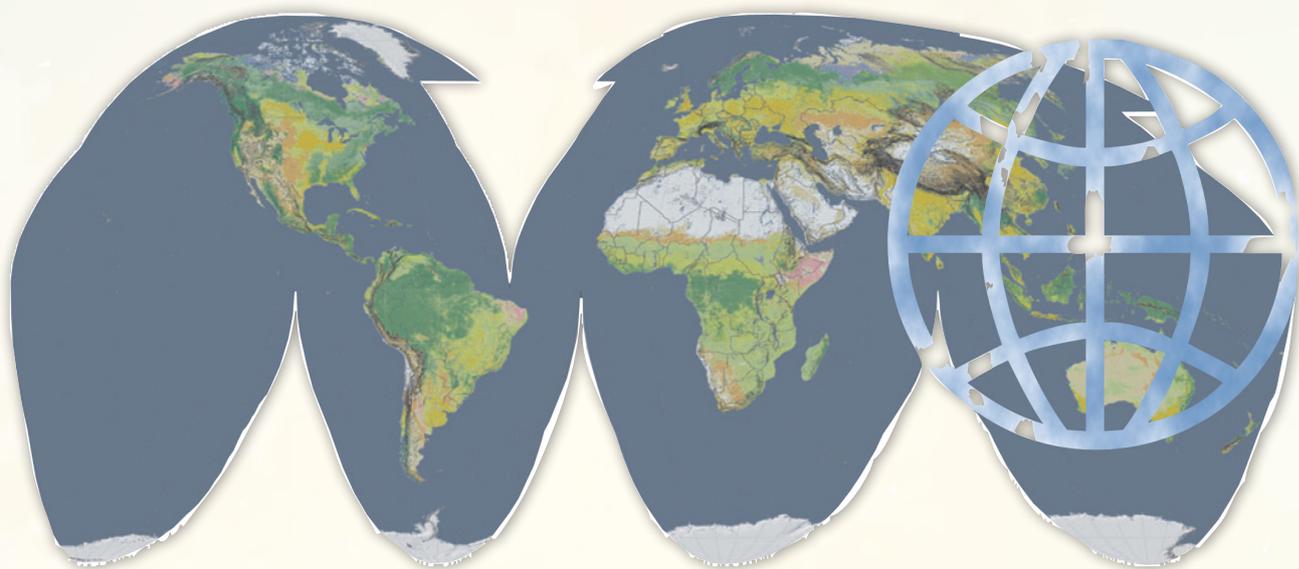


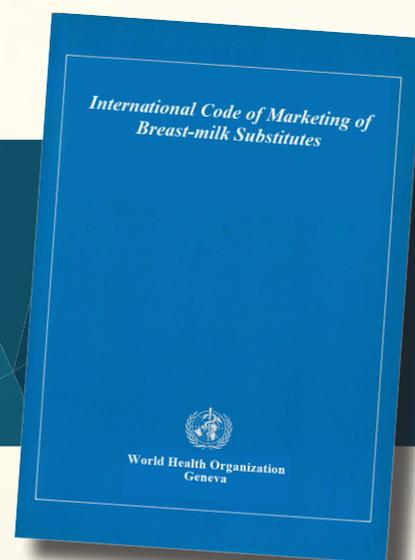
Code Essentials 2:

Guidelines for Policy Makers on Implementing the International Code of Marketing of Breastmilk Substitutes and subsequent WHA resolutions

Second Edition



2



INTERNATIONAL
CODE
DOCUMENTATION CENTRE

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Substitutes and subsequent
WHA resolutions

Second Edition



International Baby Food Action Network
International Code Documentation Centre

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

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© ICDC Penang, Malaysia, February 2018

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ISBN 978-983-9075-32-8

Published by

IBFAN Sdn Bhd
PO Box 19, 10700 Penang, Malaysia
Tel: +60 4 890 5799
Email: code@ibfan-icdc.org
www.ibfan-icdc.org

Printed by

Visual Pro Creative Sdn. Bhd., Penang

Suggested citation

IBFAN-ICDC (2018). Code Essentials 2: Guidelines for Policy Makers on Implementing the International Code of Marketing of Breastmilk Substitutes and subsequent WHA resolutions. Penang: IBFAN S/B.

First Edition February 2009

Second Edition February 2018

First Reprint, May 2018

Acknowledgments

Thanks to Jean-Pierre Allain and Alessia Bigi for their valuable comments and to David Clark, Ellen Sokol and Elisabeth Sterken for their input in the revision of the Model Law in Annex 4.

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"Breastfeeding is one of the smartest investments a country can make to build its future prosperity. It offers children unparalleled health and brain-building benefits. It has the power to save the lives of women and children throughout the world, and the power to help national economies grow through lower healthcare costs and smarter workforces. Yet many societies are failing to adequately support women to breastfeed, and as a result, the majority of the world's children - along with a majority of the world's countries - are not able to reap the full benefits of breastfeeding."

Global Breastfeeding Collective. (2017). Nurturing the Health and Wealth of Nations: The Investment Case for Breastfeeding. New York, NY.: UNICEF.

Preface

Experts on child health have repeatedly emphasised that breastfeeding is one of the highest impact interventions providing benefits for children, women, and society. If scaled up to nearly universal levels, breastfeeding could save more than 800,000 child lives and add more than \$300 billion to the global economy each year. This will be a key driver in achieving the 2030 Sustainable Development Goal (SDG) of ending hunger, achieving food security and improving nutrition (SDG 2). Countries will also be set on the right path to achieving the SDGs of improving health, ending poverty, promoting economic growth, reducing inequalities and ensuring sustainable consumption.

Yet, the practice of breastfeeding continues to decline. Most babies worldwide are not breastfed according to WHO guidelines, and baby food manufacturers and distributors continue to prosper through successful marketing. Estimates suggest that the global sales of baby milk formula will be worth USD \$71 billion by 2019, with growth expected to be more than 20 times higher in developing countries as opposed to developed ones. The baby food industry spends within the range of USD 4-6 billion (10-15% of its global sales) on marketing and promotion of formula milks. The increase of formula sales volume indicates that these marketing strategies are effective, underscoring the importance of comprehensive legislation to curb marketing practices.

A multi-pronged approach is needed to provide (i) an environment that protects, promotes, and supports breastfeeding; (ii) quality breastfeeding education for both health workers and women; (iii) supportive health services and community programmes; (iv) imaginative maternity legislation and (v) protection from commercial promotion. Regulating the baby feeding industry would be a critical step towards creating a more favourable environment for breastfeeding, and government leadership in this respect is crucial.

Code Essentials 2 (CE 2) lays out how governments can best implement the International Code of Marketing of Breastmilk Substitutes and subsequent World Health Assembly resolutions. (For brevity, collectively referred to as the 'Code and resolutions' or 'the International Code'). CE 2 contains four parts:

- Part A introduces the reader to the background of the Code and resolutions (summarised in Annexes 1 and 2) and gives an overview on how these, and other instruments, protect mothers, health workers and the health care system. This is followed by a discussion of the Code's legal status and how countries give effect to the Code and resolutions. A listing of countries grouped according to the steps they have taken to implement the Code and resolutions appears in Annex 3.
- Part B examines each article of the Code as well as the relevant WHA resolutions and explores how they are dealt with in selected countries. The suggested text for national implementation is found in a Model Law in Annex 4. Countries can emulate and adapt to suit their social and legislative framework.

- Part C focuses on the importance of monitoring and suggests practical ways to organise monitoring at the national level.
- Part D tackles other issues which are normally raised during the Code implementation process, suggests ways in which they can be handled and guides readers to relevant publications on the topics discussed.

CE 2 also addresses the following:

- What legal instruments will best give effect to the provisions of the Code and resolutions.
- What specific steps need to be taken before the law making process begins.
- How to draft effective and enforceable legal provisions based on the Code and resolutions. CE 2 incorporates a Model Law which countries can follow or adapt.
- What promotional practices constitute Code violations and how to set up a monitoring system with a view to enforcing Code-based laws.

The discussion of these points in CE 2 will assist legislators and policy makers in drafting laws that are appropriate to their individual country situation. Governments with no national measures and those that seek to review and strengthen existing measures will also find this publication useful.

Although CE 2 can stand on its own, users are encouraged to read it in conjunction with **Code Essentials 1: Annotated International Code of Marketing of Breastmilk Substitutes and subsequent WHA resolutions** to gain a deeper understanding of the Code and resolutions.

ICDC appreciates the support from UNICEF East Asia and Pacific Regional Office to produce this edition of Code Essentials 2. Although intended for the Asia Pacific region, this publication will also be useful in other regions since the Code and resolutions are universal in their application.

IBFAN-ICDC
Penang
February 2018

This is the second in a series of four booklets on the International Code of Marketing of Breastmilk Substitutes and subsequent WHA resolutions. Each one can stand on its own and is aimed at a different category of readers.

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

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

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

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

" Breastfeeding is one of the smartest investments to boost human capital, stimulate economic growth and give every child the same opportunity to thrive."

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

"Leadership is needed to pass and enforce national laws and policies that reflect the collective responsibility to protect, promote and support breastfeeding. By enacting legislation to restrict the marketing of breastmilk substitutes – and monitoring its compliance – governments can act against unethical business practices and send the message that breastfeeding matters."

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

Part A Introduction

The World Health Assembly (WHA), the forum of Member States that governs the World Health Organization (WHO) and sets its health policies, adopted the International Code of Marketing of Breastmilk Substitutes as a recommendation in 1981 through resolution WHA 34.22.

The resolution stresses that the adoption of and adherence to the Code is **a minimum requirement**, and Member States are expected to give effect to the principles and aim of the Code **in their entirety**. Member States may therefore adopt additional or stronger provisions than those set out in the Code, however, they must not omit or dilute any of its provisions. **For the Code to take legal effect at the national level, it must first be translated into legislation, regulations or other suitable measures as appropriate to the social and legislative framework of the implementing country.**

There is only one version of the Code, but many subsequent WHA resolutions adopted since 1981 clarify or extend issues covered by the Code.¹ These resolutions keep the Code up-to-date with evolving marketing trends and the latest scientific knowledge. When implementing the Code nationally, legislators must read it together with subsequent WHA resolutions.²

Code implementation is only one of several important actions required to protect optimal infant and young child feeding practices. On its own, it will not improve breastfeeding rates. For that to happen, health authorities must introduce a multi-pronged approach which includes quality breastfeeding education for health workers and women; supportive health services and community programmes and imaginative maternity legislation.

The marketing of breastmilk substitutes negatively affects breastfeeding. Global sales in 2014 of USD 44.8 billion show the industry's large and competitive claim on infant feeding. Unlike other commodities, baby milk formula seems resilient to market downturns, and by 2019 its market value is projected to reach USD 70.6 billion.³ The Code not only keeps competition posed by marketing practices at bay so that breastfeeding has a chance to thrive, but also empowers women to make informed decisions on infant and young child feeding, free from commercial pressures. While the Code does not prohibit the availability of breastmilk substitutes, it does restrict promotional practices and directs health authorities to encourage and promote breastfeeding by providing objective and consistent information. For infants who are artificially fed, the Code seeks to minimise health risks by requiring appropriate labelling of products and warnings on information materials.

There is compelling evidence to support Code implementation at the national level for the protection of breastfeeding. In January 2016, the British medical journal *The Lancet* published a major new series on breastfeeding, which represents the most in-depth analysis done to-date on the health and economic benefits that breastfeeding can produce.

1. The International Code of Marketing of Breastmilk Substitutes: Frequently Asked Questions (2017 Update), Geneva, Switzerland, World Health Organization; 2017. The resolutions are WHA 35.26, 37.30, 39.28, 41.11, 43.3, 45.34, 46.7, 47.5, 49.15, 54.2, 55.25, 58.32, 59.11, 59.21, 61.20, 63.23, 65.6, 69.9. There is also a decision adopted on maternal, infant and young child nutrition in 2014, WHA 67(9) that focused among other things on indicators to achieve global nutrition targets including Code implementation. Under Article 23 of the WHO Constitution, the normative weight given to resolutions and decisions is the same.
2. The full text of the Code and resolutions are also available at www.who.int/nutrition/netcode/resolutions/en/.
3. Euromonitor (2016) Market overview: Identifying new trends and opportunities in the global infant formula market. Retrieved from <https://www.slideshare.net/Euromonitor/market-overview-identifying-new-trends-and-opportunities-in-the-global-infant-formula-market>.

The first paper⁴ in the Series confirms what health advocates have known all along– that breastfeeding improves the survival, health, and development of all children. It saves women’s lives and contributes to human capital development. The benefits span populations living in high-income, middle-income, and low-income countries.

The second paper⁵ summarises the evidence on determinants of, and interventions to improve, breastfeeding practices. It discusses the effect the baby food industry has on breastfeeding practices and explores the reasons why some countries have been more successful in improving breastfeeding rates than others. The paper concludes from a review of the evidence that political support and financial investment are needed to protect, promote, and support breastfeeding. It underscores that best outcomes are achieved when interventions are implemented concurrently through several channels. Action points suggested to approach the challenges faced by breastfeeding include:

- The robust dissemination of evidence on breastfeeding’s fundamental role for both rich and poor societies, so that the value of breastfeeding is recognised.
- Fostering positive societal attitudes towards breastfeeding by reinforcing a “breastfeeding culture,” and a vigorous defence against incursions of a “bottle feeding culture” through expert social marketing and communication innovations.
- Mainstreaming breastfeeding into preventive measures for non-communicable diseases for both children and women, as well as for the prevention of morbidity and mortality from infections of early childhood. The economic gains provided by breastfeeding should be fully appreciated and evaluated when funding for the promotion and protection of breastfeeding is assessed.
- Regulating the multimillion dollar breastmilk substitute industry. No new interventions are needed - the Code is an effective mechanism for action. However, the paper stressed that much greater political commitment is needed to enact and enforce the relevant, comprehensive legislation and national investment to ensure implementation and accountability. Without these commitments, agreed principles of responsible marketing will continue to be violated.
- Scaling up and monitoring breastfeeding interventions and trends in breastfeeding practices. Interventions to support women in their homes, communities and through health services are effective, if tailored in response to patterns of suboptimal breastfeeding in each given setting.
- Enabling interventions to remove structural and societal barriers that hinder women’s ability to breastfeed. Legislation and accountability mechanisms should ensure that maternity protection and workplace interventions that support breastfeeding are implemented, and that all maternity health services comply with the Code and the Baby Friendly Hospital Initiative.

The paper states that knowledge of the baby food market and marketing practices are essential for understanding the competing environment in which efforts to protect, promote, and support breastfeeding operate. It reviewed studies which show that:

- Marketing by the baby food industry and the availability of formula, including the distribution of free samples, increases rates of bottle-feeding.
- Formula advertisements portray baby milk to be as good as or better than breastmilk, or present it as a lifestyle choice rather than a decision with health and economic consequences.
- Media is an important source of information. Mothers’ recollection of formula advertisements is associated with decreased breastfeeding.
- Marketing messages can also convey that breastfeeding is difficult, or that breastmilk substitutes help to settle fussy babies.
- Gifts of free milk samples are associated with shorter breastfeeding duration.
- The baby food industry often sponsors health professional associations. This might introduce conflicts of interest in their support of breastfeeding.

4. 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.

5. 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.

It is estimated that the baby food industry spends 10-15% of its global sales on marketing and promotion of formula milks.⁶ This is around USD 4-6 billion – a figure comparable to the WHO’s annual budget.⁷ The observed increase of formula sales volume⁸ indicates that these marketing strategies are effective. This underscores the importance of comprehensive legislation to curb inappropriate marketing practices, with adequate monitoring and meaningful penalties, to protect breastfeeding.

1. Orientation to the Code and resolutions

The Code and resolutions restrict inappropriate marketing practices and cover any product marketed or represented as suitable to replace, either partially or totally, the breastmilk part of the baby’s diet.

The following products come under the **scope** of the Code:

- **Infant formula:** Any preparation intended to satisfy the nutritional requirements of infants from birth until six months or older. In some countries infant formulas are marketed for infants up to 12 months. Infant formula includes 'special' formulas such as soy formula, lactose-free formula, low-birth-weight/premature formula and therapeutic milks.
- **Other milk products** that are represented as suitable for use as a partial or total replacement of breastmilk. In practical terms, this includes **follow-up formula** and **growing-up milk** marketed for babies between six months to three years.⁹
- **Any other food or beverage that is represented as suitable to be fed to infants less than six months old.** This covers products such as complementary foods and drinks labelled as suitable for use for infants below six months of age, for instance cereals, gruels, infant dinners, pureed vegetables, fruits or meats in ready-to-feed jars, infant teas, herbal drinks, baby biscuits, mineral water and juices.
- **Feeding bottles and teats:** This includes feeding bottles attached to or distributed with breast pumps. In some countries, teats are interpreted to include pacifiers.

Since infants need other foods in addition to breastmilk after six months, **complementary foods marketed for babies above six months** do not come under the scope of the Code. However, if complementary foods are promoted or represented as suitable for infants less than 6 months, or in a manner that suggests they can be fed by bottle, then these products fall under the scope of the Code.

Countries may include complementary food products for infants older than six months in the scope of their national laws as a multi-faceted response to address unethical promotion of foods for infants and young children. This can be done by integrating the recommendations of the Guidance on ending the inappropriate promotion of foods for infants and young children.¹⁰ Even before this Guidance was issued, a number of countries have gone beyond the minimum standard set by the Code to include complementary foods in the scope of their national laws. Like breastmilk substitutes, promotion of these products is banned. Countries are entitled to do so.

6. Baker, P., Smith, J., Salmon, L., Friel, S., Kent, G., Iellamo, A., ... & Renfrew, M. J. (2016). Global trends and patterns of commercial milk-based formula sales: is an unprecedented infant and young child feeding transition underway?. *Public health nutrition*, 19(14), 2540-2550.

7. Changing Markets Foundation (2017). *Milking it-How milk formula manufacturers and distributors are putting profits before science*. www.changingmarkets.org.

8. In 2008–2013, world total formula sales grew by 40.8% from 5.5 to 7.8 kg per infant/child/year, a figure predicted to increase to 10.8 kg by 2018. Growth was most rapid in East Asia particularly in China, Indonesia, Thailand and Vietnam and was led by the infant and follow-up formula categories. (see footnote 6).

9. In May 2016, the World Health Assembly issued the Guidance on ending the inappropriate promotion of foods for infants and young children. The Guidance confirms that breastmilk substitutes should be understood to include any milks that are specifically marketed for the feeding of infants and young children up to the age of 3 years, including follow-up formula and growing-up milk. Resolution WHA 69.9 [2016] welcomes the Guidance as a means to further strengthen the Code and to protect optimal infant and young child feeding practices.

10. WHO (2016). A69/7 Add.1 (Recommendations 4,5 and 6) . Retrieve from: www.apps.who.int/gb/ebwha/pdf_files/WHA69/A69_7Add1-en.pdf

The Code and WHA resolutions aim to shield breastfeeding from commercial promotion that affects mothers, health workers and health care systems.

a. Mothers

- Information and educational materials on infant and young child feeding should be objective and consistent and emphasise the importance of breastfeeding. In no case should such materials refer to a brand name of a product.¹¹
- All forms of product advertising and promotion are prohibited.
- Mothers should not be given free product samples.
- Promotional devices such as discounts and special displays at the retail level are prohibited.
- Company representatives may not initiate direct or indirect contact with mothers.
- Health risks to infants who are artificially fed or who are not exclusively breastfed should be highlighted through appropriate labelling and warnings.

b. Health workers

- The Code gives health workers the responsibility to encourage and protect breastfeeding.
- Materials regarding products given to health professionals by manufacturers and distributors should be limited to 'scientific and factual' matters. They should not be tools for promotion.
- To prevent conflicts of interest, manufacturers and distributors should not give material or financial inducements to health workers.
- Product samples may be given only when necessary for professional evaluation or research at the institutional level. In no case should these samples be passed on to mothers.

c. Health care systems

- Promotion of any product is forbidden in a health care facility. 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 those mothers or family members who need to use it and the information given should include a clear explanation of the risks of formula feeding and hazards of improper use of products.
- Donated equipment and materials should not refer to brand names of products.
- Manufacturers and distributors are prohibited from providing products to health care facilities for free or at low cost.¹² The Code allows free supplies under extremely limited circumstances (e.g. to orphanages), but this provision of the Code was much abused. Consequently, the WHA passed two resolutions (WHA 39.28 [1986] and WHA 47.5 [1994]) which ended the practice of free or low-cost supplies to any part of the health care system.

Summaries of the Code and resolutions appear as **Annexes 1** and **2**.

11. The word 'product' in CE 2 refers to products under the scope of the Code.

12. According to the UNICEF Protocol for Monitoring Cessation of Distribution of Free and Low Cost Supplies to Health Care Facilities (1993) 'low cost' means less than 80% of the retail price in the absence of a standard wholesale price.

2. Giving effect to the Code and resolutions

Resolution WHA 34.22 [1981] urges Member States to translate the Code into “**national legislation, regulations and other suitable measures**”. Clearly, the resolution calls for the Code to be implemented as enforceable laws at the national level. There is uncertainty as to the meaning of the term “other suitable measures,” but the prevailing view is that the WHA intended it to mean other types of binding legal measures such as subordinate legislation issued by government departments in pursuance of statutory powers, ministerial decrees or administrative measures.¹³

Amidst the uncertainty over the term “other suitable measures”, some countries have implemented the Code as **voluntary codes or agreements**. These are non-binding arrangements between industry and one or more other parties, usually the government, to adhere to a set of standards in their marketing practices. Voluntary codes or agreements are favoured by manufacturers and distributors because they are able to influence the wording or establish their own rules of conduct and deflect any push for regulation or severe sanctions. Voluntary codes or agreements tend to reduce standards and rules to their lowest common denominator.

Voluntary measures usually do not have mechanisms to compel compliance. Complaints regarding unethical marketing practices tend to be resolved in favour of manufacturers and distributors because of the participation of the baby food industry in adjudicating bodies¹⁴, where they normally wield considerable influence. There is no legal sanction attached to breaches of voluntary codes or agreements and their success depends on the will of industry. At worst, manufacturers and distributors found to be in breach of a rule of conduct will receive a light reprimand without any serious repercussions.

Unlike laws which are of general application and mandatory by nature, manufacturers and distributors are free to opt in or out of voluntary codes or agreements depending on whether or not these instruments are to their liking. The term ‘voluntary’ also enables manufacturers and distributors to gain credit for actions they should be taking anyway. The World Health Assembly in resolution **WHA 63.23 [2010] expressed concern over reports of the ineffectiveness of voluntary measures and called on Member States to develop and improve controls over the marketing of breastmilk substitutes through legislative, regulatory and or other effective measures.**

For all these reasons, voluntary codes and agreements are not deemed to be appropriate instruments for Code implementation at the national level. CE2 focuses on implementing the Code and resolutions through legally enforceable measures.

The law-making process is normally spearheaded by health officials after lobbying from the non-governmental (NGO) sectors. It is important to set up, right from the start, a multidisciplinary committee consisting of representatives from relevant ministries, professional organisations, civil society, NGOs and international agencies with diverse skills and talents to stimulate action. Lawyers need to be involved at an early stage to give legal definition to the social and health issues which are to be covered.¹⁵

" Left to their own devices, transnational corporations are likely to fulfil their responsibility in a minimalist and fragmented fashion. Their strategies may be conducive to economic growth and the stability of their operating environments, but not necessarily to sustainable human development. They still need strong and effective regulation and a coherent response from civil society."

Utting, P. (Ed.). (2000). Visible Hands: Taking Responsibility for Social Development: UNRISD Report for Geneva 2000. United Nations Research Institute for Social Development.

13. In law, the ejusdem generis canon of construction postulates that a general word following the specific word will have a similar meaning.

14. In Australia, New Zealand and Switzerland, the voluntary codes are administered by panels which are either fully or partially funded by industry. Singapore allows individual manufacturers and distributors to participate in its ethics committee on the sale of infant foods. Malaysia, on the other hand, keeps industry participation out of the disciplinary body which hears complaints about company practices.

15. A 2017 Implementation Manual by WHO contains useful suggestions on how the legislative process could be managed. Retrieved from <http://www.who.int/nutrition/publications/infantfeeding/guidance-ending-inappropriate-promotion-food-manual/en/>

As the party which will be regulated, industry will need to be consulted as well, but only after the multidisciplinary committee has deliberated on all aspects and formulated a specific course of action. To prevent any undue influence and to avoid conflict of interests, industry must not be party to the decision-making process.

Code implementation must be supported by media campaigns and advocacy at the grass roots. Further technical support and advice on can be obtained from WHO, UNICEF and IBFAN-ICDC.

3. Implementation by law: how some countries did it

Legislators and policy makers will have to check their national constitutions and drafting conventions to determine the appropriate legal instrument for Code implementation. Although legal systems vary from country to country, there are enough commonalities to allow the use of a model approach as advocated in this publication. Modifications may be necessary depending on the social and legislative frameworks and development objectives of the implementing country. Below is a listing of different approaches taken by countries to give effect to the Code at the national level. In CE2, these measures are collectively referred to as 'Code-based laws'.

" Historically, progress associated with corporate social and environmental responsibility has been driven, to a large extent, by state regulation, collective bargaining and civil society activism. Increasing reliance on voluntary initiatives may be undermining these drivers of corporate responsibility."

Utting, P. (2000). Business responsibility for sustainable development (No. 2). Geneva 2000 Occasional Paper.

a. Enacting new legislation

Legislation adopted by parliament is the best approach. Once legislation is adopted, it becomes entrenched in the body of laws of the country and applies to all stakeholders. A good legislation normally contains monitoring and enforcement mechanisms, and since compliance is mandatory, legislation is ideal for regulating the conduct of manufacturers and distributors.

The downside is that the adoption of legislation is a long process. Infant and young child feeding is all too often not given the priority and attention it deserves and may be sidetracked by other pressing matters. The different factions and opposing interests that comprise the legislature in many countries may delay or defeat any bill that is tabled. In India, for example, it took nearly 10 years for a comprehensive bill on the marketing of breastmilk substitutes to be adopted by parliament. Many other countries went through the same long journey before their laws were adopted. However, country experience shows that legislation is worthwhile for the commitment it creates at all levels, its binding nature and the power of enforcement it wields.

b. Using existing laws

Some countries have implemented the Code by inserting only some of its provisions - for example Article 5 on promotion, Article 9 on labelling and Article 10 on quality - into existing consumer protection or food laws. The government of Macedonia amended restrictions on advertising contained in the Law of Protection of Consumers to forbid the advertising of infant formula, other foods for infants up to six months old as well as feeding bottles, teats and pacifiers. In Malaysia, the labelling aspects of the Code are incorporated into its Food Act.

This usually takes less time than introducing a new piece of legislation and steering it through the legislative process. Legislators are less inclined to interfere in matters which they view to be technical and will rely on the recommendations of relevant government departments to adopt new provisions. The danger in this approach, however, is that it is self-limiting, and important sections of the Code may be left uncovered. For example, Article 4 on information and education and Article 11 on implementation and monitoring may be not be inserted into existing legislation and abuses may continue unchecked.

c. Subsidiary legislation

Many laws governing the marketing of foods and drugs provide governmental ministries with enabling powers under which they can expand the scope of the relevant legislation. No legislative time is required, unlike the case of a new law. Many countries in anglophone Africa (Botswana, Ghana, Malawi, Tanzania, Uganda, South Africa, Zambia and Zimbabwe) have introduced subsidiary legislation which has been successful in restricting promotion. The drawback with this form of Code implementation is that it is dependent on its parent legislation for legitimacy. On the rare occasion that such legislation is repealed, the validity of the subsidiary legislation could be challenged, as was the case with the law in Peru. It is rare for such subsidiary legislation to have its own implementing and administrative structures so that competition for resources allocated to the implementing body may occur. However, if authorised officials charged with the responsibility of executing the subsidiary legislation are well trained and committed, subsidiary legislation can produce satisfactory results.

d. Executive decrees

In systems which allow for quick and unchallenged creation of law by a single person or jointly by a group of policy or decision makers, the Code can be implemented relatively swiftly with the issuance of decrees and orders. While such pronouncements are susceptible to the whims of the person or group in power, they can also be highly effective if officials in charge are convinced of the need to regulate commercial activities in their jurisdictions and are willing to override business considerations in favour of infant and young child health. Such decrees and orders have the force of law and are commonly used in countries in the Middle East (Bahrain, Oman, Saudi Arabia and Yemen) and francophone Africa (Benin, Burkina Faso, Cameroon, Democratic Republic of Congo, Mali and Niger).

4. The State of the Code by country

As of 2016, 171 countries have taken some kind of action to adopt the Code at the national level:

- law (40)
- many provisions law (31)
- few provisions law (56)
- policy or voluntary measures (12)
- some provisions in other laws (13)
- some provisions voluntary (19).¹⁶

Annex 3 shows nine different categories of steps that have been taken by 198 countries to implement the Code.

16. IBFAN-ICDC (2016) State of the Code by Country. Penang, Malaysia: IBFAN S/B.

Part B

Section by Section Guide to Code Implementation

The Code begins with a preamble that explains its purpose, underlying philosophy and objectives. The preamble underscores the need for governments to give effect to the Code's principles and aim and is as relevant today as it was in 1981 when the Code was adopted. The preamble's far sightedness can be seen in the way its statements are able to capture the challenges which confront infant and young child feeding in the 21st century. The preamble may be relied upon to explain the intention of the drafters of the Code and will be helpful in the preparation of memoranda in support of Code legislation at the national level. The full text of the preamble is reproduced below.¹

Preamble of the International Code

The Member States of the World Health Organization:

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

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

RECOGNISING that the health of infants and young children cannot be isolated from the health and nutrition of women, their socio-economic status and their roles as mothers;

CONSCIOUS that breastfeeding is an unequalled way of providing ideal food for the healthy growth and development of infants; that it forms a unique biological and emotional basis for the health of both mother and child; that the anti- infective properties of breastmilk help to protect infants against disease; and that there is an important relationship between breastfeeding and child-spacing;

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

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

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

CONVINCED that it is important for infants to receive appropriate complementary foods, usually when the infant reaches four to six months² of age, and that every effort should be made to use locally available foods; and convinced, nevertheless, that such complementary foods should not be used as breastmilk substitutes;

1. Code Essentials 1 of the same series (IBFAN-ICDC; 2018) contains annotations to the preamble that explains the basis for the statements therein. The booklet also refers to later developments and events that legitimise those statements years later.
2. "Four to six months" is no longer applicable. As expressed in the WHO/UNICEF Global Strategy for Infant and Young Child Feeding adopted in 2002, infants should be exclusively breastfed for the first six months of life to achieve optimal growth, development and health. Thereafter, to meet their evolving nutritional requirements, infants should receive nutritionally adequate and safe complementary foods while breastfeeding continues for up to two years or beyond. This recommendation was first set out in WHA resolution 54.2 [2001] and reiterated in resolutions WHA 55.25 [2002] and 58.32 [2005].

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

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

AFFIRMING further that educational systems and other social services should be involved in the protection and promotion of breastfeeding, and in the appropriate use of complementary foods;

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

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

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

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

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

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

In the ensuing pages under this Part, each article of the Code is reproduced separately under different sub-topics. Where pertinent, excerpts from relevant WHA resolutions are paraphrased and inserted after each article.

CE 2 takes the stand that legislation is the best legal instrument to implement the Code at the national level and provides a Model Law in Annex 4 to illustrate how the Code and resolutions can be transposed into a national law. Discussions under each Code article explain their strengths and weaknesses and how relevant resolutions have clarified and extended certain provisions of the Code so readers can appreciate the approaches taken in the Model Law. The Model Law can be adapted to suit the social and legislative framework of a country.³

3. Code Article 11.1.

1. Title and aim of the Law

Article 1: Aim of the Code

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

It is a common practice for legislation to have an **introduction** at the beginning to set the perimeters of the law. In the event rules and regulations need to be promulgated for administrative purposes, this introduction ensures that peripheral issues do not usurp the subject matter of the law. Article 1 of the Code could be adopted as a prelude or introduction in the following manner:

An Act to [ensure safe and adequate nutrition for infants and young children by promoting and protecting breastfeeding and by regulating the marketing of certain foods for infants and young children and of feeding bottles, teats and pacifiers.]

The provision that usually follows contains text which gives the law its name, otherwise known as the "**short title**". See Section 1(1) of the Model Law in Annex 4.

2. Scope: what products should a national law cover?

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.

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.

Resolution WHA 69.9 [2016]

This Resolution welcomes the Guidance on ending the inappropriate promotion of foods for infants and young children (A 69/7 Add.1) which confirms that breastmilk substitutes should be understood to include any milks that are specifically marketed for the feeding of infants and young children up to the age of 3 years including follow-up formula and growing-up milk. (Recommendation 2)

Manufacturers and distributors frequently argue that the Code covers only infant formula. This very narrow interpretation is not supported by the wording of Article 2 which specifically states that the Code applies to all kinds of products when marketed or otherwise represented to be suitable for use as partial or total replacement of breastmilk. To support their argument, manufacturers and distributors selectively quote the following paragraph from the introductory speech⁴ made on 20 May 1981 by Dr. T. Mork, the Representative of the Executive Board to the 34th World Health Assembly. They use this quote to wrongly limit the scope of the Code to their advantage.

“During the first four to six months of life,² breastmilk alone is usually adequate to sustain the normal infant’s nutritional requirements. Breastmilk may be replaced (substituted for) during this period by bona fide breastmilk substitutes, including infant formula. Any other food, such as cow’s milk, fruit juices, cereals, vegetables, or any other fluid, solid or semi-solid food intended for infants and given after this initial period, can no longer be considered as a replacement for breastmilk (or as its bona fide substitute). Such foods only complement breastmilk or breastmilk substitutes, and are thus referred to in the draft code as complementary foods. They are also commonly called weaning foods or breastmilk supplements.”

The following statement in the introductory speech is often deliberately overlooked:

“Products other than bona fide breastmilk substitutes including infant formula are covered by the Code only when they are “marketed or otherwise represented to be suitable ... for use as a partial or total replacement of breastmilk.”

The Global Strategy on Infant and Young Child Feeding⁵ states 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 and beyond.

Any food marketed or otherwise represented as suitable for feeding an infant up to the age of six months is therefore included as a breastmilk substitute, because such foods necessarily replace that part of the diet that is best fulfilled by breastmilk (during the exclusive breastfeeding period). The most common products covered under this category are infant formulas, including those for infants with special medical or nutritional needs. Commercially, there is a wide range of other products that are marketed for babies below six months and are thus considered breastmilk substitutes, such as cereals, jarred foods and drinks.

4. Excerpts from this Introductory Speech are found in Annex 3 to the International Code of Marketing of Breastmilk Substitutes. They are reproduced in the booklet, "An Annotated Compilation of the International Code of Marketing of Breastmilk Substitutes and relevant WHA resolutions". IBFAN-ICDC (2016).
5. WHO (2003). 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].

Breastmilk substitutes also include any products represented as suitable to replace (either partially or totally), the part of the diet that would best be fulfilled by breastmilk, such as follow-up milks and growing-up milks⁶ marketed for babies between six months and three years of age.

The Code also applies to feeding bottles and teats. In many countries, dummies (also known as pacifiers) are considered teats and have been incorporated into national legislation.⁷

In May 2016, the World Health Assembly in resolution WHA A69.9 [2016]⁸ welcomed the **Guidance on ending the inappropriate promotion of foods for infants and young children (for brevity, hereinafter referred to as "the 2016 Guidance")**,⁹ which confirms that breastmilk substitutes should be understood to include any milks that are specifically marketed for the feeding of infants and young children up to the age of three years, including follow-up formula and growing-up milk. With these affirmative statements and recommendations, it becomes clear that follow-up milks and growing up milks are covered by the scope of the Code; something that industry has been disputing. Countries should, therefore, include these products into the scope of their national laws.

What about complementary food?

Complementary foods marketed for use after the age of six months generally fall outside the scope of the Code. However, the 2016 Guidance stipulates that foods for infants and young children 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 and beyond, and should not discourage breastfeeding. Resolution WHA 69.9 [2016] calls on Member States to implement the 2016 Guidance which covers foods that are marketed as being suitable for infants and young children from the age of six to 36 months. Complementary foods fall under this range of products. Countries with existing Code laws which do not extend to complementary foods should consider amending their laws to include them and to incorporate the essential components of the 2016 Guidance into their laws. Those countries which have yet to implement a law should certainly integrate all elements of the International Code and 2016 Guidance as a multi-faceted response to address the unethical promotion of breastmilk substitutes and foods for infants and young children.

What about ready-to-feed therapeutic food (RUTF)?

CE2 takes the position that ready-to-feed therapeutic food (RUTF) should not be promoted. In countries where RUTF is registered as a foodstuff, it should be included in a Code-based law to regulate its promotion. In countries where RUTF is registered as a medical substance, it does not need to be included in a Code-based law as promotion and distribution of RUTF will be regulated under medical rules and regulations.

Drafting the Scope provision

Section 2 (10) of the Model Law in Annex 4 illustrates how the scope provision in the Code can be integrated into a national law in a clear manner.

INNOVATION

Using the term **“designated product”** means there will be no mention or definition of the term breastmilk substitutes. In a national law important words like “advertising” and “promotion” are also defined to avoid ambiguity. Undefined words and terms can be ascribed their ordinary dictionary meaning.

6. Growing-up milks are known by different names such as ‘1-2-3 milks’, ‘toddler milks’ or ‘milk formulas’. In the Model Law, the term used is “young child formula”

7. In Botswana, the scope of the national law is extended to cover all products for feeding infants and young children up to three years of age. Products such as feeding bottles, teats, dummies (or pacifiers), breast pumps, cups with spouts and similar receptacles are also included.

8. Retrieved from: http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_R9-en.pdf

9. WHO (2016), A69/7 Add.1(Recommendation 2). Retrieved from: http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_7Add1-en.pdf

3. Terminology

Article 3: Definitions

For the purposes of this Code:

Breastmilk substitute¹⁰ means any food being marketed or otherwise represented as a partial or total replacement for breastmilk,¹¹ whether or not suitable for that purpose.

Complementary food¹² means any food, whether manufactured or locally prepared, suitable as a complement to breastmilk or to infant formula, when either becomes insufficient to satisfy the nutritional requirements of the infant. Such food is also commonly called “weaning food” or “breastmilk supplement.”

Container means any form of packaging of products for sale as a normal retail unit, including wrappers.

Distributor means a person, corporation or any other entity in the public or private sector engaged in the business (whether directly or indirectly) of marketing at the wholesale or retail level a product within the scope of this Code. A “primary distributor” is a manufacturer’s sales agent, representative, national distributor or broker.

Health care system means governmental, nongovernmental or private institutions or organisations engaged, directly or indirectly, in health care for mothers, infants and pregnant women; and nurseries or child-care institutions. It also includes health workers in private practice. For the purposes of this Code, the health care system does not include pharmacies or other established sales outlets.

Health worker means a person working in a component of such a health care system, whether professional or non-professional, including voluntary, unpaid workers.

Infant formula means a breastmilk substitute formulated industrially in accordance with applicable Codex Alimentarius standards, to satisfy the normal nutritional requirements of infants up to between four and six months of age,² and adapted to their physiological characteristics. Infant formula may also be prepared at home, in which case it is described as “home-prepared.”

Label means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed or impressed on, or attached to, a container (see above) of any products within the scope of this Code.

Manufacturer means a corporation or other entity in the public or private sector engaged in the business or function (whether directly or through an agent or through an entity controlled by or under contract with it) of manufacturing a product within the scope of this Code.

Marketing means product promotion, distribution, selling, advertising, product public relations, and information services.

Marketing personnel means any persons whose functions involve the marketing of a product or products coming within the scope of this Code.

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

Supplies means quantities of a product provided for use over an extended period, free or at a low price, for social purposes, including those provided to families in need.

10. The term “breastmilk substitute” is best avoided in national laws. See explanation at p.12

11. Breastmilk” and “breastfeeding” are spelled as one word by a number of international organisations and scientific bodies including IBFAN and UNICEF. The original spelling in the Code where these two words were hyphenated has been altered in CE2.

12. The age indication appearing on the label of a complementary food product and the way it is marketed will determine whether the product falls within the definition of “designated product” in the Model Law. See footnotes 3 and 6 in the Model Law in Annex 4.

The field of infant and young child feeding employs a number of terms that are specific to it. The Code contains a set of definitions explaining these terms. In translating the Code into various national languages some of the jargon used in the Code has been found to have no equivalent. So, while it is usual to have a dictionary definition of a word, it is equally acceptable to have a definition which arbitrarily clarifies a term in the law where it appears, given the nature of the subject matter. However, each term must be consistent in its meaning throughout its use in the law to prevent ambiguity and confusion.

Drafting the Section on Definitions

Since it was adopted in 1981, the Code has been outstripped by marketing trends and other developments. The definition of infant formula, for example, no longer matches that recommended by the standard set by the Codex Alimentarius Commission.¹³ Follow-up formula, a product that was hardly available commercially in 1981 is not mentioned in the Code. The definitions in Section 2 of the Model Law in Annex 4 are intended to overcome some of the practical problems countries face when transposing the Code into a national law. For example, the controversy over the meaning of the term “breastmilk substitute” is avoided by the use of a collective term **“designated product”** which is then defined. “Designated product” also encompasses feeding bottles, teats and pacifiers which makes for tidier drafting in later provisions.

AVOIDING THE TERM "BREASTMILK SUBSTITUTE"

The controversy over the meaning of the term “breastmilk substitute” has caused many countries to replace it with the coined term **“designated product”** in national laws. This term is then defined by a list of products so there is no uncertainty about what is covered by the law. It is an open list where the relevant health authority is vested with the power to add new products when the need arises. See section 2(10)(h) of the Model Law. This is a useful mechanism to ensure that the scope of the law can be updated easily to keep up with new marketing trends without having to resort to amendments.

Based on subsequent resolutions, prevailing marketing practices and new channels of communication, the Model Law introduces several new definitions. These include:

- advertising - Section 2(1);
- cross-promotion - Section 2(9);
- complementary food product - Section 2(7);
- designated products - Section 2(10);
- follow-up formula - Section 2(12);
- health claim - Section 2(14);
- labelling - Section 2(21);
- nutrition claim - Section 2(26);
- promote - Section 2(29);
- sponsorship - Section 2(32);
- ready-to-feed therapeutic foods - Section 2(30), and
- young child formula - Section 2(34).

LOST IN TRANSLATION

Where there is a need for reverse translation i.e. from a national language to English or any of the other five languages of the United Nations (UN), it would be useful for the translator to refer to the official translation of the Code and resolutions in any of the relevant UN languages so that concepts and meanings are captured and translated accurately. Literal translation back and forth can make the law quite incomprehensible and inelegant.

13. The Codex Alimentarius Commission is the international food standards setting body formed by the Food and Agricultural Organization (FAO) and WHO to protect the health of consumers and ensure fair practice in the international food trade. However, Codex meetings have strong industry influence. Many country delegations have industry representatives.

4. Information and Education

Article 4: Information and education

- 4.1 Governments should have the responsibility to ensure objective and consistent information is provided on infant and young child feeding for use by families and those involved in the field of infant and young child nutrition. This responsibility should cover either the planning, provision, design, and dissemination of information, or their control.
- 4.2 Informational and educational materials, whether written, audio or visual, dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children, should include clear information on all the following points:
- (a) the benefits and superiority of breastfeeding;
 - (b) maternal nutrition, and the preparation for and maintenance of breastfeeding;
 - (c) the negative effect on breastfeeding of introducing partial bottle feeding;
 - (d) the difficulty of reversing the decision not to breastfeed; and
 - (e) where needed, the proper use of infant formula, whether manufactured industrially or home-prepared.

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

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

Article 7. Health workers

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.

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

- *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 A69/7 Add.1 [2016] (Referred to as the 2016 Guidance)

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

- *donate or distribute equipment or services to health facilities.*
- *directly or indirectly provide education to parents and other caregivers on infant and young child feeding in health facilities.*
- *provide any information for health workers other than that which is scientific and factual.*

(Recommendation 6)

The provision in Article 4.1 clearly states that governments have ultimate responsibility for ensuring that information provided on infant and young child feeding is objective and consistent. Article 4.2 lists points that must be included in all information and education materials, which is not an exhaustive list and countries can (and do) set additional requirements. In Article 4.3, the Code does allow manufacturers and distributors to donate information or educational materials, but only upon request and with approval of an appropriate national authority. This is unfortunately one of the weaker areas of the Code. Some countries have imposed more stringent requirements to halt the negative impact of donated materials produced by manufacturers and distributors of products within the scope of the Code.

Article 7.2 is another avenue by which manufacturers and distributors can produce and distribute information materials related to infant and young child feeding. Although Article 7.2 allows such materials only for health professionals and restricts them to scientific and factual matters, these materials often include promotional text as well and are made available to all health workers and mothers. **The thin line between information and promotion** is often blurred and manufacturers and distributors take advantage of this to use information materials as marketing devices.

Legislators and policy makers should recognise the potential for misinformation and direct or indirect product promotion. Manufacturers and distributors are unlikely to spend money on the production of information materials unless it also serves a clear business objective such as increased sales or an improved corporate image. Resolution WHA 58.32 [2005] urges Member States to ensure that financial support and other incentives for programmes and health professionals working in infant and young child health do not create conflicts of interest; the best way for governments to avoid such conflicts of interest is to disallow infant and young child materials that are sponsored by manufacturers and distributors.

The advent of the 2016 Guidance gives countries extra leverage to introduce stronger provisions into Code-based laws. Recommendation 6 thereof calls upon manufacturers and distributors to stop creating situations of conflicts of interest in health facilities. In the area of information and education, donation of equipment and services and providing education to parents and caregivers are not allowed in health facilities. Countries can rely on the Guidance to ban such activities despite the provisions of Code article 4.3.

Recommendation 6 of the 2016 Guidance also extends the requirement of providing scientific and factual materials to health workers in general and not just health professionals, another boost to any endeavor to strengthen Code-based laws legislation.

In general, countries that implemented the Code have chosen one of the three options below:

- (a) **Prohibit manufacturers and distributors from producing such information and educational materials, except for scientific and factual information about technical aspects and methods of use of products to health professionals.** This is the option chosen by Armenia, Botswana, Pakistan and South Africa. Governments that prohibit materials produced by manufacturers and distributors should ensure that there are other sources of information to fill the gap. Are there enough local resources to produce materials? Can the government distribute information produced by sources such as WHO, UNICEF, local and foreign universities, professional associations and relevant non-governmental organisations?
- (b) **Allow manufacturers and distributors to produce and distribute information materials, but only with prior government approval.** This is the option chosen by Guatemala, Ghana, Kuwait, Malaysia and the Philippines. This approach requires the establishment of a vetting committee with responsibility to approve information materials prior to dissemination. Vetting committees can be a good mechanism if their members are properly trained and the law contains clear and complete criteria for the evaluation of materials. In order that materials do not become outdated, their validity should be for a specified period only, following which they must be re-submitted for approval. Countries which have established a National Breastfeeding Committee, as recommended by the Innocenti Declaration 1990,¹⁴ can confer a mandate on this Committee to act as a vetting agency for commercially produced materials. Such a Committee can ensure that good information is produced and distributed.
- (c) **Establish detailed provisions delineating requirements and prohibitions for materials on infant and young child feeding.** This is the option chosen by Brazil, Cambodia, India and Viet Nam. Countries taking this option have drafted detailed laws governing the production and distribution of information and education materials. Penalties will be imposed on manufacturers and distributors who fail to comply with the law. Most countries prohibit reference in the materials to any particular product and some prohibit references to the name or logo of the manufacturer or distributor as well as to particular products. In Cambodia, information materials cannot mention any products or contain the name or logo of any manufacturer and distributor except to indicate copyright. In India, information and education materials related to breastmilk substitutes, infant foods or feeding bottles may only be distributed through the health care system if “it is found necessary for the healthy growth of the infant by a medical practitioner.” Other countries have added specific topics that must be included in materials. Several countries in anglophone Africa, Viet Nam and Cambodia, for example, require that information materials mentioning formula feeding must explain how to feed the baby using a cup rather than a feeding bottle.

KILLER BUGS!

In 2002, it was discovered that powdered infant formula can be contaminated during the manufacturing process with dangerous bacteria, such as *Enterobacter sakazakii* and *Salmonella enterica*. This is called **intrinsic contamination** and can cause the death of newborns and very young babies.

Recognising the need for parents and caregivers to be fully informed of this risk, two resolutions (WHA 58.32 [2005] and WHA 61.48 [2008]) were adopted which have a direct impact on Article 4.2. Information materials on artificial feeding are now required to contain information on safe preparation, storage and handling of powdered infant formula to minimise the risk of bacterial infection following WHO/FAO guidelines.¹⁵ The required warnings and information should be made mandatory in national laws. Section 14(1)(d) of the Model Law incorporates these requirements.

14. This Declaration was issued by a group of high-level policy makers from governments and international agencies that met at the Innocenti Hospital in Florence, Italy in 1990. It spells out a set of operational targets to protect, promote and support breastfeeding including the setting up of a multi-sector national breastfeeding committee and taking action to implement the Code and resolutions. Progress made on the Declaration was assessed and reviewed 15 years later culminating in the Innocenti Declaration 2005. This later Declaration called for greater government action and investment in infant and young child feeding.

15. The guidelines can be downloaded at <http://www.who.int/foodsafety/publications/powdered-infant-formula/en/>

Drafting the Section on Information and Education

Subsection 4(1)(d) of the Model Law in Annex 4 advocates for option (a), i.e. for manufacturers and distributors to be prohibited from donating and distributing information and education materials. An exception is made for product information distributed to health professionals which can be found in Section 15 of the Model Law. Detailed requirements on the content of materials on infant and young child feeding are set down in Chapter IV for other parties who may produce such materials. It borrows heavily from Code Article 4.2, yet omits some of its weaknesses while strengthening other elements that are fundamental to the success of breastfeeding. There is also an option for all information and education materials to be vetted by the relevant authority.

Section 14(1)(d) of the Model Law sets out the information that must be provided on intrinsic contamination of powdered formula.

5. Promotion to the Public

Article 5. The general public and mothers

- 5.1 There should be no advertising or other form of promotion to the general public of products within the scope of this Code.
- 5.2 Manufacturers and distributors should not provide, directly or indirectly, to pregnant women, mothers or members of their families, samples of products within the scope of this Code.
- 5.3 In conformity with paragraphs 1 and 2 of this Article, there should be no point-of-sale advertising, giving of samples, or any other promotion device to induce sales directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales, for products within the scope of this Code. This provision should not restrict the establishment of pricing policies and practices intended to provide products at lower prices on a long-term basis.
- 5.4 Manufacturers and distributors should not distribute to pregnant women or mothers of infants and young children any gifts of articles or utensils which may promote the use of breastmilk substitutes or bottle feeding.
- 5.5 Marketing personnel, in their business capacity, should not seek direct or indirect contact of any kind with pregnant women or with mothers of infants and young children.

Resolution WHA 58.32 [2005]

Member States are requested to ensure that: nutrition and health claims are not permitted for breastmilk substitutes, except where specifically provided for in national legislation. (Reiterated in resolution WHA 63.23 [2010] which extends the ban on claims to foods for infants and young children).

Guidance A69/7 Add.1 [2016] (Referred to as the 2016 Guidance)

Products that function as breastmilk substitutes should not be promoted...there should be no cross-promotion to promote breastmilk substitutes indirectly via the promotion of foods for infants and young children (Recommendation 5).

While Article 5 bans all forms of promotion, the ban does not protect all potential targets of promotion. Firstly, Article 5.1 only bans advertising directed to the general public suggesting that certain classes of people such as health professionals are excluded. The other provisions of Article 5 are limited in similar ways. Article 5.2 only applies to “pregnant women, mothers or members of their families.” Article 5.3 applies to “the consumer at the retail level” while articles 5.4 and 5.5 apply only to “pregnant women and mothers of infants and young children.” **Loopholes in Article 5** must be closed in a national law to prevent manufacturers and distributors from taking advantage of them. All national provisions founded on Article 5 must necessarily be of general application.

There are other parts of Article 5 where the text is unduly restrictive. For example, Article 5.4 is concerned with “gifts of articles or utensils which may promote the use of breastmilk substitutes or bottle feeding”. There are many types of gifts that do not obviously promote the use of breastmilk substitutes, like baby bags for carrying diapers or baby towels, but could still entice mothers to purchase products which they otherwise might not do. The **ambiguous language** in Article 5.4 makes both compliance and enforcement difficult, subjecting it to challenge.

The term “marketing personnel” in Article 5.5 is **limiting** as it does not restrict other company personnel from contacting mothers, something major baby food manufacturers and distributors have exploited to the hilt. The words “indirect contact” are not specific enough to prevent manufacturers and distributors from encouraging mothers themselves from initiating contacts with manufacturers and distributors as via social media, the internet or mother and baby clubs. Singapore has handled this ambiguity in its voluntary code by prohibiting all “mothercraft services” such as parentcraft, homecare programmes, hotlines, helplines, soliciting of mothers, baby clubs, newsletters, talks on infant care and websites.

Quite a few countries have improved on the **restrictive wording** of Article 5 by imposing a complete ban on promotion and advertising, regardless of the target audience. For example, India and Bangladesh prohibit all forms of advertising and promotion without limitation. The Botswana law does not allow any person to promote in any way a product within its scope. Promotion is defined to include every activity that introduces or encourages the purchase or use of a designated product including telephone and internet helplines, mother and baby clubs, and internet websites. Clothing, stationary or other items that refer to a designated product or its brand name and “practices that create an association between a manufacturer or distributor and breastfeeding” are similarly banned. In an early attempt to restrict cross promotion, Malaysia has an innovative provision in its Code that provides that labels of one product may not be used as vehicles for advertising another product. For example, a tin of infant formula may not include an insert under the lid advertising follow-up formula, a practice that some manufacturers and distributors have instituted.

There is an upsurge of marketing messages that will have parents believe that visual, cognitive and intellectual advantages, as well as many other benefits can be derived from additives to formula products. Parents are persuaded by intense advertising to buy these products even though there may be unknown adverse side-effects and little evidence to show that the additives perform the functions as claimed. These claims are misleading and unsubstantiated by scientific evidence. Due to their promotional nature, they violate the Code. **Nutrition and health claims** are prohibited by resolutions 58.32 [2008] and 63.23 [2010] except where specifically provided for in relevant Codex Alimentarius standards or national legislation. In all other cases they should be ban in Code-based laws.

When drafting a national law, policy makers should pay special attention to modern communication methods and innovative marketing trends highlighted in the preamble of resolution WHA 54.2 [2001]. The 2016 Guidance broadly interprets “promotion” to include the communication of messages that are designed to persuade or encourage the purchase or consumption of a product or raise awareness of a brand. **Promotional messages may be communicated through traditional mass communication channels, the internet or other marketing media using a variety of promotional methods.** Promotional techniques can be aimed directly at consumer, or to consumers or health workers through other intermediaries.

The Guidance explains that there does not have to be a reference to a brand name of a product for the activity to be considered as advertising or promotion

The Guidance also introduces the concept of **cross-promotion**. This is defined as a form of marketing where customers of one product or service are targeted with promotion of a related product. This can include packaging, branding and labelling of a product to closely resemble that of another (brand extension). In this context, it can also refer to use of particular promotional activities for one product and/or promotion of that product in particular settings to promote another product.

Recommendation 5 of the Guidance states that there should be **no cross-promotion for breastmilk substitutes via the promotion of other foods for infants and young children**.

This means that:

- The packaging design, labelling and materials used for the promotion of complementary foods must be different from those used for breastmilk substitutes so that they cannot be used in a way that also promotes breastmilk substitutes (for example, different colour schemes, designs, names, slogans and mascots other than company name and logo should be used).
- Manufacturers and distributors that market breastmilk substitutes should refrain from engaging in the direct or indirect promotion of their other food products for infants and young children by establishing relationships with parents and other caregivers (for example through baby clubs, social media groups, childcare classes and contests).

The scope of the 2016 Guidance applies to all commercially produced foods that are marketed as being suitable for infants and young children from the age of 6 months to 36 months; these would include **complementary food products**. For countries where a decision has been made to allow promotion of complementary food products, Recommendation 4 of the Guidance states that the messages used to promote foods for infants and young children should support optimal feeding, and inappropriate messages should not be included. Irrespective of the form, messages should 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 6 months of age and include the appropriate age of introduction of the food which must not be less than 6 months.

If a country wishes to offer multi-faceted response to address the unethical promotion of breastmilk substitutes and other foods for infants and young children, these elements of the Guidance could be integrated into Code implementation at the national level. Countries can also opt to prevent the promotion of all complementary food products.

Drafting the Section on Promotion

Subsections 4(1) and 4(2)(d)-(e) of the Model Law in Annex 4 set out the prohibitions on promotion to the public including the ban on claims and cross-promotion. Additional provisions to give effect to the 2016 Guidance are found in Subsections 4(4) and 4(5) where there are restrictions on how complementary food products are to be promoted. Footnotes 3 and 6 of the Model Law explain how countries can ban all forms of promotion of complementary food products should they decide on this option.

See also the definition of "advertise" and "promote" in Section 2(1) and 2(29).

6. Promotion in Health Care Facilities

Article 6. Health care systems

- 6.1 The health authorities in Member States should take appropriate measures to encourage and protect breastfeeding and promote the principles of this Code, and should give appropriate information and advice to health workers in regard to their responsibilities, including the information specified in Article 4.2.
- 6.2 No facility of a health care system should be used for the purpose of promoting infant formula or other products within the scope of this Code. This Code does not, however, preclude the dissemination of information to health professionals as provided in Article 7.2.
- 6.3 Facilities of health care systems should not be used for the display of products within the scope of this Code, for placards or posters concerning such products, or for the distribution of material provided by a manufacturer or distributor other than that specified in Article 4.3.
- 6.4 The use by the health care system of 'professional service representatives', 'mothercraft nurses' or similar personnel, provided or paid for by manufacturers or distributors, should not be permitted.
- 6.5 Feeding with infant formula, whether manufactured or home-prepared, should be demonstrated only by health workers, or other community workers if necessary; and only to the mothers or family members who need to use it; and the information given should include a clear explanation of the hazards of improper use.
- 6.6 Donations or low-price sales to institutions or organisations of supplies of infant formula or other products within the scope of this Code, whether for use in the institutions or for distribution outside them, may be made. Such supplies should only be used or distributed for infants who have to be fed on breastmilk substitutes. If these supplies are distributed for use outside the institutions, this should be done only by the institutions or organisations concerned. Such donations or low-price sales should not be used by manufacturers or distributors as a sales inducement.
- 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.

Resolution WHA 39.28 [1986]

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

Resolution WHA 43.3 [1990]

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

Resolution WHA 45.34 [1992]

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

Resolution WHA 47.5 [1994]

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

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 A69/7 Add.1 [2016] (Referred to as the 2016 Guidance)

Manufacturers and distributors that market foods for infants and young children should not create conflicts of interest in health facilities or throughout health systems. Such manufacturers and distributors, or their representatives, should not donate or distribute equipment or services to health facilities. (Recommendation 6)

Health care facilities are fertile grounds for product promotion because of the **endorsement by association** which they confer on manufacturers and distributors and their products. Since many pregnant women and mothers of newborns will make infant feeding decisions based on the overt and covert messages they receive in health care facilities, national laws must ensure that health care facilities do not send out messages which may undermine breastfeeding.

Code provisions are not as strong as they should be, and manufacturers and distributors have been able to take advantage of their inherent weaknesses.

For example, hand-in-hand with the industry's tendency to market its products through the health care system, there is a long-established industry practice of donating large quantities of infant formula and other breastmilk substitutes to health care facilities. The availability of free milk in health care facilities entrenches the practice of artificial feeding. Even a single feed of formula given to a baby immediately after birth significantly reduces the likelihood of a mother breastfeeding successfully. Moreover, mothers interpret hospital use of infant formula as an endorsement not only of artificial feeding, but also of the particular brand that was fed to their baby, harming efforts to promote breastfeeding.

Article 6 was historically unsuccessful in discouraging the practice of free or low-cost supplies. Several WHA resolutions clarified the matter, culminating in a clear call in 1994 for Member States to ensure that there are **no donations of free or subsidised supplies of products covered by the Code in any part of the health care system**. The cessation of free and low-cost supplies has been incorporated as a condition of the Baby Friendly Hospital Initiative, and in keeping with WHO and UNICEF policy,¹⁶ national laws should prohibit manufacturers and distributors from providing free supplies of all products or selling them to health care facilities at less than the published wholesale price, or in its absence, at less than 80 percent of the retail price.

For discussion on free supplies in the context of HIV and emergencies, and for the interpretation of "infants who have to be fed" on breastmilk substitutes, see Part D on Matters related to Code Implementation.

16. 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."

Another area of difficulty is in **donation of equipment and materials**. The wording in Article 6.8 allows manufacturers and distributors to argue that promotional items such as posters depicting a breastfeeding mother, an adorable infant or a growth chart can carry the company name, logo, trademark or slogan, and be displayed in a health care setting. Although Article 6.3 indicates otherwise, manufacturers and distributors exploit this grey area and provide materials because they understand very well the promotional value of these items. Georgia has addressed this weakness in its national law by not only prohibiting the display in health care facilities of advertising, information or teaching materials related to products within the scope of its law, but also prohibiting the use of items that bear a mark, logo, name or symbol of a manufacturer or distributor.

Code Article 6.8 is frequently abused through the indiscriminate use of brand names of products which are not breastmilk substitutes, or which manufacturers and distributors do not consider to be breastmilk substitutes. These brand names, often the same or similar to the company's infant formula, are found on a wide array of items such as posters, calendars, note pads, pen holders, health monitoring cards etc. (similar to the concept of cross-promotion, see p.20). These items are put on display or distributed to mothers in health care facilities, allowing manufacturers and distributors who are well-versed in stretching the rules to get away with unethical promotion.

The 2016 Guidance has implications on Code implementation in this respect and can be used as leverage to strengthen Code-based laws. It explains that manufacturers and distributors that market foods for infants and young children should not create conflicts of interest in health facilities or throughout health systems. Recommendation 6 thereof states that manufacturers and distributors that market foods for infants and young children 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; and
- sponsor meetings of health professionals and scientific meetings.

National laws can add a ban on promotion of complementary food products in health care facilities in view of the 2016 Guidance. They are similar to prohibitions already in place for products covered by the scope of the Code and reinforce them.

Drafting the Section on Promotion in Health Care Facilities

Subsections 4(2)(a)-(c) of the Model Law in Annex 4 sets out the prohibitions on promotion in health care facilities. Additional provisions to give effect to the 2016 Guidance in so far as they relate to promotion of complementary food products in health care facilities are incorporated into Subsections 4(4) and 4(5). These provisions are only applicable to countries that choose to permit certain types of promotion for complementary food products, e.g. in retail outlets. Countries that choose, across the board, to prohibit all forms of promotion for complementary food products in the national law need not include these provisions.

7. Promotion to Health Workers

Article 7. Health workers

- 7.1 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.
- 7.2 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.
- 7.3 Manufacturers and distributors of products within the scope of this Code should disclose to the institution to which a recipient health workers 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.

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 :

- *ensure that clinicians and other health care personnel, community health workers..., 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...*
- *financial support and other incentives for programmes and health professionals working in infant and young child health do not create conflicts of interest.*

Guidance A69/7 Add.1 [2016] (Referred to as the 2016 Guidance)

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

The extent to which hospital personnel and hospital routines foster or discourage breastfeeding among pregnant women and new mothers is one of the principal determinants for the successful initiation and maintenance of breastfeeding or its failure. Manufacturers and distributors spend a large part of their budget on promotion that will reach health workers. They know health workers are able to influence parents' decisions about infant and young child feeding, as well as the brand of choice, once the decision to artificially feed has been made.

Article 7.1 of the Code is intended to **minimise the impact of commercial promotion** by making health workers responsible for the encouragement and protection of breastfeeding. Article 7.2 provides a means of protection by restricting information that manufacturers and distributors provide to health workers to **scientific and factual matters** (see, however, discussion at p.16).

Other sub-articles in Article 7 are rather loose and allow more than they prohibit. For example, Article 7.3 prohibits **financial or material inducements to promote products**, a phrase which is difficult to monitor or enforce due to the difficulty in proving intent. Moreover, manufacturers and distributors often deny that low cost items of professional utility such as measuring tapes, weighing scales, stethoscopes or thermometers constitute "inducements". Article 7.4, which allows samples to be given **for the purpose of professional evaluation or research at the institutional level**, has led to the widespread distribution of product samples to health workers even though it is rare for clinical health workers to perform professional evaluations or research of products.

Article 7.5 allows manufacturers and distributors to sponsor health workers for fellowships, study tours, research grants, attendance at professional conferences or the like. In return for such sponsorship, manufacturers and distributors get to promote their names, products or services either through the health workers directly or the institution they represent. By linking their name to health workers and prestigious institutions, manufacturers and distributors create the image that they are responsible corporate citizens. **Sponsorship** gives rise to situations in which the health worker or the institution they represent are in a position to exploit a professional or official capacity in some way for their personal or institutional benefit. This is known as **conflict of interest**, and it exists even if no unethical or improper act results from it.

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 resolve problems created by physicians' conflicts of interest is unfounded for many reasons: health workers differ in what they consider to be a conflict, which makes the disclosure of conflicts of interest incomplete; because such declarations are usually unverified, their accuracy is uncertain; disclosure may also be used to "sanitise" a problematic situation, suggesting that no ill effects will follow from the disclosed relationship.¹⁷

As a whole, Article 7 has not been effective in shielding health workers from the worst effects of marketing. The situation is not helped by the low **level of awareness** among health workers regarding the risks and disadvantages of artificial feeding, as well as their lack of understanding of how marketing practices influence their behaviour. While the **Baby Friendly Hospital Initiative (BFHI)**¹⁸ has made major inroads in educating health workers, there are still a majority of doctors, nurses and others who believe that artificial feeding is a good alternative to breastfeeding, and who view manufacturers and distributors as friends.

Defining Conflicts of Interest with Industry.

Conflicts of interest occur when physicians have motives or are in situations for which reasonable observers could conclude that the moral requirements of the physician's roles are or will be compromised. In terms of industry influences, financial conflicts of interest occur when physicians are tempted to deviate or do deviate from their professional obligations for economic or other personal gain.

*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.*

17. Brennan, T. A., Rothman, D. J., Blank, L., Blumenthal, D., Chimonas, S. C., Cohen, J. J., ... & Smelser, N. (2006). Health industry practices that create conflicts of interest: a policy proposal for academic medical centers. *Jama*, 295(4), 429-433.

18. BFHI is a designation awarded by the WHO and the UNICEF to hospitals worldwide that foster the implementation of evidence-based strategies concerning infant feeding. The revised BFHI operational guidance (<http://www.who.int/nutrition/events/consultation-protection-promotion-support-breastfeeding/en/>) proposes to make adherence to the Code and resolution a distinct step within the Ten Steps to Successful Breastfeeding. (Yet unpublished at the time of writing in December 2017)

Sponsorship of health workers and their associations by manufacturers and distributors is by far the most important link a national law must sever. Justification for this can be found in several WHA resolutions which caution against conflicts of interest, namely resolutions WHA 49.15 [1996]; WHA 58.32 [2005] and 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, which would encompass projects within schools or colleges, medical or health education, support for research or community outreach activities in infant and young child nutrition. Avoidance of conflicts of interest was reiterated in the 2008 resolution. It is crucial that Article 7.5 of the Code is read in light of these resolutions.

Those who have been inculcated into a **culture of dependency** argue that collaboration with industry is the only way forward, in light of diminishing public funds for research, education and training.¹⁹ The experience of some professional organisations in the United Kingdom and India shows that programmes can run successfully, albeit less luxuriously, without sponsorship. Where a certain amount of sponsorship is routinely available, programme budgets tend to reflect this, in terms of the level of accommodation and catering offered, travel expenses and honoraria paid. These can be scaled down without compromising quality.²⁰

In this respect, Recommendation 6 of the 2016 Guidance contains a number of implications for the Code and its implementation into national laws. The Guidance recommends that health workers, health systems, health professional associations and nongovernmental organisations should avoid such conflicts of interest and not:

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

The above recommendations are coherent with the Code and resolutions and reinforce them. Texts in **bold** indicate the places where there are significant improvements on existing Code provisions. They can be used as leverage for stronger Code-based laws.

Drafting the Section on Promotion to Health Workers

Subsections 4(3), 4(5) and 7(1)(e) of the Model Law in Annex 4 deter health workers from engaging in harmful promotional practices that will give rise to conflicts of interest. Subsections 4(4) and 4(5) are not needed in countries that choose, across the board, to prohibit all forms of promotion for complementary food products in the national law.

Section 12 sets out the responsibilities of health workers for the encouragement and protection of breastfeeding.

19. A yet unpublished 2017 survey conducted by WHO, with assistance from IBFAN and the International Paediatric Association found that 53% of paediatric association websites documented sponsorship by BMS manufacturers and 67% of the associations that holding conferences had received company sponsorship for the conference.

20. 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.

8. Manufacturers and distributors

Article 8. Persons employed by manufacturers and distributors

- 8.1 In systems of sales incentives for marketing personnel, the volume of sales of products within the scope of this Code should not be included in the calculation of bonuses, nor should quotas be set specifically for sales of these products. This should not be understood to prevent the payment of bonuses based on the overall sales by a company of other products marketed by it.
- 8.2 Personnel employed in marketing products within the scope of the Code should not, as part of their job responsibilities, perform educational functions in relation to pregnant women or mothers of infants and young children. This should not be understood as preventing such personnel from being used for other functions by the health care system at the request and with written approval of the appropriate authority of the government concerned.

Resolution WHA 69.9 [2016] (*The Guidance on ending the inappropriate promotion of foods for infants and young children (WHA A69.7 Add.1 [2016]) is welcomed in this resolution.*)

Manufacturers and distributors of foods for infants and young children are called upon to end all forms of inappropriate promotion, as set forth in the guidance recommendations.

Article 8.1 is intended to prevent company personnel from aggressively marketing products that potentially may be harmful to the health and well-being of babies. An effective way to do this is by ensuring that **incentive packages** which normally apply to marketing personnel to increase sales are curtailed. There is resistance among policy makers to regulate manufacturers and distributors in this manner due to the perception that internal practices are difficult for governments to monitor. Manufacturers and distributors can conspire with marketing personnel to record earnings from sales of breastmilk substitutes as derived from sales of other products. This is not a legitimate basis for not implementing this Code provision. As with other unethical practices, the law acts as a deterrent. Multinational companies will be compelled to ensure clean records backed by ethical corporate practices, especially when they are required by their investors or public pressure to set up corporate compliance procedures. The threat of disgruntled former employees becoming whistle-blowers on unethical company practices will also help to curtail illegal activities to a large extent.

Article 8.2 prohibits marketing personnel from performing **educational functions** in relation to pregnant women or mothers of infants and young children. Recommendation 6 of the 2016 Guidance adds force to this Article by stating that a company directly or indirectly providing education to parents and other caregivers on infant and young child feeding in health facilities creates **conflict of interest**. However, the Code allows company personnel to be used for other functions if requested and approved by an appropriate authority. This provides leeway for abuse, and any discretionary power to approve such practice should be exercised with caution.

Drafting the Section on Persons Employed by Manufacturers and Distributors

Subsections 4(2)(d)-(f) of the Model Law in Annex 4 prevent some of the more common activities that take place in both health care facilities and in public places by persons employed by manufacturers and distributors. The second limb of Code Article 8.2 regarding the use of company personnel for other functions in the health care system is not incorporated into the Model Law so as to avoid any possibility of abuse.

9. Labelling

Article 9. Labelling

- 9.1 Labels should be designed to provide the necessary information about the appropriate use of the product, and so as not to discourage breastfeeding.
- 9.2 Manufacturers and distributors of infant formula should ensure that each container has a clear, conspicuous, and easily readable and understandable message printed on it, or on a label which cannot readily become separated from it, in an appropriate language, which includes all the following points:
- (a) the words 'Important Notice' or their equivalent;
 - (b) a statement of the superiority of breastfeeding;
 - (c) a statement that the product should be used only on the advice of a health worker as to the need for its use and the proper method of use;
 - (d) instructions for appropriate preparation, and a warning against the health hazards of inappropriate preparation. Neither the container nor the label should have pictures of infants, nor should they have other pictures or text which may idealise the use of infant formula. They may, however, have graphics for easy identification of the product as a breastmilk substitute and for illustrating methods of preparation. The terms 'humanised', 'maternalised' or similar terms should not be used. Inserts giving additional information about the product and its proper use, subject to the above conditions, may be included in the package or retail unit. When labels give instructions for modifying a product into infant formula, the above should apply.
- 9.3 Food products within the scope of this Code, marketed for infant feeding, which do not meet all the requirements of an infant formula, but which can be modified to do so, should carry on the label a warning that the unmodified product should not be the sole source of nourishment of an infant. Since sweetened condensed milk is not suitable for infant feeding, nor for use as a main ingredient of infant formula, its label should not contain purported instructions on how to modify it for that purpose.
- 9.4 The label of food products within the scope of this Code should also state all the following points:
- (a) the ingredients used;
 - (b) the composition/analysis of the product;
 - (c) the storage conditions required; and
 - (d) the batch number and the date before which the product is to be consumed, taking into account the climatic and storage conditions of the country concerned.

Resolution WHA 55.25 [2002]

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

Resolution WHA 58.32 [2005]

Member States are requested to ensure that:

- *nutrition and health claims are not permitted for breastmilk substitutes, except where specifically provided for in national legislation.*

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

Resolution WHA 61.20 [2008]

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

Guidance WHA A69.7 Add 1 [2016] (referred to as the 2016 Guidance)

The packaging design, labelling and materials used for the promotion of complementary foods must be different from those used for breastmilk substitutes so that they cannot be used in a way that also promotes breastmilk substitutes (for example, different colour schemes, designs, names, slogans and mascots other than company name and logo should be used) (Recommendation 5).

Good labelling provisions are vital, as a product's label is often the only opportunity for a consumer to obtain essential information about the product's content and use. Labels are however also devices for manufacturers and distributors to promote their products through idealising text or images. Article 9.1 of the Code is of **general application**. It requires all labels to contain the necessary information about the appropriate use of the product, and to not discourage breastfeeding.

Article 9.2 explains how to go about doing this, but only in relation to labels of infant formula products. The second limb of Article 9.2 bans labels from having **pictures or text that may idealise its use** but it is also confined only to infant formula. Other products which are covered by the scope of the Code are not mentioned and it is unclear what the word "idealise" means. National laws must expand on the Code in order to be comprehensive and indeed, many countries have made improvements to Article 9 in their national laws. Brazil and South Africa are in the forefront with national laws that have detailed and specific requirements for the labels of the full range of products covered by the scope of their laws.

Many other countries have also improved and expanded on the limited wording of Code Article 9.2 in an effort to stop promotional images on labels of all products covered by the scope of the Code. For example, the law in Ghana bans "any photograph, drawing or other graphic representation other than for illustrating the method of preparation", a sweeping provision which prohibits not just pictures of babies, mothers or health workers, but any pictures of toys, fuzzy animals or other attractive drawings which are normally found on product labels. The Uganda regulations specify that labels of infant formula may never show a feeding bottle, even in the preparation instructions.

The laws of many countries require **specific warnings and notices** to appear on labels of not just infant formula but other products such as follow-up formula, complementary foods, feeding bottles and dummies. For example, in Brazil, the following text is required on the labels of growing-up milks: "Ministry of Health Warning: This product should not be used to feed children under one year of age. Breastfeeding prevents infections and allergies and is recommended up to two years of age or beyond." On labels of feeding bottle, teats and dummies, the following text is required: "Ministry of Health Warning: a breastfed child does not need feeding bottles, teats or dummies."

Article 9.3 addresses products that are marketed for infant feeding which do not meet all the requirements of an infant formula, but can be modified to do so. Article 9.4 requires labels of food products to include basic information such as the product's ingredients, composition, storage conditions and expiry date. These requirements are often included in national food laws and are based on Codex Alimentarius standards but they deserve to be repeated in Code-based laws.

Several WHA resolutions impact on labelling, and their recommendations should be incorporated into national laws. Under resolution WHA 58.32 [2005], nutrition and health claims for breastmilk substitutes should not be permitted unless allowed by national legislation. This is to tackle an upsurge of **unsubstantiated claims** appearing on product labels that assert improvements in the child's intelligence, visual acuity and immune system from additives such as DHA (docosahexaenoic acid), AA (arachidonic acid) and probiotics, the formulations of which have become major promotional tools. The prohibition on claims is extended to all foods for infants and young children in resolution WHA 63.23 [2010]. A country that started early to ban nutrition and health claims is Botswana, and a number of other countries have followed suit.

The problem of **powdered formula contamination** is addressed in resolution WHA 58.32 [2005] which requires explicit warnings on labels to inform consumers about the risks of contamination of powdered formula with pathogenic microorganisms. Resolution WHA 61.20 [2008] requires labels to conform to the WHO/FAO Guidelines²¹ on safe preparation, storage and handling of powdered infant formula. The Philippines and South Africa are two among only a few countries that have introduced provisions on the need for warning about intrinsic contamination of powdered infant formula.

The concept of **cross-promotion** through labelling is addressed in the WHO Guidance on ending the inappropriate promotion of foods for infants and young children. Under Recommendation 5, the packaging design, labelling and materials used for the promotion of complementary foods must be different from those used for breastmilk substitutes so that they cannot be used in a way that also promotes breastmilk substitutes (e.g., different colour schemes, designs, names, slogans and mascots other than company name and logo should be used).

A comprehensive Code-based law must include all of the above elements.

Drafting the Sections on Labelling

Sections 5 to 11 of the Model Law in Annex 4 contain detailed prohibitions relating to labelling of all products covered by the law. Apart from Section 5 which is of general application and bans promotional graphics and texts as well as claims, every Section that follows is reserved for the labelling content of a particular range of products. Matters such as appropriate languages, age indication, preparation instructions, list of ingredients, storage conditions, warning notices, placement and font sizes of important messages are covered.

As a whole, the labelling sections in the Model Law incorporate all the recommendations made by relevant resolutions and the 2016 Guidance to improve on existing Code provisions.

21. The guidelines can be downloaded at <http://www.who.int/foodsafety/publications/powdered-infant-formula/en/>

10. Quality standards

Article 10. Quality

- 10.1 The quality of products is an essential element for the protection of the health of infants and therefore should be of a high recognised standard.
- 10.2 Food products within the scope of this Code should, when sold or otherwise distributed, meet applicable standards recommended by the Codex Alimentarius Commission and also the Codex Code of Hygienic Practice for Foods for Infants and Children.

Resolution WHA 55.25 [2002] requests the Codex Alimentarius Commission to promote the safe and proper use of processed foods for infants and young children at an appropriate age, including through adequate labelling, consistent with the policy of WHO, in particular the International Code of Marketing of Breastmilk Substitutes, Resolution WHA 54.2, and other relevant resolutions of the Health Assembly.

Guidance WHA A69.7 Add1 [2016] (Referred to as the 2016 Guidance)

Foods for infants and young children that are not products that function as breastmilk substitutes should be promoted only if they meet all the relevant national, regional and global standards for composition, safety, quality and nutrient levels and are in line with national dietary guidelines. Nutrient profile models should be developed and utilized to guide decisions on which foods are inappropriate for promotion. Relevant Codex standards and guidelines should be updated and additional guidelines developed in line with WHO's guidance to ensure that products are appropriate for infants and young children, with a particular focus on avoiding the addition of free sugars and salt.

Article 10 of the Code recommends that food products within the scope of the Code should meet applicable Codex standards. National laws can refer to national standards on food products where they exist, or in their absence, the Codex quality standards which are devised to ensure fair practices in international trade and to protect the health of consumers.

Following Recommendation 3 of the 2016 Guidance, nutrient profile models should be developed and utilised to guide decisions on which foods function as breastmilk substitutes and which are thus inappropriate for promotion. Such nutrient profiling will be useful in determining the scope of national laws as not all products marketed in every country are the same.

Reference to national or Codex standards does not obviate the necessity of specific labelling provisions, since Codex standards deal mainly with **list of ingredients, product composition, date markings, storage instructions and information for utilisation**. The incorporation of national or Codex standards can normally be done through the definition of a particular product. See the Section on Definitions in the Model Law in Annex 4, particularly those on infant formula (Section 2(18)) and follow-up formula (Section 2(12)).

11. Implementation and Monitoring

Article 11. Implementation and monitoring

- 11.1 Governments should take action to give effect to the principles and aim of this Code, as appropriate to their social and legislative framework, including the adoption of national legislation, regulations or other suitable measures. For this purpose, governments should seek, when necessary, the cooperation of WHO, UNICEF and other agencies of the United Nations system. National policies and measures, including laws and regulations, which are adopted to give effect to the principles and aim of this Code, should be publicly stated, and should apply on the same basis to all those involved in the manufacture and marketing of products within the scope of this Code.
- 11.2 Monitoring the application of this Code lies with governments acting individually, and collectively through the World Health Organisation as provided in paragraphs 6 and 7 of this Article. The manufacturers and distributors of products within the scope of this Code, and appropriate nongovernmental organisations, professional groups and consumer organisations should collaborate with governments to this end.
- 11.3 Independently of any other measures taken for implementation of this Code, manufacturers and distributors of products within the scope of this Code should regard themselves as responsible for monitoring their marketing practices according to the principles and aim of this Code, and for taking steps to ensure that their conduct at every level conforms to them.
- 11.4 Nongovernmental organisations, professional groups, institutions, and individuals concerned should have the responsibility of drawing the attention of manufacturers or distributors to activities which are incompatible with the principles and aim of this Code, so that appropriate action can be taken. The appropriate governmental authority should also be informed.
- 11.5 Manufacturers and primary distributors of products within the scope of this Code should apprise each member of their marketing personnel of the Code and of their responsibilities under it.
- 11.6 In accordance with Article 62 of the Constitution of the World Health Organisation, Member States shall communicate annually to the Director-General information on action taken to give effect to the principles and aim of this Code.
- 11.7 The Director-General shall report in even years to the World Health Assembly on the status of implementation of the Code; and shall, on request, provide technical support to Member States preparing national legislation or regulations, or taking other appropriate measures in implementation and furtherance of the principles and aim of this Code.

Resolution WHA 34.22 [1981]

- *Stresses that the adoption and adherence to the International Code of Marketing of Breastmilk Substitutes is a minimum requirement and Member States are urged to give full and unanimous support to the implementation of the provisions of the Code in its entirety as an expression of the collective will of the membership of the World Health Organization.*
- *Requests WHO to give all possible support to Member States, as and when requested, for the implementation of the International Code, in particular in the preparation of national legislation and other related measures.*

Similar calls are made in Resolutions WHA 34.22[1981], 35.26 [1982], 37.40[1984], 39.28[1986], 41.11[1988], 43.3[1990], 45.34 [1992], 47.5 [1994], 49.15 [1996], 59.21 [2006], 61.20 [2008], 63.23 [2010] and 69.9 [2016].

The Global Strategy on Infant and Young Child Feeding formulated in 2002 by WHO and UNICEF (endorsed by resolution WHA 55.25 [2002]) considered implementing and monitoring existing measures to give effect to the International Code and subsequent Health Assembly resolutions, and, where appropriate, strengthening them or adopting new measures as an area of high priority action.

The Innocenti Declarations of 1990 and 2005, which were welcomed under resolutions WHAs 45.34 [1992] and 59.21 [2006], also make calls for the implementation and monitoring of the Code.

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.*
- *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.*

The discussion here outlines practical matters that need to be considered before an instrument becomes law, and what actions need to be taken when there is non-compliance of the law.

Once a decision has been made to enact a law, the first step to take is to check the constitution or basic law of the country to establish:

- where the law-making authority lies on issues of health, food or consumer protection;
- where the law is to originate;
- what the law-making procedure is before an instrument gets adopted as law;
- who should be brought on board to provide the political will, technical and legal know-how for the drafting of the bill that will eventually get adopted as law;
- where consultation is necessary, how to go about the process to obtain the necessary feedback from relevant stakeholders in the field of infant and young child feeding; and
- if the country is a member of the World Trade Organization (WTO) or is a signatory to any other bilateral or multilateral trade agreements, to consider whether notifications are required to WTO or any other entities or state parties.

Customs and procedures vary from country to country and the list above sets out only the broad outlines to give readers a general idea of the processes involved.²² It is absolutely necessary to obtain legal advice from the relevant government authority before embarking on a Code implementation initiative.

Health authorities have to be the prime movers behind Code-based laws, but it is necessary to get other parties involved to garner commitment and support from the outset. This will help to ensure a smooth passage of the law during the adoption process and accelerate execution when the time comes.

22. A 2017 Implementation Manual by WHO contains useful suggestions on how the legislative process could be managed. Retrieved from <http://www.who.int/nutrition/publications/infantfeeding/guidance-ending-inappropriate-promotion-food-manual/en/>

Some important steps to consider are:

- **Getting lawyers involved at an early stage**

It is important to give legal definition to a health and social issue and to determine what the law can and cannot cover under the country's constitution or basic law. Many health authorities have their own lawyers to refer to, others may have to get legal advice from outside the ministry. Lawyers who are experts in a country's legal system may still find that a law to protect breastfeeding is a completely new area, as they are not normally exposed to **matters that intersect between breastfeeding and marketing**. It is therefore imperative that these lawyers are provided with a sound foundation on the need for a law to protect breastfeeding. In this regard, the Code's preamble is a good primer and support should be sought from WHO and UNICEF. IBFAN-ICDC also has capacity and experience to render legal support.

- **Setting up a multi-disciplinary, inter-ministerial committee**

This should be done early to gain the support and commitment of other ministries. Some countries already have a **national breastfeeding committee** which could assume this role and stimulate action. The involvement of other ministries such as information, trade, education and justice from the outset is important, since their help would be required later to execute, monitor and enforce the law, once it is adopted. The involvement of international trade and investment authorities is also important as their help must be enlisted to prepare notifications and responses to international trade bodies and other entities.

A stumbling block that many countries face while attempting to draft and enact legislation to implement the Code is opposition that stems from a lack of understanding of the issues at hand. Ministries of commerce, authorities in charge of international trade and investment, as well as professional organisations such as national paediatric associations or pharmacists, to name a few, may initially oppose certain restrictions on advertising and assistance from industry, for example for educational and hospital equipment and services. To counter potential opposition, it is useful to develop and identify advocates who can explain what the law will do and why. **National and regional trade associations whose constituents are baby food manufacturers and distributors are a force to reckon with**. Their ability to influence, hold and roll back public health legislation must never be underestimated. This negative influence must be held at bay by timely and appropriate advocacy of decision makers in government.

The committee should complement the law-making process with media campaigns, breastfeeding promotion and education. Public interest NGOs could be invited to sit on this committee as ad hoc members. They normally have good networking support to provide platforms for advocacy work at the grassroots level.

While manufacturers and distributors may offer or even insist on being part of this committee, this would not be appropriate. Their inherent role is to produce and sell products which come under the scope of the Code, not to protect breastfeeding. Their participation in such a committee would constitute a **conflict of interest**, which absolutely must be avoided.

- **Consultations**

For the sake of transparency, many systems of government allow for consultations with stakeholders whose interest may be affected by a new law that is being adopted. Public interest NGOs, professional organisations and the baby food industry are all **interested parties**.

Members of industry may use business-friendly politicians and professional organisations to **lobby for a non-binding measure or a weak law** so that they can proceed with business as usual. Industry will want to have a say in drafting legislation, but its undue intervention may put infant health at risk, and should be contained by timing it after all government sectors have i) been properly briefed, ii) are fully aware of what is at stake, and iii) are ready to respond cohesively. All interventions in the drafting process must be in writing so as to rule out illegal threats based on unfounded allegations and false arguments.

Resolution WHA 61.20 [2008] reminds Member States to avoid conflicts of interest when implementing, monitoring and enforcing national measures. Resolution 65.60 [2012] urges Member States to establish adequate mechanisms to safeguard against potential conflicts of interest in nutrition action.

It is important that government authorities are aware that their duty under the Convention of the Rights of the Child and other human rights instruments is to protect the health of children. To do this, they need to put health above business considerations. For a discussion on Human Rights and the Code, see Part D on Matters related to Code implementation.

Execution

In order for the law to take effect, there must be **administrative, monitoring and enforcement mechanisms** in place. This requires the designation of an appropriate authority (normally the Ministry of Health) and within it a specific department like the Mother and Child Health Department or an independent agency like the Food and Drugs Board or Commission to take responsibility. Such an authority will oversee the execution of the law, set rules and procedures on administration and, if necessary, set up a registry of products to facilitate **monitoring and inspection**. It is also recommended that an **advisory board** of technical specialists be appointed to carry out special functions, such as vetting of information materials, reviewing of monitoring reports and advising on breastfeeding promotion. **To avoid conflicts of interest, no one with any interest in manufacturers and distributors manufacturing or distributing products under the scope of the Code should be appointed to this advisory board.**

There is a need for a policing force to ensure that the law is enforced. Such a force must be vested with the necessary authority to carry out inspection and investigation, and in the event of non-compliance, to set enforcement proceedings in motion. In most countries, there are inspection teams in Ministries of Health or Commerce which are vested with the power to take on policing duties including issuing notices and summonses, administering fines, and where necessary taking offenders to court. Existing policing systems have to be examined to see how they can be incorporated into the law so as to avoid setting up parallel bodies with overlapping duties resulting in competition for resources. All officials charged with the responsibility of executing the law must be **trained** so that they can carry out their duties effectively.

Exercising controls

Where a national law provides for controls in areas such as information, education materials and labelling, **vetting procedures** need to be set up by the controlling authority. There is a need to establish a set of rules which allows for certainty in the vetting process. In the Philippines, the Inter-Agency Committee set up to vet company material prescribes the internal and operational procedures for the exercise of its powers and functions. The Malaysian Code also contains procedures for vetting by the Vetting Committee. This way, from the outset, interested parties become aware of administrative matters such as to whom and to where to submit their materials (if required), which forms to fill (if any) and in what format, the estimated time for an application to be approved and the validity period of the approval.

Setting up procedural rules is a relatively simple administrative matter. The approval criteria may prove more difficult. A checklist would be helpful in ensuring consistency in the decision-making process and this could be drawn up following the legal provisions in the relevant sections of the law. Where legal provisions are clear, objective standards can apply and the vetting process becomes a simple exercise requiring an uncomplicated application of the law.

Invariably, though, there will be words and phrases which call for a subjective assessment and the exercise of discretion. Very often, messages which idealise a product are couched in language designed to blur the line between scientific and factually correct information and product propaganda. When this happens, a rule of thumb is to ask for references to support any representation that is made and to ensure the studies are recent, peer-reviewed and from reputable sources.

Past experience has shown that most claims that appear on company materials suggesting a link between a product or a constituent ingredient and health, growth and development of an infant are not supported by unbiased scientific evidence. Studies submitted are mostly funded or done by manufacturers and distributors themselves. A quick search on the internet will sometimes reveal controversies around a particular subject. Advice could also be sought from international agencies such as WHO and UNICEF, and NGOs such as IBFAN. When in doubt, the controlling authority should always act in favour of breastfeeding protection. Health must take precedence over business considerations.

Monitoring

Monitoring is a system of information gathering which can be carried out by any interested party, not just government officials who are vested with powers to inspect and investigate. Monitoring is important as it indicates whether a law is being observed and whether previous achievements are being maintained. In order to be objective and credible, the monitoring process itself must be transparent, independent and free from commercial influence. NGOs, professional groups, institutions and individuals who are actively involved in public health and safety can play a useful and complementary role to that of the government by monitoring the implementation of the law and possible violations. Manufacturers and distributors are encouraged to monitor their own activities (Article 11.3 of the Code) but this should be separate from the monitoring carried out by others. It is important that the function of monitoring is written into the law. This enables the public to forward official complaints to the designated policing authority for legal action to be taken. A monitoring mechanism should be written into the law. For discussion on how to establish a monitoring system, see Part C: Code Watch – Monitoring.

Enforcement

A law that is not enforced is very often disregarded. Governments must show they are serious about upholding the law by punishing offenders. The inspection and investigative work carried out by relevant policing bodies must culminate in the **imposition of administrative sanctions or prosecution in court**, depending on the country's legal system. The law must include a system of sanctions that can be imposed once an offender is found guilty. **Penalties imposed must be heavy to act as a deterrent.** Apart from fines and imprisonment which, are the sanctions normally imposed by a court of law, other forms of sanctions such as warnings, improvement notices, confiscation of goods (useful for violations relating to labelling or quality of the product), suspension or revocation of a licence or permit to manufacture, sell or import a product may be considered.

Stopgap measure

Laws take time to get adopted and enforced. Meanwhile, interim steps can be taken to minimise the harm caused by uncontrolled marketing of breastmilk substitutes on infant health. Once there is political agreement to implement the Code as law, health authorities should consider issuing a **communiqué to health care facilities and health workers** to respect the aim and principles of the Code. The health care system must be geared to uphold the impending law with a directive to root out practices which could give parents the impression that there is medical endorsement of a particular brand of product. Displays of products, company materials, the acceptance of gifts and samples and the distribution of free and low-cost supplies are some of the activities which should cease under the directive. Health workers must be informed of their responsibilities to promote and support breastfeeding and to avoid dealings with manufacturers and distributors which could give rise to conflicts of interest. While such communiqués do not have the force of law they can exert strong moral pressure and demonstrate the government's commitment to the Code and to breastfeeding.

Drafting the Sections on Administration

Chapter V of the Model Law in Annex 4 contains detailed provisions on implementation, enforcement and sanctions. This part of Code-based laws is often overlooked. There is a need for countries to initiate action to bring about better compliance by manufacturers and distributors.

Part C

Code Watch

Monitoring is essential in order to ensure that manufacturers and distributors who market breastmilk substitutes, feeding bottles or teats adhere to the International Code and to national measures, where they exist. For countries that have yet to implement the International Code, it is important to know what manufacturers and distributors are doing to promote breastmilk substitutes. Information obtained from monitoring marketing practices can then be used to advocate for Code implementation. If national measures already exist, it is important to determine if those measures are being complied with, and what necessary steps can be taken to strengthen measures or bolster weak administrative structures.

Resolution WHA 49.15 [1996] calls on Member States to ensure that monitoring the application of the International Code and subsequent WHA resolutions is carried out in a **transparent, independent manner, and is free from commercial influence**. This effectively precludes any collaboration with manufacturers and distributors in the monitoring process. Nevertheless, manufacturers and distributors are required under Article 11.3 to monitor their own marketing practices to ensure that their conduct conforms to the International Code at every level.

Monitoring is different from **enforcement**. Monitoring is centred on fact gathering with a view to admonishing, cautioning or reminding key players on matters relating to marketing. It is a watchdog and whistle-blowing mechanism which has proven effective by shaming corporations into behaving better. Enforcement on the other hand leads to sanctions, and must meet stringent legal procedures on investigation and prosecution, something which is not required for monitoring.

Enforcement is useful to compel obedience to laws and regulations but it relies upon an efficient policing system, a sound legal infrastructure and an independent judicial system. These factors are not always present and thus monitoring is a useful mechanism to encourage Code compliance. Indeed, monitoring and enforcement can co-exist and complement one another; recorded cases where manufacturers and distributors were prosecuted for Code violations were initiated through evidence gathered during monitoring.

1. Framework for monitoring

How monitoring is carried out within a country depends on whether or not there are provisions in national laws which govern the monitoring process. Where such provisions exist, they need to be followed. Not many national laws have monitoring provisions and they are often restricted to structures and procedures and not the practical aspects like how, where, what, why and when to monitor. As the success of a national monitoring system depends largely on feedback from health workers and members of the public as and when violations are uncovered, a statistical approach is not needed.¹ Manufacturers and distributors carry out their marketing on a large scale and if monitors can discover even one violation, it can confidently be inferred that the practice is occurring many times elsewhere.

Monitoring should be purposeful and focused on places where violations are occurring. Since it is impossible to catch all violations at any one time, monitoring systems should be designed to capture Code violations as they are being observed.² Done consistently over a period of time, it is possible to discern marketing trends and to establish whether a manufacturer and distributor is generally compliant or a serial violator.

1. 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) has developed a toolkit where a statistical approach is used. This toolkit is available at <http://www.who.int/entity/nutrition/publications/infantfeeding/netcode-toolkit-periodic-assessment.pdf?ua=1>. This toolkit is suitable, not for holding errant manufacturers and distributors to account, but for measuring the level of compliance with the Code and national laws, assessing trends and prioritising key issues to be addressed with strengthened legislation, interventions and funding.

2. NetCode also has a protocol for establishing a national ongoing monitoring system aims to assist governments in establishing a sustainable system that will monitor, detect and report violations of national laws. This toolkit is available at <http://apps.who.int/iris/bitstream/10665/259441/1/9789241513180-eng.pdf?ua=1>

2. Who monitors

Whether monitoring is being carried out by the government sector or an NGO, it is important to appoint a national coordinator who is well versed with breastfeeding and Code issues. The **national coordinator** must then select a team of 10 -15 monitors. This is a manageable size for most countries. It allows for proper briefing, sufficient coverage and the necessary creation of commitment and trust. Monitoring requires a certain amount of discretion and confidentiality so a larger team is not recommended as it becomes harder to keep track, to give guidance and to follow-up. Anyone who is committed to protecting breastfeeding can be a monitor. No special qualifications are required. Health and social workers active in health care facilities are ideally suited for carrying out monitoring since these are places where manufacturers and distributors infiltrate. Some health workers may have to deal with manufacturers and distributors in their official position and it would be important to verify first whether they are supportive of the Code's aim and principles and are not working with manufacturers and distributors to promote breastmilk substitutes directly or indirectly.

Once selected, monitors must be briefed on a) the aim and principles of the International Code, b) how it is related to the national law, and c) the purpose of the monitoring exercise so that they can perform their task well. They need to be well versed in the Code/national law and be familiar with monitoring forms necessary for fact gathering. Monitoring forms can be obtained from IBFAN-ICDC and may be modified to suit national laws where they exist. A simple, user-friendly **Quick and Easy Form** to record Code violations appears in **Annex 5**. This form can be modified to suit national circumstances. IBFAN-ICDC is able to provide monitoring training and has a do-it-yourself training kit for monitors who need to know more about monitoring.

As promotional targets, pregnant women and mothers also make good ad hoc monitors as manufacturers and distributors often approach them with gifts and offers. There must be an avenue for the public to submit their complaints directly to the national coordinator or a central collection point. They can be encouraged to use the simple monitoring form in Annex 5 and follow the general monitoring guidelines under Points 4, 5 and 6 below.

3. Scheduling monitoring

Marketing activities occur all year round, so anytime is a good time to monitor. There are however certain times in the year where promotional activities will peak, for example during festive seasons when gifts are distributed on a larger scale. Monitoring could be planned to coincide with these seasons. Ideally, monitoring should be continuous, but this is only possible if a system is already in place, normally with periodic review factored in. For start-up or pilot projects with new untried monitors, it is important to set a time frame so that there is a beginning and an end and results to show for the monitoring efforts made.

A period of three to six months is ideal. This can then become a yearly exercise. Some countries maximise resources by combining monitoring with other annual events such as World Breastfeeding Week or BFHI re-assessment.

However, if such a practice becomes entrenched, manufacturers and distributors become vigilant and clean up their acts during certain periods when they know they are being watched. It is therefore important to put in place a system of continuous monitoring – an avenue where anyone can be a watchdog or whistle blower and where complaints can be lodged at a central collection point and be followed up.

4. Where to monitor

To obtain enough information to discern habits and trends, national monitoring should cover both urban and rural areas. If resources are limited, monitoring can be done on a small scale; say 10 healthcare facilities in total for all areas. Monitors should visit all types of health care facilities, pharmacies and shops ranging in size from small grocery stores to large supermarkets. Monitors could be assigned specific areas, for example some could monitor health care facilities while others could monitor shops or the media - TV, radio, the internet, newspapers and magazines etc.

They could also check billboards, banners, direct mailings and junk mails. Another group could be assigned to check out labels. Everyone could be asked to interview mothers and this can be done anywhere. Interviews should preferably be conducted with mothers of babies less than six months old to ensure information is current.

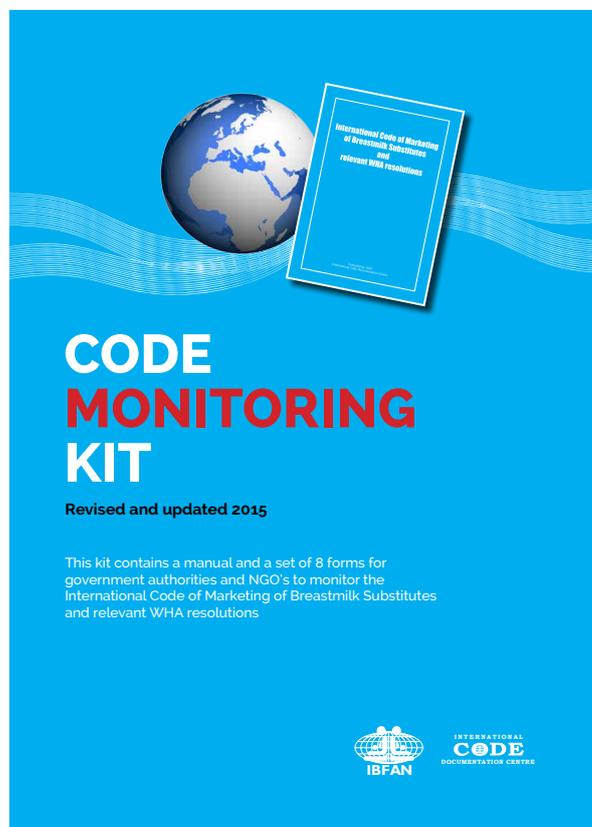
5. How to monitor

There is no single best way to collect information. Generally, monitors are required to conduct casual interviews, investigate, observe, confirm and record information. Monitors should be encouraged to talk to staff in health facilities, ask about routines, speak with mothers, observe what is going on and use any other appropriate means to find answers to questions.

The Code Monitoring Kit (IBFAN-ICDC Penang, December 2015) contains a manual and a set of 8 forms that cover monitoring in a variety of situations:

- Form 1- Interview with Mothers;
- Form 2- Promotion in Shops;
- Form 3- Hospitals, Clinics and Health workers;
- Form 4A, 4B & 4C– Labels; and
- Form 5– Company Materials and Practices.

A **Quick & Easy Form** is available for people who want to convey information without going into deeper analysis. The Quick & Easy Form is originally in English (see Annex 5) but is also available in French, Spanish, German and Chinese to encourage monitoring all over the world.



The Code Monitoring Kit serves as a blueprint for monitoring national laws and contains practical hints on monitoring and reporting. To address the rapid changes in technology and marketing tactics, the forms have been modified to address violations via the internet, social media and phone applications. The national coordinator can work with the monitors to modify the forms for national use.

With the aim to provide easy, on-the-go access for monitors, IBFAN-ICDC has developed two new monitoring tools: the online monitoring forms and the smart monitoring app, both built on KoBoCollect.³ All data collected and submitted through these tools will be transmitted to IBFAN-ICDC's KoBoCollect database instantly.⁴

6. What is a violation of the Code and resolutions?

Below is a list of commonly occurring practices, some of which are outright violations. Others require careful consideration. Monitors in countries which have national laws must bear in mind that national provisions may differ from the Code and subsequent WHA resolutions on which this brief summary is based. For every potential violation, it must first be determined whether it involves a product that is within the scope of the Code. See Code summary in Annex 1 for a listing of products under the scope of the Code.

3. 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.

4. The online monitoring forms, which are adapted from the forms in the Code Monitoring Kit, can be retrieved from the IBFAN-ICDC website: <https://www.ibfan-icdc.org/report/>. The KoBoCollect smart phone app, available for free on all Android smart phones, also allows all forms to be downloaded. A set of "10 Easy Steps" Instructions for download can be found on IBFAN-ICDC's website: <http://www.ibfan-icdc.org/wp-content/uploads/2017/03/KoboCollect-steps.pdf>. Monitors with iPhones can access monitoring forms on IBFAN-ICDC's website through their web browser.

a. Mass media

All advertisements (TV, radio, newspapers, magazines, billboards, internet, QR Codes, etc.) for products within the scope of the Code are violations. When monitoring for violations, monitors cannot ignore the internet, social media and phone apps. These electronic communication methods have infiltrated all facets of daily life and have propelled product promotion into the public and private realms through innovative means.

Resolution WHA 69.9 [2016] addresses the pervasive promotion that has rapidly increased over social media in recent years. The resolution urges media and creative industries to ensure their activities across all communication channels and media outlets are in accordance with the Guidance on ending the inappropriate promotion of foods for infants and young children [A69/7 Add.1 (Referred to as the 2016 Guidance)].

Even if no product name is mentioned in a company material, it is to be considered a violation if its content is presented in a way that leaves the reader in no doubt as to what product is being promoted (e.g. use of slogan, logo and icon or colour tones).

b. Point-of-sale

When visiting a shop or pharmacy, monitors should collect evidence of any of the following practices that involve a product within the scope of the Code:

- Posters, signs, LCD screens or notices attached to the product shelf (called “shelf talkers”).
- Special displays of products such as a stack of formula in the shop window or in a special rack. Find out from the shopkeeper if the distributor requested the display or if the idea originated with the shop.
- Product samples available to customers.
- Give-aways with the purchase of a product.
- Discount coupons, rebates or the like.
- Any other device or gimmick designed to encourage more sales of the product.
- Contact with the public by marketing personnel.

c. Hospitals and clinics

The following practices which undermine breastfeeding and induce health workers to promote products either directly or indirectly are violations.

- Free supplies.
- Any poster, calendar, clock, growth chart, leaflet, booklet, information sheet, cot/crib card or any other item decorating the walls or visible within a maternity, nursery or paediatric ward which displays a picture, logo or other reference to a product within the scope of the Code.
- Educational or informational posters, charts, leaflets and booklets dealing with infant feeding. If the item refers in any way to a product within the scope of the Code, it is a violation. If no product is mentioned, find out whether:
 - i. the item complies with Article 4.2, which requires specific details and warnings in educational and information materials. There should be no pictures or text that idealise the use of breastmilk substitutes, and
 - ii. the item was donated at the request and with the formal approval of the appropriate government authority.
- Free give-aways (pens, pencil holders, calendars, diaries, feeding implements, bibs, hats, toys, note pads, prescription pads, car window/bumper stickers, etc.)
- Product samples to the public. Any sample of a product within the scope of the Code given out within a health care facility is a violation. Coupons or other offers to receive a sample are also violations.

- Gift packs to new mothers upon discharge from hospital.
- Donations of equipment. Manufacturers and distributors may not donate equipment to health care facilities if the item refers to a product within the scope of the Code. A company may, however, donate equipment bearing the company name or logo.
- Medical representatives, professional service representatives, mothercraft nurses, etc. Company marketing personnel, no matter what they are called, should not have contact with new mothers or their families.

d. Promotion to health workers

Monitors should look out for evidence of interaction between manufacturers and distributors and health workers. Some of the signs to look out for are:

- **Product samples.** If monitors discover that samples of products within the scope of the Code were given to health workers, determine the answers to the following questions:
 - i. Was the product given for professional evaluation? Ask the recipient whether he or she receives regular samples of the same product, or more than one or two containers, how often and whether those samples are used as part of a professional evaluation of the product. Even if the container is marked “for professional evaluation only”, the facts will point to the donor’s intent.
 - ii. Was the product given for research at institutional level? In that case, there should be a specific research protocol for which the health worker requested the product samples. If the answer is NO to both questions, the sample is a Code violation.
- **Gifts.** Report as a violation
 - i. Any personal gift to a health worker, from a manufacturer or distributor of products within the scope of the Code, such as cash, meals or flowers, unless the gift is a contribution for a fellowship, a study tour, a research grant or for attendance at a professional meeting (which could include money to pay for airfares, lodgings, materials and food).
 - ii. Any item given in a health care facility (as long as it is not informational or educational) that advertises a brand within the scope of the Code, including use of slogans and logos relating to products within the scope.
- **Contributions.** Contributions to health workers for fellowships, study tours, research grants, attendance at professional conferences or the like are permitted under Article 7.5, as long as they are disclosed to the institution to which the health worker is affiliated. However, disclosure by itself does not eliminate the influence on health workers’ behaviour. It also does not mitigate conflicts of interest inherent within these contributions, but will help identify where the conflicts of interest lie and facilitate follow up action to eliminate or manage them. Do gather information about such contributions as the information will be useful to determine whether there are conflicts of interest. Resolution WHA 58.32 [2005] reiterates and strengthens resolution WHA 49.15 [1996] by calling on Member States to ensure that financial support and other incentives for programmes and health professionals working in infant and young child health do not create conflicts of interest. Resolution WHA 65.60 [2012] calls on Member States to safeguard against potential conflicts of interest in the implementation of nutrition programmes.
- **Professional meetings and seminars.** The above considerations apply. Additionally, any promotion such as banners, posters or free give-aways referring to a product within the scope of the Code distributed at such gatherings of health workers are promotional and hence are violations.
- **Professional journals.** Advertising in journals directed at health professionals is not specifically prohibited, but such advertisements will necessarily contain information about products within the scope of the Code, so they must comply with Article 7.2. To analyse

product advertisements in professional journals, answer the following questions:

- i. Is the advertisement restricted to scientific and factual matters?
- ii. Does the advertisement include the information specified in Article 4.2?

If the answer is NO to either question, the advertisement is a violation.

Product information leaflets, flyers and other handouts to health professionals: Follow the same criteria as above.

e. Product labels

- **All products:** Article 9.1 applies to all products under the scope of the Code. An attractive label on a box of infant cereal picturing a baby with a bottle and a statement such as “from the start” or “for all ages” can be considered a violation of Article 9.1 because it discourages breastfeeding. Article 9.1 applies to labels of feeding bottles and teats. Collect examples of labels that idealise bottle feeding.

Since 2005, there are two more factors which monitors should look out for in labels of all products under the scope of the Code. They pertain to **product claims and to warnings about intrinsic contamination**.⁵ Unless claims are allowed by national legislation, monitors should check for claims on labels that state or suggest that the product or its ingredients confer special benefits including the physiological role of a nutrient in growth, development or normal functions of the body. An example of a prohibited claim would be a statement that asserts that a particular product “increases resistance to infection”, “enhances brain development” or “improves eyesight”. Warnings regarding intrinsic contamination of powdered infant formula are still rare but monitors should look out for such warnings on labels and if they are present, verify that they have not been distorted.

- **Infant formula products:** Article 9.2 applies only to infant formula and not to the other products within the scope of the Code. Monitors must be careful when claiming label violations. A checklist will help.
- **Milk products unsuitable for infant feeding (without being modified):** products such as whole milk powder which are marketed as suitable for infant feeding are a violation of Article 9.3 if the label does not have a warning that the unmodified product should not be the sole source of nourishment for an infant.
- **Sweetened condensed milk:** the label of sweetened condensed milk must not state that the product is suitable for infant feeding or as a main ingredient in infant formula, and should not contain instructions on how to modify the product for infant feeding.
- **Cross-promotion:** The 2016 Guidance defines cross-promotion (also called brand crossover promotion or brand stretching) as a form of promotion where customers of one product or service are targeted with promotion of a related product. This can include packaging, branding and labelling of a product to closely resemble that of another (brand extension). Labels of complementary food products and other foods for infants and young children should not allow for cross-promotion. Look out for colour schemes, designs, names, slogans or mascots (other than company name and logo) that are used for both the promotion of complementary food and for breastmilk substitutes.

7. Conflicts of interest

- The 2016 Guidance contains a specific recommendation on conflicts of interest in health facilities and health systems. Companies that market foods for infants and young children, as well as health workers, health systems, health professional associations and non-governmental organisations should not create or allow conflicts of interest in health facilities and throughout health system. The list of promotional activities that could give rise to conflicts of interest are listed in section ‘Promotion in health care facilities’ (see p.25).

5. Resolutions WHA 58.32 [2005] and 63.23 [2010].

Part D

Matters related to Code implementation

1. Is the Code a barrier to trade?

Certain aspects of a Code-based law, especially those touching on food safety or labelling measures which govern product characteristics, could be viewed as imposing unnecessary obstacles to trade under international trade agreements. However, World Trade Organization (WTO) jurisprudence, on several occasions, has confirmed that WTO Members have the right to determine the level of health protection they deem appropriate.¹ So, if a WTO Member can show that a national law contributes to the achievement of a legitimate objective such as protecting human health, it is unlikely for any complaint that the law is trade restrictive to be upheld. To date, no Code-based law has been challenged under WTO trade agreements as a barrier to trade. This does not prevent industry from using WTO agreements to deter countries from implementing strong national laws. It is important for legislators and policy makers to understand some basic principles about trade agreements to fend off challenges that seek to derail Code implementation at the national level.

a. Relevant WTO Agreements

The main WTO Agreements which have some bearing on Code provisions are:

- i. the **General Agreement on Tariffs and Trade (GATT)** which prohibits discrimination among members and between imported and domestically produced goods;
- ii. the **Agreement on Sanitary and Phytosanitary Measures (SPS)** which requires that countries do not set unnecessary, arbitrary, scientifically unjustifiable or disguised restrictions on international trade when they adopt national measures to ensure food safety and protection of human life from plant or animal-carried diseases;
- iii. the **Agreement on Technical Barriers to Trade (TBT)** which requires that technical regulations and standards governing product characteristics, production methods and their related processes do not unnecessarily restrict trade; and
- iv. the **Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)** which obliges WTO Members to provide minimum protection to a range of intellectual property rights.

b. Key principles

The key principles which are a common feature of these agreements are:

- i. **Most favoured nation** – this means not discriminating among nationals of trading partners. Every time a country lowers or introduces a trade barrier or opens a market, it must do so for the same goods and services or service suppliers everywhere.
- ii. **National treatment** – this means treating foreign nationals no less favourably than one's own nationals. Imported and locally produced goods must be treated the same, in terms of competitive opportunities in the importing country's market.
- iii. **Health exceptions** – this means WTO members have the right to impose necessary measures to protect health and to achieve health objectives. They can themselves determine the level of health protection they deem appropriate based on scientific evidence, international standards, guidelines and recommendations.

Code implementation through a national law is unlikely to constitute a barrier to trade that would be actionable within the legal provisions of the WTO agreements **if** a country ensures that:

- there is non-discrimination among trading partners;
- the national law applies equally to foreign and domestic products; and
- there is cause to subordinate trade-related considerations to other legitimate policy objectives and constraints, such as health.

1. WTO/WHO (2002). WTO Agreements and Public Health – A joint study by the WTO and WHO Secretariat. Geneva, Switzerland.

On the last point, there are numerous studies that demonstrate the importance of breastfeeding and the risk of artificial feeding to the health of infants and young children. They provide the scientific justification for any law regulating the marketing of breastmilk substitutes. While it remains unclear if the Code and resolutions and other international recommendations on health and nutrition can be considered international standards under the WTO trade regime, there is definitely policy space in trade agreements for nutrition actions. **Code implementation is an area identified for policy coherence**² so whether or not the Code and resolutions are international standards may not be an issue.

"...the rules and provisions of the WTO agreements most relevant to health generally permit countries to manage trade in goods and services in order to achieve their national health objectives, as long as health measures respect basic trade principles such as non-discrimination. Even these provisions may be waived under exceptions for public health reasons as provided in many WTO agreements."

*WTO/WHO (2002). WTO Agreements and Public Health
– A joint study by the WTO and WHO Secretariat.
Geneva, Switzerland.*

It could be argued that when a WTO Member bases its national law on the Code and resolutions, it is facilitating rather than obstructing trade. The approach avoids the creation of multiple types of technical requirements and conformity assessment procedures at the national level.³ Should a WTO Member wish to impose a national law that **goes beyond the minimum standard** set by the Code and resolutions, it must be able to justify the decision if required by another Member to do so. The country must show that **deviations were necessary** as the international standard was ineffective or inappropriate **for the fulfilment of the legitimate objectives pursued by the national law**.⁴ In this respect, it must be emphasised that many national laws prohibit and restrict the use of trademarks, trade names, logos, symbols etc. on information materials and labels and in symbols to pursue the public health objective of protecting breastfeeding. Such provisions do not violate any WTO agreement, in particular TRIPS, as there is no positive right to use or exploit any intellectual property. In general, countries have a broad discretion to curtail the use of private trade mark assets associated with products.⁵

c. Notifications

Even though a Code-based law is unlikely to constitute an actionable barrier to trade, it is increasingly being viewed as a **notifiable measure**. This means that WTO Members are required to **submit a notification** to a central registry so that other WTO Members can be informed about a country's policies affecting trade.⁶ There is an elaborate system of notifications and cross notifications put in place under the terms of most WTO agreements which many developing countries find burdensome. The WTO Secretariat runs technical assistance activities to assist these countries in meeting their notification obligations.⁷

d. Other trade regimes

Apart from WTO administered trade agreements, there are a multitude of **regional and bilateral trade and investment treaties** which manufacturers and distributors may try to use as arguments against strong Code measures. These treaties normally contain chapters on the reduction of technical barriers to trade, on intellectual property rights and the all-important **industry-state dispute settlement (ISDS)** chapter. The ISDS chapter would allow industry to sue governments directly at an international arbitration tribunal for measures put in place for the protection of the public welfare, but which industry sees as having infringed upon its investment or expected profits.

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2. Hawkes, C. (2015). Enhancing Coherence between Trade Policy and Nutrition Action.
 3. WTO/WHO (2002). WTO Agreements and Public Health – A joint study by the WTO and WHO Secretariat. Geneva, Switzerland.
 4. UNICEF (2009). Report on a legal expert consultation on overcoming challenges to implementation and enforcement of the International Code of Marketing of Breastmilk Substitutes Nairobi, Kenya, 20 to 22 July 2009: Unpublished.
 5. TRIPS, Article 20. Retrieved from: https://www.wto.org/english/docs_e/legal_e/27-trips_04_e.htm#24.
 6. See Decision on Notification Procedures. Retrieved from: https://www.wto.org/english/docs_e/legal_e/33-dnotf_e.htm
 7. See Trade Related Technical Assistance. Retrieved from: https://www.wto.org/english/tratop_e/devel_e/teccoop_e/tctdnot_e.htm

As Code measures intersect with trade in a few important aspects, national fears of being locked in long and expensive legal tussles at a foreign tribunal have led to many **self-imposed regulatory chills or standstills**. Child health suffers as a result of inaction.

In this regard, policy makers can now take courage from a July 2016 ruling issued by the World Bank's International Centre for Settlement of Investment Disputes (ICSID) against tobacco giant, Philip Morris International (PMI).⁸ In this case, PMI's attempt to use a bilateral investment treaty to defeat Uruguayan laws restricting the use of trademarks on tobacco packaging failed. The tribunal found that **a trademark holder does not enjoy an absolute right of use, free of regulation**. A trademark holder only has an exclusive right to exclude third parties from the market so that only the trademark holder has the possibility to use the trademark in commerce, subject to the State's regulatory power.

This ruling is in line with the general concept that trademarks confer their holders **only the right to prevent others from using their marks**, and are still subject to state regulations. What is more important is the reinforcement of the principle that States have a sovereign right to decide on their laws and regulations to protect their population.⁹

The defeat of PMI in this high-profile case is a useful precedent and should, by analogy, deter the baby feeding industry from making attempts to challenge and delay public health protection measures that implement the Code.¹⁰

e. National court cases on trade

It is worth noting that the **European Court** has ruled in one case¹¹ that a Greek law which provides that only pharmacies can sell processed milk for infants does not hinder trade between Member States in the European Union as it relates to selling arrangements and is applied in a non-discriminatory manner. In the **Philippines**, the **Supreme Court** ruled¹² that although the Philippine Constitution enshrines free enterprise, it does not call for the removal of protective regulations. Anyone seeking to challenge the validity of such regulations as unnecessary and oppressive must clearly explain and prove how the marketing activities proscribed in the law would hamper the trade of breastmilk substitutes.

2. Human rights and the Code: Recasting the role of manufacturers and distributors

The human right to food and nutrition is well established in international human rights law. The foundation to human rights lies in the **Universal Declaration of Human Rights [1948]** which asserts in Article 25(1) that "everyone has the right to a standard of living adequate for the health and well-being of himself and his family including food..." This right is affirmed in the **International Covenant on Economic, Social and Cultural Rights [1976]** (Article 11) and the Convention on the Elimination of all forms of Discrimination against Women [1981] (Article 12). The UN Committee on Economic, Social and Cultural Rights (CESCR) in adopting **General Comment No. 12 on the Right to Adequate Food [1999]**, states that Governments "may need to take measures to maintain, adapt or strengthen dietary diversity and appropriate consumption and feeding patterns, including breastfeeding" and highlighted the need for **"legislation to enable breastfeeding" and for "the regulation of marketing of breastmilk substitutes."**¹³

8. Philip Morris Brands SARL v. Oriental Republic of Uruguay, ICSID, Case No. ARB/10/7, Award 7/8/16). Retrieved from: <http://www.italaw.com/cases/460>.

9. Nightingale, A. (2016) "The Significance Of Uruguay's Win Over Philip Morris International; Intellectual Property Watch, 21/07/2016. <http://www.ip-watch.org/2016/07/21/the-significance-of-uruguays-win-over-philip-morris-international/> 35 E/C.12/1999/5; 30. This document can be downloaded at <http://www.unhcr.ch/tbs/doc.nsf/0/3d02758c707031d58025677f003b73b9?Opendocument>.

10. In another case brought by PMI, Australia successfully fended off an attempt to use an ISDS clause to overturn the country's plain packaging law, but that case was won on purely procedural ground.

11. Commission vs. Hellenic Republic [1995] ECR 1621. This case relates to European Competition Law but is a useful analogy to use against trade arguments. Retrieved from: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:61992CJ0391&from=EN>

12. Pharmaceutical and Health Care Association of the Philippines v. Health Secretary Francisco T. Duque III et al. (GR No. 173034) where industry tried to invalidate a set of regulations which give effect to the Code and resolutions on a number of constitutional grounds, many of which failed, like the argument on restraint of trade.

13. E/C.12/1999/5. Retrieved from: http://www.fao.org/fileadmin/templates/righttofood/documents/RTF_publications/EN/General_Comment_12_EN.pdf

Before that, the **Convention on the Rights of the Child [1990]** (CRC) links the human right to food and nutrition with the right to the best attainable standard of health (Article 24). Article 24 of the CRC spells out the right of the child to **“the enjoyment of the highest attainable standard of health.”** Among the appropriate measures that governments are obliged to take to implement that right is “to ensure that all segments of society, in particular parents and children, are informed, **have access to education and are supported in the use of basic knowledge of...the advantages of breastfeeding.”**

Although the Code precedes the CRC by nine years, it has **human rights implications**. The Committee on the Rights of the Child, which reviews progress and makes recommendations to governments about implementing the provisions of the CRC, recognises implementation of the Code and resolutions as an appropriate measure for the fulfilment of government obligations under the CRC.

a. Recommendations made by the CRC Committee to State Parties

While reviewing compliance with the CRC through the period **2002-2012**, the Committee made recommendations to the following countries that they should regulate the marketing of breastmilk substitutes by drafting a national law or enforcing an existing measure:

2002: Lebanon and the United Kingdom.

2003: Viet Nam and Singapore.

2008: Eritrea, Serbia and Sierra Leone.

2009: Democratic Republic of Congo, Netherlands, France, Mauritania, Romania, Mozambique, Philippines, Bolivia and Pakistan.

2010: Ecuador, Argentina, Belgium, Macedonia, Grenada, Angola, Burundi, Guatemala, Montenegro, Nicaragua, Cameroon, El Salvador and Paraguay.

2011: Afghanistan, Denmark, Lao PDR, New Zealand, Singapore, Ukraine, Bahrain, Costa Rica, Cuba, Egypt, Iceland, Panama, Seychelles, Syria, Czech Republic and Italy.

2012: Thailand, Australia, Cyprus, Turkey, Bosnia & Herzegovina, Canada, Liberia, Namibia, Azerbaijan, Madagascar, Greece, Viet Nam and Austria.

From **2013-2016**, 20 countries received direct recommendations from the CRC Committee to either implement and/or enforce the Code: Bulgaria, China, Colombia, Dominican Republic, Fiji, the Gambia, Gabon, Germany, Guinea-Bissau, Hungary, India, Indonesia, Kyrgyzstan, Rwanda, Slovakia, Switzerland, Turkmenistan, Ghana, Mexico, Timor-Leste, Uzbekistan, United Kingdom, Venezuela and Yemen. 6 countries were urged by the CRC Committee to either regulate or strengthen their regulations on the marketing of breastmilk substitutes: Brazil, Croatia, Eritrea, Jamaica, Portugal and Slovenia.

In **2017**, full Code implementation was recommended to Serbia and to Saint Vincent and the Grenadines. Recommendations were given to Cameroon and Mongolia to strengthen Code implementation. The Democratic People’s Republic of Korea, Tajikistan and Vanuatu were recommended to implement the Office of the High Commissioner on Human Rights (OHCHR) Technical Guidance on the application of a human rights-based approach to the implementation of policies and programmes to reduce and eliminate preventable mortality and morbidity of children under 5 years of age.¹⁴ The OHCHR Technical Guidance makes direct reference to breastfeeding protection and support, and specifically calls for implementation and monitoring of the Code.

Manufacturers and distributors often claim that Code implementation interferes with a mother’s right to information. On the contrary, one of the principal aims of the Code is to protect this right.

14. A/HRC/27/31. Retrieved from <http://www.ohchr.org/EN/HRBodies/HRC/RegularSessions/Session27/Pages/ListReports.aspx>.

The belief that artificial feeding is the normal way to feed infants persists in society and is largely due to misinformation and manipulation by manufacturers and distributors. Global monitoring reveals that women are not protected from influences that disrupt breastfeeding.¹⁵ In implementing the Code and resolutions as a national law, governments are fulfilling their duties towards parents and children to protect them from commercial influence at crucial moments when infant and young child feeding decisions are being made.

b. Recasting the role of manufacturers and distributors

A human rights approach gives a different understanding about those who hamper the fulfilment of the right of children to good nutrition, including manufacturers and distributors who impede the fulfilment of the right of the child to the best attainable standard of health. In the words of Stephen Lewis, former Deputy Executive Director of UNICEF, **“those who make claims about infant formula that intentionally undermine women’s confidence in breastfeeding are not to be regarded as clever entrepreneurs just doing their job, but as human rights violators of the worst sort.”**

The case for recasting the role of manufacturers and distributors was strengthened when the Committee on the CRC released **General Comments No.15 (2013)**¹⁶ and **No.16 (2013)**¹⁷ which specifically urge State Parties to implement the Code and for industry to comply with it.

The Committee on the Elimination of Discrimination against Women followed suit by issuing **CEDAW General Recommendation No. 34 (2016) on the rights of rural women**. It declared that States should ensure that information on breastfeeding and its impact on child and maternal health is widely disseminated in local languages and dialects through several media, including in writing, illustrations and verbally. The recommendation also declares that childcare facilities, breastfeeding rooms and counselling on childcare and breastfeeding are made available, and finally that women must be allowed to breastfeed during working hours.¹⁸

The growing influence of industry at many levels does make the regulation of their marketing practices a daunting task. In 2016, the **UN Special Rapporteurs on the Right to Food,¹⁹ the Right to Health,²⁰ the Working Group on discrimination against women in law and in practice, and the Committee on the Rights of the Child** issued a statement in support of increased efforts to promote, support and protect breastfeeding.²¹ The statement notes the clear signs of lack of progress made in the adoption of effective measures by States to eliminate harmful or inappropriate marketing strategies and practices. It stresses that States should do more to support and protect breastfeeding and end inappropriate marketing of breastmilk substitutes.

In August 2017, the CESCR Committee released General Comment No. 24 (2017) on State obligations under the International Covenant on Economic, Social and Cultural Rights in the context of business activities.²² This General Comment provides important clarification on State Parties’ obligation to respect, protect and fulfil the economic, social and cultural rights with a view to preventing and addressing the adverse impacts of business activities on human rights.

15. ICDC (2017). “*Breaking the Rules, Stretching the Rules 2017*”, *Evidence of violations of the International Code of Marketing of Breastmilk Substitutes and subsequent resolutions*. IBFAN-ICDC, Penang, 2017. Available from <https://www.ibfan-icdc.org/product/breaking-the-rules-stretching-the-rules-2017-single-copy/>

16. CRC/C/GC/15. Retrieved from www2.ohchr.org/english/bodies/crc/docs/GC/CRC-C-GC-15_en.doc.

17. CRC/C/GC/16. Retrieved from www2.ohchr.org/english/bodies/crc/docs/GC/CRC-C-GC-16_en.doc.

18. CEDAW/C/GC/34. Retrieved from www.ohchr.org/EN/HRBodies/CEDAW/Pages/Recommendations.aspx

19. In various reports submitted to the Human Rights Council between 2014 and 2016, the Special Rapporteur on the Right to Food repeatedly emphasised the need for Code implementation and Code compliance. For example, in the 2016 Interim report, it was observed that one of the major obstacles to breastfeeding is the misleading marketing by baby food companies of breastmilk substitutes and the lack of corporate accountability for the adverse consequences of such abuses. Countries are thus encouraged to adopt, amend and strengthen legal measures in line with the Code and resolutions. In particular, the need for national legislation to adequately cover substitute products aimed at children older than 12 months was stressed. The Human Rights Council was called upon to endorse the 2016 WHO Guidance on ending the inappropriate promotion of foods for infants and young children. Retrieved from www.ohchr.org/EN/Issues/Food/Pages/FoodIndex.aspx

20. In a 2015 Report on the right to health in early childhood the UN Special Rapporteur on the Right to Health stressed the need for countries to ensure that mothers have an enabling and supportive environment to breastfeed children including adequate maternity protection and Code implementation and enforcement. Retrieved from <http://www.ohchr.org/EN/Issues/Health/Pages/AnnualReports.aspx>

21. Retrieved from: <http://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=20871>.

22. E/C.12/GC/24. Retrieved from http://tbinternet.ohchr.org/_layouts/treatybodyexternal/Download.aspx?symbolno=E%2fC.12%2fGC%2f24&Lang=en

It reiterates that the obligation to protect “sometimes necessitates direct regulation and intervention. States parties should consider measures such as restricting marketing and advertising of certain goods and services in order to protect public health, [...] such as of breastmilk substitutes, in accordance with the Code and resolutions.”

The various General Comments and reports issued under different human rights instruments show how a human rights approach can provide a **solid legal foundation for regulation**. The morality and legality surrounding the issue call for a different treatment of industry. For a start, manufacturers and distributors should not be taken on as ‘partners’ in the formulation of infant and young child feeding policies. Neither should they be involved in Code implementation nor the monitoring process.

LIMITED ROLE OF INDUSTRY: The **Global Strategy on Infant and Young Child Feeding**²³ explicitly defines the role of all concerned parties for the fulfilment of the right of children to the highest attainable standard of health and the right of women to full and unbiased information and adequate health care and nutrition. **The role of manufacturers and distributors is limited to two specific functions** under paragraph 44 of the Strategy:

- (a) to ensure that processed food products for infants and children, when sold, meet applicable Codex Alimentarius standards and the Codex Code of Hygienic Practice for Foods for Infants and Children; and
- (b) to be responsible for monitoring their marketing practices according to the principles and aim of the Code. They should ensure that their conduct at every level conforms to the Code, subsequent relevant WHA resolutions, and national measures that have been adopted to give effect to both.²⁴

3. The Code, HIV and infant feeding

The fact that HIV can be transmitted by an HIV-positive mother to her child through breastfeeding means feeding choices may not be straightforward, but it should not be used to undermine breastfeeding. In fact, breastfeeding can improve the health and chances of survival of the majority of infants of HIV-positive women. The Code is of particular relevance in this context, as misinformation (such as the idea that all breastfed babies of HIV-positive mothers get infected, therefore formulas are necessary) can be used by baby food manufacturers to justify promotional activities. This can come in the form of unsolicited supplies, charitable donations or discounts.

When the WHO HIV and Infant Feeding Technical Consultation was held in Geneva in 2006, there was insufficient data supporting the use of anti-retrovirals (ARVs) to prevent transmission through breastfeeding. Infant feeding options were decided with an individualised approach, and women who were HIV-positive were advised to avoid all breastfeeding if replacement feeding met the AFASS conditions (acceptable, feasible, affordable, sustainable and safe).

Since then, significant changes have been made to WHO Guidelines on HIV and Infant Feeding in 2010,²⁵ 2012,²⁶ and 2016.²⁷ At the time of writing, the global recommendation is that mothers living with HIV should breastfeed for at least 12 months (with 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.²⁷

23. WHO (2003). 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].

24. While companies are encouraged to monitor their own marketing practices, other monitoring efforts by governments, NGOs, professional groups, institutions and individuals should not receive financial support from industry— Resolution WHA 49.15 [1996]

25. 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/

26. 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/

27. 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. World Health Organization. 2016. Retrieved from http://www.who.int/maternal_child_adolescent/documents/hiv-infant-feeding-2016/en/

a. The 2010 Guidelines: Key principles and recommendations

In 2010, the WHO revised its previous guidelines on HIV and infant feeding, and recommended ARV interventions to prevent postnatal transmission of HIV through breastfeeding.²⁵ The following principles and recommendations in the 2010 Guidelines are of particular relevance to policy makers:

- National (or subnational) authorities should decide either breastfeeding with ARV intervention OR avoidance of all breastfeeding as national policy.²⁸ This was a paradigm shift from the individualised approach that was previously advocated.
- National authorities should integrate HIV testing, care and treatment interventions for all women into maternal and child health services.
- Mothers known to be living with HIV should be provided with lifelong ART or ARV drug prophylaxis interventions to reduce HIV transmission through breastfeeding.^{29, 30}
- The AFASS conditions for replacement feeding used prior to 2010 are further clarified. Necessary conditions now include: safe water and sanitation at household level; caregivers' ability to reliably provide sufficient infant formula to support infant's normal growth and development, to prepare it cleanly and frequently enough to ensure it is safe from risks of diarrhoea and malnutrition, and to exclusively give infant formula for the first six months; family support; and access to healthcare for comprehensive child health services.
- Counseling and support to mothers diagnosed with HIV should be carefully delivered to avoid undermining optimal breastfeeding practices among the general population.

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

As a result of updates on guidelines on ARV use for treating and preventing HIV infection in 2013 and 2016³¹ by WHO, the Guideline on HIV and Infant Feeding was also updated in 2016.²⁷ Since lifelong ART for **all** adults and children when HIV is first diagnosed is now recommended, 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 longer while being fully supported for ART adherence.³²
- Health authorities should coordinate and implement services in workplaces, communities and homes to protect, promote and support breastfeeding among women living with HIV.

Thus, public health policies should ensure that services are in place to support access and adherence to lifelong ART, and that breastfeeding is protected, promoted, and supported among women living with HIV. For countries that decide on replacement feeding for mothers living with HIV as national policy, there should be effective interventions to support safe and adequate replacement feeding.

c. The Code, HIV and infant feeding

The WHO Updated Framework for Priority Action (2012)²⁶ highlights that implementation and enforcement of the International Code and subsequent relevant WHA resolutions is one of the priority actions for governments in relation to HIV/AIDS. Implementation and enforcement should aim to protect breastfeeding as the recommended infant feeding practice for mothers living with HIV (with lifelong ART); and **protect those who are artificially fed** by ensuring product labels contain necessary information for safe preparation and consumption, and that decisions are free from commercial influence. There should be mechanisms to **avoid spillover** of breastmilk substitutes to the general population.

28. 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.

29. The recommended duration of breastfeeding and HIV treatment is revised in the 2016 Guidelines.

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

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

32. 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.

d. Implications for policymakers on Code implementation in the context of HIV

In accordance with the aforementioned WHO Framework, public policies should ensure the following:

- Existing measures that give effect to the Code and relevant WHA resolutions are implemented. Where appropriate, strengthen and adopt new measures.
- Ongoing monitoring that is independent and free from commercial influence.
- The relevance of the Code in the context of HIV is defined, and **that the prevalence of HIV is not used to misinform and undermine the Code and breastfeeding.**
- **The response to the HIV pandemic does not include the introduction of non-Code-compliant donations of breastmilk substitutes or the promotion of breastmilk substitutes.**
- (For countries that have decided to provide breastmilk substitutes for infants of HIV-positive mothers) Establish appropriate criteria for who should receive them and for how long, and adequate procurement and distribution systems.
- The conduct of manufacturers and distributors at every level conforms to the Code.
- Financial support and other incentives for programmes and health professionals in infant and young child health do not create conflicts of interest.

4. Infant feeding in emergencies and the Code

Emergencies such as droughts, floods, earthquakes, tsunamis, epidemics and wars are characterised by population displacement and food insecurity. The care and feeding of infants and young children are often compromised in these situations and this has contributed to the high disease and death rate among this group. In all circumstances, and especially in emergency situations, emphasis should be on protecting, promoting and supporting breastfeeding and ensuring timely, safe and appropriate complementary feeding. There will, however, be infants who for one reason or another cannot be breastfed. These include infants who have become separated from their mothers, infants whose mothers are ill or have died, those whose mothers' milk production has become very low or babies who were already artificially fed prior to the emergency situation. In response, large donations of infant formula, powdered milk and other breastmilk substitutes are often received from various sources in time of crisis. Although intentions are generally good, there is lack of awareness that such donations can do more harm than good as there are neither basic infrastructure nor adequate conditions to reduce the risks linked to the preparation of infant formula and other breastmilk substitutes.

A study³³ in Indonesia found strong associations between receipt of donated breastmilk substitutes and changes in feeding practices, and between receipt of infant formula and diarrhoea. The study concluded that uncontrolled distribution of infant formula exacerbates the risk of diarrhoea among infants and young children in emergencies.

Uncontrolled donations should therefore be avoided. Instead, suitable substitutes forming part of the regular inventory of foods and medicines must be procured, distributed and fed only to the small number of infants who have to be fed on breastmilk substitutes after a proper needs assessment. This helps prevent situations where excessive availability of breastmilk substitutes results in mothers forsaking breastfeeding when it is in fact a lifeline. In emergencies more than ever, early initiation, exclusive breastfeeding until six months, and continued breastfeeding until two years or beyond, as recommended by WHO, need to be promoted, protected and supported for child health and survival.

The danger of formula milk in humanitarian aid

A UNICEF study found rates of diarrhoea in Yogyakarta in the aftermath of the 2006 earthquake increased sixfold as the consumption of formula doubled.

"Donations of powdered milk in an emergency situation can literally increase the rate of death of young babies, while the people mean to do good."

*- Anne H. Vincent,
Head, Health & Nutrition Department
UNICEF Indonesia.
(The Jakarta Post, 7 July 2008)*

33. Hipgrave, D. B., Assefa, F., Winoto, A., & Sukotjo, S. (2012). Donated breastmilk substitutes and incidence of diarrhoea among infants and young children after the May 2006 earthquake in Yogyakarta and Central Java. *Public Health Nutrition*, 15(2), 307-315.

In this regard, principles of the Code and resolutions are vital to protect infants and young children.

Resolution WHA 47.5 [1994] addresses supplies in the context of emergency situations. This resolution urges governments to exercise extreme caution when planning, implementing or supporting emergency relief operations. It calls on governments to ensure that donated supplies of breastmilk substitutes be given only if all the following conditions apply:

- the infants have to be fed on breastmilk substitutes, as outlined in the guidelines concerning the main health and socio-economic circumstances in which infants have to be fed on breastmilk substitutes;
- the supply is continued for as long as the infants concerned need it; and
- the supply is not used as a sales inducement.

In 2010, resolution WHA 63.23 called on Member States to ensure that national and international preparedness plans and emergency responses follow the evidence-based **Operational Guidance on infant and young child feeding in emergencies**.

The latest Guidance on this topic is **Operational Guidance for Emergency Relief Staff and Programme Managers Version 3.0 – October 2017** (OG-IFE).³⁴ One of the key points of this Guidance is that donations of breastmilk substitutes, complementary foods and feeding equipment should not be sought or accepted in emergencies; supplies should be **purchased based on assessed need**. Section 6 of the OG-IFE discusses the subject of procurement and distribution of relevant products in ways which are Code compliant. The OG-IFE also stresses that **there should be no promotion of infant formula at the point of distribution, including displays of products or items with company logos**. The criteria set out in resolution WHA 47.5 [1994] regarding donated supplies in emergency relief operations must be read in the light of the OG-IFE.

5. Clarifying Article 6.6: “Infants who have to be fed” on breastmilk substitutes

At the 1985 World Health Assembly, delegates from a number of countries requested WHO to clarify the meaning of the phrase “infants who have to be fed on breastmilk substitutes.” A Technical Consultation held in December 1985 concluded that the number of infants who need to be fed on breastmilk substitutes for absolute physiopathological or socioeconomic reasons is very small; smaller still in maternity wards and hospitals since some of the conditions on which this need is based manifest themselves only after a mother and her infant have been discharged. Thus, the routine availability of free or subsidised breastmilk substitutes, unnecessary and potentially dangerous, should not be permitted in maternity wards and hospitals. **The experts’ conclusion effectively ruled out the inclusion of infants whose mothers chose not to breastfeed from the meaning of the phrase “infants who have to be fed on breastmilk substitutes”**.³⁵

The World Health Assembly incorporated the conclusion of the Technical Consultation in Resolution WHA 39.28 [1986]. This resolution urges Member States to ensure that the small amounts of breastmilk substitutes needed for the minority of infants who require them in maternity wards and hospitals are made available through the normal procurement channels and not through free or subsidised supplies. These products should be purchased, as any other food. Maternity wards and hospitals should not be recipients of free or subsidised supplies of breastmilk substitutes. Industry, however, found ways to continue giving free formula to other sections of health care facilities and further resolutions were needed to institute a complete ban on donations.³⁶

WHO has a 2009 updated list of acceptable medical reasons for supplementation with breastmilk substitutes, or for not using breastmilk at all.³⁷ This list does not override the position in Resolution WHA 47.5 [1994] that there should be no donations of free or subsidised supplies of breastmilk substitutes and other products under the scope of the Code, in any part of the health care system.

34. Retrieved from: http://s3.enonline.net/attachments/2671/Ops-G_2017_WEB.pdf

35. 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>;

36. Resolutions WHA 43.3 [1990], 45.34 [1992] and 47.5 [1994].

37. World Health Organization. [2009]. Acceptable medical reasons for use of breastmilk substitutes. Geneva, Switzerland: WHO. Retrieved from: http://www.who.int/nutrition/publications/infantfeeding/WHO_NMH_NHD_09.01/en/.

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 artificial 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.

State of the Code by Country

The table below shows the current position on Code implementation by 198 countries. Many countries have taken more than one type of action and thus fall within more than one category. However, for purposes of this table, they have been placed in the category for the most significant step they have taken.

1. Law [36]

Afghanistan
Albania
Armenia
Bangladesh
Bahrain
Benin
Bolivia
Botswana
Brazil
Cape Verde
Dominican Republic
Gabon
Gambia
Georgia
Ghana
India
Kosovo
Kuwait
Lebanon
Madagascar
Maldives
Mozambique
Nepal
Pakistan
Palau
Panama
Peru
Philippines
South Africa
Sri Lanka
Tanzania
Uganda
Venezuela
Viet Nam
Yemen
Zimbabwe

2. Many provisions law [31]

Azerbaijan
Burkina Faso
Burundi
Cambodia
Cameroon
Colombia
Comores
Costa Rica
Congo, Dem.Rep. of
Cote d'Ivoire
Egypt
El Salvador
Fiji
Guatemala
Indonesia
Kenya
Kyrgyzstan
Malawi

Mali
Mexico
Mongolia
Myanmar
Nigeria
Rwanda
Saudi Arabia
Serbia
Syria
Tajikistan
Thailand
Tunisia
Zambia

3. Few provisions law [61]

Argentina
Austria
Belgium
Bosnia Herzegovina
Bulgaria
Chile
Croatia
Cyprus
Czech Republic
Denmark
Djibouti
Ecuador
Estonia
Ethiopia
Finland
France
Germany
Greece
Guinea Bissau
Honduras
Hungary
Iceland
Iran
Iraq
Ireland
Italy
Jordan
Korea, Republic of
Laos
Latvia
Liechtenstein
Lithuania
Luxembourg
Malta
Monaco
Netherlands
Niger
Nicaragua
Norway
Oman
Palestine
Papua New Guinea

Paraguay
Poland
Portugal
Puerto Rico, C' wealth of
Romania
Senegal
Seychelles
Solomon Islands
Slovakia
Slovenia
Spain
Sudan
Sweden
Switzerland
Turkey
Turkmenistan
United Kingdom
Uruguay
Uzbekistan

4. Voluntary Code or Policy [12]

Australia
Barbados
Bhutan
Dominica
Guyana
Hong Kong, SAR China
Jamaica
Macao, SAR China
Malaysia
New Zealand
Swaziland
Tonga

5. Some provisions in other laws or guidelines [13]

Algeria
Belarus
China
Cuba
Kazakhstan
Macedonia
Moldova
Qatar
Russian Federation
Taiwan
Trinidad & Tobago
Ukraine
United Arab Emirates

6. Some provisions voluntary [17]

Bahamas
Belize
Brunei
Cook Islands

Grenada
Japan
Kiribati
Liberia
Marshall Islands
Mauritius
Morocco
Samoa
Singapore
St Kitts & Nevis
St Lucia
St Vincent
Vanuatu

7. Measure drafted [12]

Angola
Chad
Congo, People's Rep. of
Haiti
Lesotho
Libya
Micronesia
Namibia
Sao Tome & Principe
Sierra Leone
Timor Leste
Togo

8. Being Studied [16]

Antigua & Barbuda
Canada
Central African Rep.
Equatorial Guinea
Eritrea
Guinea
Israel
Korea, Dem. P.R.
Mauritania
Montenegro
Nauru
Somalia
South Sudan
Surinam
Tuvalu
United States

Country positions are valid as at April 2018.

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

KEY TO CATEGORIES

1. Law: These countries have enacted legislation or adopted regulations, decrees or other legally binding measures encompassing all or nearly all provisions of the International Code and subsequent WHA resolutions.

2. Many provisions law: These countries have enacted legislation or adopted regulations, decrees or other legally binding measures encompassing many provisions of the Code and subsequent WHA resolutions.

3. Few provisions law: These countries have enacted legislation or adopted regulations, directives, decrees or other legally binding measures covering only few of the provisions of the Code or subsequent WHA resolutions.

4. Voluntary Code or policy: In these countries the government has adopted all or most of the provisions of the Code and subsequent WHA resolutions through a voluntary Code, a government policy or other non-binding measure. There are no enforcement mechanisms.

5. Some provisions in other laws or guidelines applicable to the health sector: In these countries, i) the government has adopted some provisions of the Code and subsequent WHA resolutions in other laws in

particular those pertaining to quality, labelling or consumer protection, or ii) the government has directives applicable to the health sector only.

6. Some provisions voluntary: In these countries, the government has adopted some of the provisions of the Code and subsequent WHA resolutions through voluntary measures, official guidelines or other non-binding measures.

7. Measure drafted, awaiting final approval: In these countries, a draft law or other draft measure exists to implement all or most of the provisions of the Code and subsequent WHA resolutions, and the draft is pending approval/adoption as a law.

8. Being studied: The government in each of these countries is still studying how to best implement the Code and subsequent WHA resolutions.

Model Law

An Act¹ to ensure safe and adequate nutrition for infants and young children by protecting breastfeeding and by regulating the marketing of food products manufactured for infants and young children and of feeding bottles, teats and pacifiers.

It is hereby enacted as follows:

Chapter I Introductory

Section 1. Short Title and Commencement

- (1) This Act may be called the *[Marketing of Foods and Related Products for Infants and Young Children Act or Protection of Breastfeeding Act]*.²
- (2) This Act shall come into effect 60 days after the date of enactment.
- (3) This act extends to the whole of *[Anyland]*.

Section 2. Definitions

For purposes of this Act

- (1) “**Advertise**” means to make any communication or representation by any means whatsoever for the purpose of promoting the sale or use of a designated product, including but not limited to:
 - (a) written publication, television, radio, film, electronic transmission including the Internet, social media, video, telephone or mobile application;
 - (b) display of signs, billboards, or notices; or
 - (c) exhibition of pictures or models.
- (2) “**Advisory Board**” means a Board set up under Section 18.
- (3) “**Artificial feeding**” means feeding with any manufactured food product which replaces breastmilk either partially or totally.
- (4) “**Brand name**” means a name given by the manufacturer to a product or range of products.
- (5) “**Bottle feeding**” means feeding liquid or semi-solid food from a bottle with a nipple.
- (6) “**Complementary food**” means any food suitable or represented as suitable as an addition to breastmilk, infant formula or follow-up formula for infants from the age of six months (180 days) up to the age of 36 months.³
- (7) “**Complementary food product**” means a complementary food that is commercially processed.
- (8) “**Container**” means any form of packaging of a designated product for sale as a retail unit, including wrappers.
- (9) “**Cross-promotion**” means the use of similar brand names, packaging designs, labels, text, images, colour schemes, symbols or slogans or other means for the purpose of promoting another product.

1. In common law jurisdictions, a law adopted in parliament is known as an ‘Act’ and this is the approach taken in CE2. Each distinct article in an Act is called a ‘section’. If the Code is implemented as subsidiary legislation under an existing Act, it is usually referred to as a set of ‘Regulations’. In civil law jurisdictions, the terminology used and the drafting convention may differ but the substance of legal provisions should be the same.

2. Text in [] brackets can be replaced with different wording that is more appropriate to national circumstances.

3. The definition of “complementary food”, in particular its age range, will determine which complementary food product falls within the definition of “designated product”. The upper age limit for “complementary food” can be adjusted if a country chooses to limit the ban on promotion of complementary food products to say, infants or young children up to 12 or 24 months. Such discretion on age range cannot be exercised for formula products. See also Subsections 4(4) and 4(5) and footnote 6.

- (10) “**Designated product**”⁴ means
- (a) infant formula;
 - (b) any other product marketed or otherwise represented as suitable for feeding infants up to the age of six months;
 - (c) follow-up formula;
 - (d) young child formula;
 - (e) ready-to-use therapeutic food;
 - (f) complementary food product;
 - (g) feeding bottles, teats, pacifiers; and
 - (h) such other product as the Minister of Health may, by Notice in the Official Gazette, declare to be a “designated product” for the purposes of this Act.
- (11) “**Distributor**” means a person, corporation or other entity engaged in the business of marketing any designated product, whether wholesale or retail.
- (12) “**Follow-up formula**” means a milk or milk-like product of animal or vegetable origin formulated industrially in accordance with [*citation to the country’s standard for follow-up formula or, in the absence of such standard, citation to the Codex Alimentarius Standard for Follow-up Formula*] and marketed or otherwise represented as suitable for feeding infants and young children older than six months of age. It is also referred to as “follow-on formula” or “follow-on milk”. For the purposes of this Act, the term ‘follow-up formula’ includes any follow up formula for special medical purposes or dietary requirements and any follow-up therapeutic milk product for acutely malnourished infants and young children.
- (13) “**Health care facility**” means a public or private institution or organisation or private practice engaged directly or indirectly in the provision of health care or in health care education. It also includes a day-care centre, a nursery or other infant and young child-care facility.
- (14) “**Health claim**” means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health. A health claim includes but is not limited to the following:
- (a) a nutrient function claim that describes the physiological role of the nutrient in growth, development and normal functions of the body;
 - (b) any other function claim concerning specific beneficial effects of the consumption of foods or their constituents that relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health; and
 - (c) a reduction of disease risk claim relating to the consumption of a food or food constituent, in the context of the total diet, to the reduced risk of developing a disease or health-related condition.

In this context, health means a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity

- (15) “**Health professional**” means a health worker with a professional degree, diploma or licence, such as a medical practitioner, a registered nurse or midwife or such other person as may be specified by the Minister of Health by a Notice in the Official Gazette.
- (16) “**Health worker**” means a person providing or in training to provide health care services in a health care facility, whether professional or non-professional, including voluntary unpaid workers.
- (17) “**Infant**” means a child from birth up to the age of 12 months.
- (18) “**Infant formula**” means a milk or milk-like product of animal or vegetable origin formulated industrially in accordance with [*citation to the country’s standard for infant formula or, in the*

4. By introducing this collective term, one can avoid the use of the term “breastmilk substitute”, the meaning of which is a subject of long drawn controversy. If a full range of products is listed as being covered by the term “designated product” like in this Model Law, there will be no room for dispute about the scope of the law. Text in the substantive parts of the law will be neater and easier to read as well.

absence of such standard, citation to the Codex Alimentarius Standard for Infant Formula] and intended to satisfy, by itself, the nutritional requirements of infants from birth and/or during the first six months and includes products that continue to meet part of an infant's nutritional requirements after the first six months. For the purposes of this Act, the term 'infant formula' includes any formula for special medical purposes or dietary requirements and any therapeutic milk product for acutely malnourished children.

- (19) "**Inspector**" means an inspector appointed under Section 22.
- (20) "**Label**" means a tag, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, attached or otherwise appearing on a container of a designated product. For the purposes of Sections 5(1), 5(3), 10 and 11, the term "label" includes packaging and inserts.
- (21) "**Labelling**" includes any written, printed or graphic matter that is present on the label, accompanies the food, or is displayed near the food, including that for the purpose of promoting its sale or disposal.
- (22) "**Logo**" means an emblem, picture or symbol by means of which a company or a product is identified.
- (23) "**Manufacturer**" means a person, corporation or other entity engaged in the business of manufacturing a designated product whether directly, through an agent, or through a person controlled by or under an agreement with it.
- (24) "**Market**" means to promote, distribute, sell, or advertise a designated product and includes product public relations and information services.
- (25) "**Minister**" means Minister of Health of [Anyland].
- (26) "**Nutrition claim**" means any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals. The following do not constitute a nutrition claim:
- (a) the mention of substances in the list of ingredients;
 - (b) the mention of nutrients as a mandatory part of nutrition labelling;
 - (c) quantitative or qualitative declaration of certain nutrients or ingredients on the label if required by national legislation.
- (27) "**Pacifier**" means an artificial teat for babies to suck, also referred to as a "dummy".
- (28) "**Prescribed**" or "as prescribed" means prescribed or as prescribed by rules or written decision made pursuant to this Act.
- (29) "**Promote**" means to employ any method of directly or indirectly encouraging a person, a health facility or any other entity to purchase or use a designated product whether or not there is reference to a brand name.
- (30) "**Ready-to-use therapeutic food**" means an energy-dense, vitamin- and mineral-enriched food specifically designed to treat severe acute malnutrition in children above 6 months.
- (31) "**Sample**" means a single or small quantity of a designated product provided without cost.
- (32) "**Sponsorship**" means any financial or in-kind assistance to a person or a group of persons or an entity, whether public or private, and sponsor has a corresponding meaning.
- (33) "**Young child**" means a child from the age of 12 months up to the age of three years (36 months).
- (34) "**Young child formula**" means an industrially formulated milk or milk-like product of animal or vegetable origin that is marketed or otherwise represented as suitable for feeding young children from 12 months of age. It is also referred to as "growing up milk", "formulated milk" or "toddler milk"(note: There is as yet no international quality standard for young child formula).

Chapter II Prohibitions

Section 3. Sale of a designated product

A person shall not distribute for sale, sell, stock or exhibit for sale any designated product that

- (a) is not registered according to Section 21 of this Act or is not in accordance with the conditions of its registration; or
- (b) has exceeded its date of minimum durability.

Section 4. Promotion

- (1) [Except as provided in Subsections 4(4) and 4(5)]⁵, a manufacturer or distributor shall not him or herself, or by any other person or entity on his or her behalf, promote any designated product. Prohibited promotional practices include but are not limited to:
- (a) advertising;
 - (b) sales devices such as special displays, discount coupons, premiums, rebates, special sales, loss-leaders, tie-in sales, prizes or gifts;
 - (c) giving of one or more samples of a designated product to any person;
 - (d) donation or distribution of information or education material referring to infant or young child feeding or performance of educational functions related to infant or young child feeding, except as provided in Section 15;
 - (e) the use of health or nutrition claims on labels of designated products or in any information and education materials referring to infant and young child feeding, except as provided in Section 15; and
 - (f) cross-promotion of a designated product.
- (2) A manufacturer or distributor shall not him or herself, or by any other person or entity on his or her behalf
- (a) donate, waive payment through any means or provide at lower than the published wholesale price where one exists, and in its absence, lower than 80 per cent of the retail price, any quantity of a designated product to a health worker or a health care facility;
 - (b) donate to or distribute within a health care facility equipment, services or materials such as pens, calendars, posters, note pads, growth charts and toys or any other materials which refer to or may promote the use of a designated product;
 - (c) offer or give any gift, contribution, sponsorship, benefit, financial or otherwise, of whatever value to a health worker or to an association of health workers engaged in maternal and child health, including but not limited to fellowships, research grants or funding for meetings, seminars, continuing education courses or conferences;
 - (d) sponsor events, telephone counselling lines, campaigns or programmes related to reproductive health, pregnancy, childbirth, infant or young child feeding or related topics;
 - (e) directly or indirectly establish relationships with parents and other caregivers through baby clubs, social media groups, child care classes, contests and any other means; or
 - (f) include the volume of sales of designated products in the calculation of its employee remuneration or bonuses, nor set quotas for sales of designated products.
- (3) A health worker or an association of health workers engaged in maternal and child health shall not:
- (a) accept any gift, contribution, sponsorship, benefit, financial or otherwise, of whatever value, from a manufacturer or distributor or any person on his or her behalf;

5. Delete as appropriate. See footnote 6 below.

- (b) accept or give samples of designated products to any person; or
 - (c) demonstrate the use of infant formula, except to individual mothers or members of their families in very special cases of need, and in such cases, shall give a clear explanation of the risks of the use of infant formula as well as the other information required by Chapter IV.
- (4)⁶ A manufacturer or distributor may promote a complementary food product provided that:
- (a) such promotional practice does not take place in a health care facility;
 - (b) any material promoting a complementary food product must include a statement in characters *[insert particulars relating to character size, placement, appearance, etc. For example, “no less than one-third the size of the characters in the product name, and in no case less than 2mm in height”]* on:
 - i. the importance of exclusive breastfeeding for the first six months and of continued breastfeeding up to two years or beyond; and
 - ii. the recommended age of introduction which is not less than six months (180 days) and a statement that early introduction of complementary foods negatively affects breastfeeding.
- (5)⁷ Notwithstanding Subsection 4(4), a manufacturer or distributor shall not him or herself, or by any other person or entity on his or her behalf, promote a complementary food product through the use of messages in any form or media that are prohibited by Subsection 7 (1) (a) – (f).

Section 5. Prohibitions related to labelling of designated products

- (1) Except as provided in Subsection 7(1), a manufacturer or distributor shall not offer for sale or sell a designated product if the labelling thereto includes a photograph, drawing or other graphic representation other than for illustrating methods of preparation.
- (2) A manufacturer or distributor shall not offer for sale or sell a designated product, other than a feeding bottle, teat or pacifier, unless the labelling thereto indicates in a clear, conspicuous and easily readable manner, in *[insert appropriate language(s)]*, the following particulars:
 - (a) instructions for appropriate preparation and use in words and in easily understood graphics;
 - (b) the age in numeric figures after which the product is recommended;
 - (c) a warning about the health risks of improper use, preparation or storage and of introducing the product prior to the recommended age;
 - (d) the list of ingredients and the declaration of nutritional value in accordance with relevant national standards or, in the absence of such standard, with the relevant Codex Alimentarius Standard;
 - (e) the required storage conditions both before and after opening, taking into account climatic conditions;
 - (f) the batch number, date of manufacture and date before which the product is to be consumed, taking into account climatic and storage conditions;
 - (g) the name and national address of the manufacturer or distributor; and
 - (h) such other particulars as may be prescribed.
- (3) A manufacturer or distributor shall not offer for sale or sell a designated product if the labelling thereto contains any health or nutrition claim or any representation that states or suggests that a relationship exists between the product or constituent thereof and health, including the physiological role of a nutrient in growth, development and normal functions of the body.

6. Subsections 4(4) and 4(5), based on the Guidance on ending the inappropriate promotion of foods for infants and young children (69/7 Add.1) and WHA resolutions, are only applicable to countries that choose to permit certain types of promotion for complementary food products f.eg, in retail outlets. Countries that choose to prohibit ALL promotion of complementary food products should delete these Subsections. Otherwise; there will be a contradiction with preceding Subsections 4(1), 4(2) and 4(3) which ban the promotion of ALL designated products. See also footnote 3.

7. Delete as appropriate; see footnote 6 above

Section 6. Prohibitions related to labelling of infant formula, follow-up formula and young child formula.

- (1) A manufacturer or distributor shall not offer for sale or sell infant formula or follow-up formula unless the container or label affixed thereto, in addition to the requirements of Section 5, conforms to the following:
- (a) contains the words, “IMPORTANT NOTICE” in capital letters and indicated thereunder, the statement “Breastfeeding is the normal and optimal way to feed infants and young children. Breastmilk is important for the healthy growth and development of infants and young children. It protects against diarrhoea and other illnesses” in characters *[insert particulars relating to character size, placement, appearance, etc. For example, “no less than one-third the size of the characters in the product name, and in no case less than 2mm in height”]*;
 - (b) contains the word, “WARNING” and indicated thereunder, the statement, “Before deciding to supplement or replace breastfeeding with this product, seek the advice of a health professional. It is important for your baby’s health that you follow all preparation instructions carefully. If you use a feeding bottle, your baby may refuse to feed from the breast. It is more hygienic to feed from a cup” in characters *[insert particulars relating to character size, placement, appearance, etc. For example, “no less than one-third the size of the characters in the product name, and in no case less than 1.5mm in height”]*;
 - (c) has preparation instructions for infant or follow-up formula in powdered form that state that:
 - i. powdered formula is not sterile and may be contaminated with pathogenic microorganisms during the manufacturing process or may become contaminated during preparation;
 - iii. it is necessary for formula to be prepared one feed at a time using water first boiled and then cooled to not less than 70 °C; and
 - iii. any unused milk must be discarded immediately after every feed.
 - (d) includes a feeding chart in the preparation instructions;
 - (e) does not use the terms “maternalised”, “humanised” or terms similar thereto or any comparison with breastmilk;
 - (f) does not use text that may tend to discourage breastfeeding;
 - (g) specifies the source of the protein; and
 - (h) in the case of follow-up formula, states that the product shall not be used for infants less than six months old or used as the sole source of nutrition of infants in characters *[insert particulars relating to character size, placement, appearance, etc.]*
- (2) A manufacturer or distributor shall not offer for sale or sell young child formula unless the container or label affixed thereto, in addition to the requirements of Subsections 5 and 6(1)(c) – (g), states that the product shall not be used to feed infants below 12 months or used as the sole source of nutrition for young children” in characters *[insert particulars relating to character size, placement, appearance, etc.]*

Section 7. Prohibitions related to labelling of ready-to-feed therapeutic food and complementary food product.

- (1) In addition to the requirements of Subsections 5(2) and 5(3), a manufacturer or distributor shall not offer for sale or sell a ready-to-feed therapeutic food or a complementary food product if the container or label affixed thereto contains:
 - (a) any text, image or other representation that suggests the suitability of the product for infants under six months including but not limited to references to development milestones clearly reached before six months, the use of pictures of infants appearing to be younger than six months;
 - (b) any text, image or other representation that idealises the product or is likely to undermine or discourage breastfeeding or create a belief that the product is equivalent or superior to breastmilk;
 - (c) any text, image or representation that undermines or discourages appropriate complementary feeding or that may suggest that the product is inherently superior to home prepared complementary foods;
 - (d) any recommendation to feed the product in a bottle or otherwise promote the use of bottle feeding;
 - (e) any endorsement, or anything that may be conveyed or construed as an endorsement by a health professional, an association of health professional or other body; and
 - (f) any element that allows for cross-promotion of any other designated product.
- (2) In addition to the requirements of Subsection (1), the label of a ready-to-feed therapeutic food or a complementary food product shall include:
 - (a) A statement in characters *[insert particulars relating to character size, placement, appearance, etc. For example, “no less than one-third the size of the characters in the product name, and in no case less than 2mm in height”]* on:
 - i. the importance of exclusive breastfeeding for the first six months and of continued breastfeeding up to two years or beyond; and
 - ii. the recommended age of introduction which is not less than six months (180 days) and a statement that early introduction of complementary foods negatively affects breastfeeding.
 - (b) instructions for preparation, storage, handling and use; and
 - (c) a feeding chart showing the appropriate ration/serving size consistent with guiding principles issued by the World Health Organization.

Section 8. Prohibitions related to labelling of skimmed or condensed milk.

A manufacturer or distributor shall not offer for sale or sell skimmed or condensed milk in powder or liquid form, unless the container or label affixed thereto contains the words, “This product should not be used to feed infants” in characters *[insert particulars relating to character size, placement, appearance, etc.]*

Section 9. Prohibitions related to labelling of low-fat and standard milk

A manufacturer or distributor shall not offer for sale or sell low-fat or standard milk in powder or liquid form, unless the container or label affixed thereto contains the words, “This product should not be used as an infant’s sole source of nourishment” in characters *[insert particulars relating to character size, placement, appearance, etc.]*

[Note: The milks in Sections 8 and 9 do not fall within the scope of this Act unless they are marketed or otherwise represented as suitable for infants. It is recommended that these labelling provisions be incorporated into the country's food labelling laws. In addition, Sections 8 and 9 will require revision according to the types of milk products available in individual countries.]

Section 10. Prohibitions related to labelling of feeding bottles and teats

A manufacturer or distributor shall not offer for sale or sell a feeding bottle or teat unless the package or label affixed thereto, in addition to the requirements of Section 5(1), indicates in a clear, conspicuous and easily readable manner, in *[insert appropriate language(s)]*, the following particulars:

- (a) the words, "IMPORTANT NOTICE" in capital letters and indicated thereunder, the statement, "Breastfeeding is best. Breastmilk is the ideal food for the healthy growth and development of infants and young children. It protects against diarrhoea and other illnesses" in characters *[insert particulars relating to character size, placement, appearance, etc. For example, "no less than one-third the size of the characters in the product name, and in no case less than 2mm in height"]*;
- (b) the statement, "Warning: It is important for your baby's health that you follow the cleaning and sterilisation instructions very carefully. If you use a feeding bottle, your baby may no longer want to feed from the breast" in characters *[insert particulars relating to character size, placement, appearance, etc. For example, "no less than one-third the size of the characters in the product name, and in no case less than 2mm in height"]*;
- (c) instructions for cleaning and sterilisation in words and graphics;
- (d) a statement explaining that feeding with a cup is more hygienic than bottle feeding;
- (e) a warning that children should not be left to self-feed for long periods of time because extended contact with sweetened liquids, including infant formula, may cause severe tooth decay; and
- (f) the name and national address of the manufacturer or the distributor.

Section 11. Prohibitions related to labelling of pacifiers (dummies)

A manufacturer or distributor shall not offer for sale or sell a pacifier unless, in addition to the requirements of Section 5(1), it is labelled with the words, "Warning: Use of a pacifier can interfere with breastfeeding" in characters *[insert particulars relating to character size, placement, appearance, etc. For example, "no less than one-third the size of the characters in the product name, and in no case less than 1.5mm in height"]*.

Chapter III

Health Worker Responsibilities

Section 12. Health worker responsibilities

1. Heads of health care facilities and national and local health authorities shall take measures to encourage and protect breastfeeding and to implement this Act, and shall give information and advice to health workers regarding their responsibilities and particularly ensure that health workers are familiar with all of the information specified in Chapter IV.
2. Health workers shall encourage, support and protect breastfeeding. They are expected to know the provisions of this Act, particularly the information specified in Chapter IV.
3. Health workers shall work to eliminate practices that directly or indirectly impede the initiation and continuation of breastfeeding, such as prelacteal feeds.
4. Health workers shall make in writing a report to the head of their work place, who shall in turn report to the Advisory Board, on any offer a health worker receives for a sample or gift or other benefit from a manufacturer or distributor or on any other contravention of the provisions of this Act.

Chapter IV

Information and Education

Section 13. Information and education materials about infant and young child feeding

Information and education materials, whether written, audio or visual, which refer to infant and young child feeding shall:

- (1) contain only correct and current information and shall not use any pictures or text that encourage artificial feeding, or the use of feeding bottles or that discourage breastfeeding;
- (2) be written in [insert appropriate language(s)];
- (3) not give an impression or create a belief that a designated product is equivalent to, comparable with or superior to breastmilk or to breastfeeding;
- (4) not contain the brand name or logo of any designated product nor of any manufacturer or distributor of a designated product; provided that this clause shall not be applicable to information about designated products intended for health professionals as authorised by Section 15 of this Act; and
- (5) clearly and conspicuously explain each of the following points:
 - (a) the benefits and superiority of breastfeeding;
 - (b) the value of exclusive breastfeeding for six months followed by sustained breastfeeding for two years or beyond;
 - (c) how to initiate and maintain exclusive and sustained breastfeeding;
 - (d) why it is difficult to reverse a decision not to breastfeed;
 - (e) the importance of introducing complementary foods from the age of six months;
 - (f) how and why any introduction of artificial feeding, the use of a feeding bottle or the early introduction of complementary foods negatively affects breastfeeding; and
 - (g) that complementary foods can easily be prepared at home using local ingredients.

Section 14. Information and education materials about artificial feeding or feeding bottles.

- (1) If the material referred to in Section 13 includes the topic of artificial feeding or the use of a feeding bottle, it must also include the following points:
 - (a) instructions for the proper preparation, storage and use of the product including cleaning and sterilisation of feeding utensils;
 - (b) how to feed infants with a cup;
 - (c) the health risks of artificial feeding, the use of a feeding bottle and improper preparation of the product;
 - (d) explain that
 - i. powdered formula is not sterile and may be contaminated with pathogenic microorganisms during the manufacturing process or may become contaminated during preparation;
 - ii. it is necessary for powdered formula to be prepared one feed at a time using water first boiled and then cooled to not less than 70 °C; and
 - iii. any unused milk must be discarded immediately after every feed.
 - (e) the approximate financial cost of feeding an infant or a young child with such a product in the recommended quantities and
 - (f) that the practice of providing follow-up formula and young child formula is not necessary.
- (2) Except as provided in Section 15 concerning product information for health professionals, materials that include the topic of artificial feeding shall not contain any health or nutrition claims or other representation that states or suggests that a relationship exists between the product or constituent thereof and health, including the physiological role of a nutrient in growth, development or normal functions of the body.

Section 15. Product information for health professionals

Manufacturers and distributors may give materials about designated products to health professionals if such materials

- (1) are restricted to scientific and factual matters regarding the technical aspects and methods of use of the product;
- (2) provide references to published and peer-reviewed studies to support any representation or claim that states or suggests that a relationship exists between the product or a constituent thereof and health, growth or development; and
- (3) are otherwise in accordance with Sections 13 and 14 of this Act.

Section 16. Submission of materials to Advisory Board (OPTIONAL)

Any person who produces or distributes any materials referred to in this Chapter shall submit copies to the Advisory Board according to procedures as shall be prescribed.

Chapter V Administration

Section 17. Implementation

- (1) The Ministry of Health is principally responsible for the implementation of this Act.
- (2) The Minister of Health shall, when necessary, call upon other ministries to ensure the implementation of this Act.
- (3) For the purpose of implementing this Act, the Minister of Health shall have the following powers and functions:
 - (a) to promulgate such rules as are necessary or proper for the implementation of this Act and the accomplishment of its purposes and objectives;
 - (b) to call for consultations with government agencies and other interested parties to ensure implementation and strict compliance with the provisions of this Act and the rules promulgated hereunder;
 - (c) to cause the enforcement of this Act and to appoint an official within the Ministry of Health to carry out this function on his or her behalf; and
 - (d) to exercise such other powers and functions that may be necessary for or incidental to the attainment of the purposes and objectives of this Act.

Section 18. National Advisory Board for the Promotion and Protection of Breastfeeding

- (1) There shall be a National Advisory Board for the Promotion and Protection of Breastfeeding to be composed of the following members:

[In this section, list the members to be included in this inter-disciplinary committee. Countries usually include representatives of relevant ministries such as Health, Education, Communications and Trade, and representatives of organisations of health professionals, consumers, breastfeeding support groups as well as experts in relevant fields. The proviso excludes manufacturers and distributors of designated products from the committee because their involvement would create conflicts of interest. Such conflicts would compromise independence, integrity and credibility of a committee that advises the government on enforcement of the law.]

 - (a) The Minister of Health or his representative who shall be its ex officio Chairman;
 - (b)
 - (c) . . .
 - (x) Such other persons as the Minister may, by Notice in the Official Gazette, appoint as members of the Advisory Board; provided that no person shall be appointed who has any direct or indirect financial interest in any designated product.
- (2) The Minister shall appoint the members of the Advisory Board within 90 days of the date of enactment.
- (3) The members of the Advisory Board shall hold office for a term of 3 years and shall be eligible for renomination.
- (4) Any member of the Advisory Board may, at any time, resign his or her office by writing to the Minister or shall vacate his or her office if the Minister so directs. A vacancy shall be filled in the same manner as the original appointment for the balance of the unexpired term.

- (5) The Advisory Board may invite national or foreign experts to take part in the meetings as observers and may constitute committees or appoint experts for the purpose of detailed study of any matter set before it.
- (6) The Minister may, by Notice published in the Official Gazette, change the size and composition of the Advisory Board.

Section 19. Administration of the Advisory Board

- (1) The Minister shall appoint the Secretary of the Advisory Board and such other officers as he or she deems necessary to carry out the purposes of this Act.
- (2) The Advisory Board shall hire permanent staff necessary to carry out its functions, subject to the budgetary approval of the Minister.
- (3) The Advisory Board shall meet as often as it deems necessary, but not less than once every month at such time and place as the Secretary shall indicate.
- (4) The Secretary shall call meetings at the direction of the Chairman; shall maintain minutes of the meetings and shall perform such other duties as may be directed by the Advisory Board.
- (5) Two-thirds of the members of the Advisory Board shall constitute a quorum for a meeting.
- (6) A majority vote of the members present shall be sufficient to approve any business presented in a meeting of the Advisory Board.
- (7) Decisions of the Advisory Board shall be certified by the Secretary.
- (8) The Advisory Board may make such other administrative rules as may be required for its proper functioning.

Section 20. Powers and functions of the Advisory Board

- (1) The Advisory Board shall have the following powers and functions:
 - (a) to advise the [*insert Head of State*] and the Minister on national policy for the promotion and protection of breastfeeding;
 - (b) to create regional committees to carry out the functions of the Advisory Board at the regional level, as may be prescribed;
 - (c) to advise the Minister on designing a national strategy for developing communication and public education programmes for the promotion of breastfeeding; information and educational materials on the topics of infant and young child feeding; continuing education for health workers on lactation management and the requirements of this Act; curricula for students in the health professions that include lactation management and to ensure widespread distribution of and publicity concerning this Act, in a method as may be prescribed;
 - (d) to review reports of violations or other matters concerning this Act;
 - (e) to issue instructions to inspectors as to actions to be taken, or take such other actions as the case may be, against any person found to be violating the provisions of this Act or the Rules promulgated pursuant thereto;
 - (f) to scrutinize materials submitted in accordance with Section 16 and recommend appropriate actions to be taken in the case of a violation of Chapter IV; and
 - (g) such other powers and functions, including the powers of an Inspector, as are conferred by the provisions of this Act and as may be prescribed.

Section 21. Registration of designated products

- (1) The Minister of Health shall cause all designated products to be registered in accordance with such conditions and procedures as may be prescribed.
- (2) The Minister of Health shall, by notification in the Official Gazette, fix the date after which no designated product that is not registered may be imported, manufactured or sold.
- (3) A person applying for registration of a designated product shall furnish such information and samples as may be prescribed.
- (4) Once the registration of a designated product has been approved, a Certificate of Registration shall be issued.
- (5) No Certificate of Registration shall be granted unless the designated product is in accordance with the [insert applicable Food Quality Standards] and has a label which is in accordance with the requirements contained in Chapter II of this Act.

Section 22. Inspectors

The Minister shall appoint such persons as he or she sees fit having the prescribed qualifications to be Inspectors for purposes of this Act within such local limits as he or she may assign to them respectively, provided that no person who has any direct or indirect financial interest in any designated product shall be so appointed.

Section 23. Powers of inspectors

- (1) An inspector may, within the local limits for which he or she is appointed:
 - (a) inspect any premises where any designated product is imported, manufactured, sold, stocked, exhibited for sale, advertised or otherwise promoted and all relevant records;
 - (b) institute prosecution with respect to violations of this Act and the Rules made pursuant thereto; and
 - (c) exercise such other powers as may be prescribed.

Section 24. Procedure for inspectors

- (1) Inspectors shall inspect, not less than the number of times as may be prescribed, the premises as may be prescribed.
- (2) After each inspection, the inspector shall submit a report including any finding of a violation of this Act and the Rules made pursuant thereto, to the Advisory Board and seek instructions as to the action to be taken in respect of such contravention.
- (3) Institute enforcement, where applicable.

Chapter VI

Sanctions, Procedure

Section 25. Penalties

- (1) Any person who him or herself or on behalf of any other person contravenes Sections 3 and 4 shall be punishable with imprisonment for a term which shall not be less than *[time]* or a fine which shall not be less than *[amount]* or both.
- (2) Any person having been convicted of an offence under Subsection (1) and who is again convicted of an offence under that Subsection, shall be punishable with imprisonment for a term which shall not be less than *[time]* or with a fine that shall not be less than *[amount]*.
- (3) Any person who contravenes any other provision of this Act or the Rules made pursuant thereto may be subject to a fine of up to *[amount]* or a period of imprisonment of up to *[time]*.

Section 26. Improvement Notices, Cease and desist orders, etc.

- (1) If the Minister or any official appointed by the Minister has reasonable grounds for believing that any person is failing to comply with the provisions of this Act or the Rules promulgated thereto, he or she may, by a notice served on that person (in this Act referred to as an “improvement notice”):
 - (a) state the grounds for believing that the person is failing to comply with this Act or the Rules promulgated thereto;
 - (b) specify the matters which constitute the person’s failure so to comply;
 - (c) specify the measures which the person must take in order to secure compliance; and
 - (d) require the person to take those measures, or measures which are at least equivalent to them, within such period (not being less than 14 days) as may be specified in the notice.
- (2) In addition to the powers conferred under Subsection (1), the Minister or any official appointed by the Minister shall have the power to make cease and desist orders upon receiving a report from an inspector or the Advisory Board of a violation of the provisions of this Act or the Rules promulgated pursuant thereto.
- (3) Any person who fails to comply with an improvement notice or cease and desist order under Subsection (1) or (2) shall, after notice and an opportunity to be heard have been given, be guilty of an offence.

Section 27. Suspension or revocation of certificate of registration

Where any person has been found to have contravened any of the provisions of this Act, or the Rules pursuant thereto, the Minister, upon written recommendation of the Advisory Board, and after notice and an opportunity to be heard have been given, may suspend or revoke any Certificate of Registration that has been issued to that person pursuant to this Act.

Section 28. Suspension or revocation of professional licence

Where any health professional has been found to have contravened any provision of this Act, or the Rules pursuant thereto, the Minister may recommend to the relevant authority the suspension or revocation of any licence for the practice of that person’s profession.

Section 29. Suspension or revocation of licence, permit or authority

[Note: If a licence to manufacture, import or sell is required, give the Minister the power to suspend or revoke that licence.]

Section 30. Appeal

There shall be a right of appeal to the [*insert higher court*] within 35 days of the judgment.

Section 31. Strict liability for officers, directors, etc.

When the person guilty of an offence under this Act is a corporation, company, partnership, firm or other association, every director, officer, partner, and employee of the corporation, company, partnership, firm or other association, shall also be liable for that offence unless he or she proves that the offence was committed without his or her knowledge or consent.

Section 32. Institution of prosecution

- (1) Prosecution under this Act may be instituted only by:
 - (a) an Inspector appointed pursuant to Section 22;
 - (b) a member of the Advisory Board; or
 - (c) a representative of such voluntary organisation engaged in the field of child welfare and development or child nutrition as the Minister, by notification in the Official Gazette, may authorise in this behalf

Section 33. Public enforcement

- (1) Any person has the right to lodge a formal complaint to the Advisory Board, which may recommend that proceedings be instituted against any person relating to a violation of any provision that constitutes an offence under this Act or Rules made pursuant thereto.
- (2) Any person has the right to commence an action for damages in [*a court of law*] against any manufacturer or distributor or other person for any harm suffered as a result of a violation of any provision that constitutes an offence under this Act or Rules made pursuant thereto.

Section 34. Power to make Rules

- (1) The Ministry of Health may, by notification in the Official Gazette, make Rules for carrying out the purposes of this Act.
- (2) In particular but notwithstanding the generality of the foregoing provision, such Rules may prescribe:
 - (a) the functions of the Advisory Board;
 - (b) conditions and procedures for the registration of designated products;
 - (c) qualifications and powers of and procedures for Inspectors appointed pursuant to this Act; and
 - (d) procedures for submitting educational or informational materials to the Advisory Board.

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?**

<i>Company</i>	<i>Brand</i>	<i>Type of product¹</i>	<i>Type of violation²</i>

¹ Type of product

- | | |
|---|--|
| A. Infant formula including special formula | F. Juice/tea/mineral water |
| B. Follow-up formula | G. Bottle |
| C. Growing-up milk | H. Teat |
| D. Cereal | L. Other (write under 'type of product') |
| E. Fruit/vegetables/meat puree | |

² Type of violation

- | | |
|--|---|
| A. Advertisement - in print/online | F. Gift to health worker |
| B. Commercial promotion in health facility | G. Gift to mothers |
| C. Company contact with mothers -
in person/via internet/social media/phone app | H. Inadequate labelling |
| D. Donation of products to health facilities | I. Promotion in shops |
| E. Free sample | 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 companies into more ethical behaviour. IBFAN also helps to promote and support breastfeeding in other ways.



About ICDC

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

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

IBFAN-ICDC
P.O. Box 19
10700 Penang, Malaysia
Email: code@ibfan-icdc.org
Web: www.ibfan-icdc.org

