981	WHA 34.22	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Recognises that commercial promotion of breastmilk substitutes contributes to an increase in formula feeding and calls for renewed attention to implement and monitor the Code at national and international levels.
1984	WHA37.30	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Requests the Director General to provide legal and technical assistance to Member States in drafting national measures to implement the Code
1990	WHA43.3	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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)	<p>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.</p>
2016	WHA69.9	<p>This Resolution welcomes the WHO Guidance on ending the inappropriate promotion of foods for infants and young children. It calls upon</p> <ol style="list-style-type: none"> Member States to take all necessary measures to implement the Guidance 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.

Quick & Easy Form

IBFAN continuously compiles violations and welcomes your input

Have you noticed any company practices lately which violate the International Code or subsequent resolutions? Or which discourage breastfeeding? If so, help us collect the information by photocopying and completing the form below and sending it to - IBFAN-ICDC, P.O. Box 19, 10700 Penang, Malaysia. E-mail: code@ibfan-icdc.org
An electronic form is also available online at <https://www.ibfan-icdc.org/report/>

Name: Which IBFAN group, if any:

Address:

E-mail:

The above information is necessary to enable IBFAN-ICDC to double-check the information you have given, if necessary.
Your identity will be kept confidential

Description of Code violation (please answer all questions, especially the when, where, who, what and how)

1. Short description (include heading or slogan found on company materials)
2. **When** was the violation observed? (dd/mm/yyyy)
3. **Where?** (place, city and country)
4. **Who** is violating the Code and **how?**

Company	Brand	Type of product ¹	Type of violation ²

- ¹ Type of product

A. Infant formula including special formula

B. Follow-up formula

C. Growing-up milk

D. Cereal

E. Fruit/vegetables/meat puree

F. Juice/tea/mineral water

G. Bottle

H. Teat

L. Other (write under 'type of product')
- ² Type of violation

A. Advertisement - in print/online

B. Commercial promotion in health facility

C. Company contact with mothers - in person/via internet/social media/phone app

D. Donation of products to health facilities

E. Free sample

F. Gift to health worker

G. Gift to mothers

H. Inadequate labelling

I. Promotion in shops

J. Sponsorship

K. Other (please explain, use another sheet of paper if necessary)

If specimen or picture is attached, tick here ☐

5. **Observation/details** (please use another sheet of paper if necessary)

• Where possible, include actual specimen, photographs or scanned images of Code violations with your form



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 manufacturers and distributors 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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