

# THE INTERNATIONAL CODE OF MARKETING OF BREAST-MILK SUBSTITUTES

2017 Update

Frequently Asked Questions



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### The International Code of Marketing of Breastmilk Substitutes

### **Frequently Asked Questions**

2017 Update

Many people who have heard about the International Code of Marketing of Breast-milk Substitutes have expressed interest in knowing more about it.

The purpose of this booklet is to provide easy-to-read detailed information on specific questions related to the Code. It is intended for policy-makers, health workers and others concerned with the Code, as well as the general public.

# Q. WHAT IS THE INTERNATIONAL CODE OF MARKETING OF BREAST-MILK SUBSTITUTES?

The Code is a set of recommendations to regulate the marketing of breast-milk substitutes, feeding bottles and teats. The Code aims to stop the aggressive and inappropriate marketing of breast-milk substitutes. The 34th session of the World Health Assembly (WHA) adopted the International Code of Marketing of Breast-milk Substitutes in 1981¹ as a minimum requirement to protect and promote appropriate infant and young child feeding.

The Code aims 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 breast-milk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution" (Article 1).

The Code advocates that babies be breastfed. If babies are not breastfed, for whatever reason, the Code also advocates that they be fed safely on the best available nutritional alternative. Breast-milk substitutes should be available when needed, but not be promoted.

The Code represents an expression of the collective will of governments to ensure the protection and promotion of optimal feeding for infants and young children.

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<sup>&</sup>lt;sup>1</sup> Resolution WHA34.22 (1981).

# Q. WHAT ARE THE CURRENT WHO RECOMMENDATIONS FOR FEEDING INFANTS AND YOUNG CHILDREN?

To achieve optimal growth, development and health, WHO recommends that infants should initiate breastfeeding within one hour of birth and be exclusively breastfed for the first six months of life. Thereafter, to meet their nutritional requirements, infants should receive adequate and safe complementary foods while breastfeeding continues up to two years of age and beyond.

Exclusive breastfeeding from birth is possible for most women who choose to do so. It is recommended for all children except for a few medical conditions, such as maternal medication with radioactive substances.<sup>2</sup> Exclusive breastfeeding as often and as long as the baby wants results in ample milk production.

### Q. WHY IS BREASTFEEDING IMPORTANT?

Breastfeeding is unparalleled in providing the ideal food for infants. Breast milk is safe, clean and contains antibodies which help protect the infant against many common childhood illnesses.

The protection, promotion and support of breastfeeding rank among the most effective interventions to improve child survival. Increasing breastfeeding to near-universal levels could save more than 820 000 lives every year.<sup>3</sup> In addition, increased rates of breastfeeding could prevent nearly half of all diarrhoeal diseases and one-third of all

<sup>&</sup>lt;sup>2</sup> WHO/UNICEF. Breastfeeding counseling: A training course. WHO/CDR/93.4, Geneva, World Health Organization 1993, <a href="http://www.who.int/child-adolescent-health/publications/NUTRITION/BFC.htm">http://www.who.int/child-adolescent-health/publications/NUTRITION/BFC.htm</a>

<sup>&</sup>lt;sup>3</sup> Victora CG, Bahl R, Barros A et al. Breastfeeding in the 21st century: epidemiology, mechanisms, and lifelong effects. Lancet. 2016;387:475-490.

respiratory infections in children in low- and middle-income countries. Children who were breastfed are less likely to become overweight or obese and less prone to develop diabetes later in life.

Mothers who breastfeed also reduce their risk of developing breast and ovarian cancers. At current breastfeeding rates, an estimated 20 000 deaths from breast cancer are prevented; this could be doubled if rates improved.<sup>4</sup> In addition, breastfeeding delays early return of fertility in the mother, and reduces her risk of postpartum haemorrhage.

In addition to the risks posed by not having breast milk's protective qualities, breast-milk substitutes and feeding bottles in particular carry a high risk of contamination that can lead to life-threatening infections in young infants. Infant formula is not a sterile product and it may carry germs that can cause fatal illnesses. Artificial feeding is expensive, requires clean water, the ability of the mother or caregiver to read and comply with mixing instructions and a minimum standard of overall household hygiene - factors not readily met in many households in the world.

Beyond the health benefits, there are economic advantages. Interventions to improve breastfeeding practices are cost-effective and rank among those with the lowest cost-benefit ratio. The cost per child is low compared to that for curative interventions. Studies in Brazil, China, United Kingdom, and the United States of America have shown that boosting rates of exclusive breastfeeding for infants less than 6 months would significantly cut treatment costs of common childhood illnesses such as pneumonia, diarrhoea and asthma.<sup>5</sup>

<sup>5</sup> Idem.

<sup>&</sup>lt;sup>4</sup> Idem.

Children who have been breastfed perform better on intelligence tests. It is estimated that global economic losses from lower cognition associated with not breastfeeding reached more than US\$ 300 billion in 2012, equivalent to 0.49% of the world's gross national income.

#### Q. WHY IS THE CODE IMPORTANT?

The Code is an important part of creating an overall environment that enables mothers to make the best possible feeding choice, based on impartial information and free of commercial influences, and to be fully supported in doing so.

Inappropriate marketing of food products that compete with breastfeeding is an important factor that often negatively affects the choice of a mother to breastfeed her infant optimally.

Given the special vulnerability of infants and the risks involved in inappropriate feeding practices, usual marketing practices are therefore unsuitable for these products.

### Q. HAS THE CODE BEEN UPDATED SINCE 1981?

There is only one version of the Code. However, there have been a number of WHA resolutions adopted since 1981 that refer to the marketing and distribution of breast-milk substitutes and clarify or extend issues covered in the Code.<sup>6</sup> For example,

<sup>&</sup>lt;sup>6</sup> World Health Assembly Resolutions 33.32, 34.22, 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.

- WHA 39.28 clarifies that maternity wards should purchase breastmilk substitutes through normal distribution channels, not receive free or subsidized supplies from companies;
- WHA 49.15 urges Member States to ensure that complementary foods are not marketed in ways that undermine exclusive and sustained breastfeeding;
- WHA 54.2 updated the recommendations on exclusive breastfeeding to 6 months instead of 4-6 months;
- WHA 58.32 urges Member States to ensure that nutrition and health claims are not permitted for breast-milk substitutes.

The 2016 resolution on ending inappropriate promotion of foods for infants and young children (WHA 69.9) urges Member States, manufacturers and distributers, health care professionals and the media to implement new WHO Guidance recommendations that contain a number of implications for the Code:

- Clarification that "follow-up formula" and "growing-up milks" fall under the scope of the Code and should not be promoted.
- Recommendation that messages on complementary foods should always include a statement on the need for breastfeeding to continue through 2 years and that complementary foods should not be fed before 6 months.
- Recommendation that the labels and designs on products other than breast milk substitutes need to be distinct from those used on breast-milk substitutes to avoid cross-promotion.
- Recognition that any donations to the health care system (including health workers and professional associations) from companies selling foods for infants and young children represent a conflict of interest and should not be allowed.
- Recommendation that sponsorship of meetings of health professionals and scientific meetings by companies selling foods for infants and young children should not be allowed.

The Code and subsequent relevant WHA resolutions must be considered together in the interpretation and translation into national measures.

# Q. IS THE CODE STILL RELEVANT 35 YEARS AFTER ITS ADOPTION?

The Code remains as relevant and important as when it was adopted in 1981, if not more so. The World Health Assembly has reiterated the importance of the Code numerous times over the past thirty-five years. As recently as 2016, the Assembly urged Member States to continue to implement the Code.

In spite of clear messages on the importance of breastfeeding, global sales of breast-milk substitutes continue to grow at a rapid pace. Sales of breast-milk substitutes totalled US\$ 44.8 billion in 2014, and this number is expected to rise to US\$ 70.6 billion by 2019.<sup>7</sup>

Various studies showing the prevalence of inappropriate marketing of breast-milk substitutes demonstrate that these practices are persistent in many countries, and continues to undermine efforts to improve breastfeeding rates.

Marketing practices are increasingly targeted beyond traditional settings such as retail outlets and health facilities. The rise in, and popularity of, social media channels, as well as internet sites dedicated to pregnant women and mothers, often provide manufacturers and distributors with new and unregulated entry points to market their products.

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<sup>&</sup>lt;sup>7</sup> Victora CG, Bahl R, Barros A et al. Why invest, and what it will take to improve breastfeeding practices? Lancet. 2016;387:491-504.

In addition, there is increasing promotion of breast-milk substitutes for older infants and young children, including follow-up formula and growing-up milks. These products undermine sustained breastfeeding up to two years or beyond. Because the packaging and marketing of these products often resemble those of infant formula, mothers may also use them in the first six months of life.<sup>8</sup>

In spite of the continued threat of inappropriate marketing to efforts to improve exclusive and continued breastfeeding rates, the number of countries having adopted comprehensive legal measures to regulate marketing practices remains low. As of 2014, only 39 out of 194 countries had legislation that is fully reflective of the Code and subsequent relevant WHA resolutions. In addition, very few countries have functioning mechanisms in place to monitor and enforce Code-related laws and regulations. Much more needs to be done to end the inappropriate marketing of breast-milk substitutes.

### Q. WHAT PRODUCTS ARE COVERED BY THE CODE?

The Code applies to the marketing and related practices of the following products:

• breast-milk substitutes, including infant formula. This should be understood to include <u>any</u> milks (or products that could be used to replace milk) that are specifically marketed for feeding infants

<sup>&</sup>lt;sup>8</sup> Scientific Advisory Committee on Nutrition, United Kingdom, Infant Feeding Survey 2005: A commentary on infant feeding practices in the UK, position statement by the Scientific Advisory Committee on Nutrition, 2008. Nina J Berry, Sandra Jones, Don Iverson, It's all formula to me: women's understandings of toddler milk ads, Breastfeeding Review, Vol. 18 No. 1, 2010.

Sobel H. et al. Isn unimpeded marketing for breast milk substitutes responsible for the decline in breastfeeding in the Philippines? An exploratory survey and focus group analysis. Social Sciences & Medicine 2011; 73: 1445-1448.

Mintzes B. Regulation of formula advertising in the Philippines and promoition and protection of breastfeeding: A commentary on Sobel, Iellamo, Raya, Padilla, Olivé and Nyunt-U. Social Sciences & Medicine 2011; 73: 1449-1451.

<sup>&</sup>lt;sup>9</sup> WHO, UNICEF, IBFAN. Marketing of breast-milk substitutes: national implementation of the International Code, Status Report 2016, Geneva 2016

- and young children up to the age of 3 years, including follow-up formula and growing-up milks<sup>10</sup>;
- other foods and beverages promoted to be suitable for feeding a baby during the first six months of life when exclusive breastfeeding is recommended. This would include baby teas, juices and waters;
- feeding bottles and teats.

### Q. WHAT ASPECTS DOES THE CODE COVER?

The Code sets out detailed provisions with regard to:

- 1. Information and education on infant feeding;
- 2. Promotion of breast-milk substitutes and related products to the general public and mothers;
- 3. Promotion of breast-milk substitutes and related products to health workers and in health care settings;
- 4. Labelling and quality of breast-milk substitutes and related products; and
- 5. Implementation and monitoring of the Code.

# Q. WHAT DOES THE CODE SAY ABOUT INFORMATION AND EDUCATION ON INFANT FEEDING?

The Code and subsequent relevant WHA resolutions call upon governments to ensure that objective and consistent information is provided on infant and young child feeding, both to families and others involved in infant and young child nutrition.

<sup>&</sup>lt;sup>10</sup> WHO. Guidance on Ending Inappropriate Promotion of Foods for Infants and Young Children, Geneva 2016.

Informational and educational materials should clearly state the benefits and superiority of breastfeeding, the social as well as financial costs of using infant formula, the health hazards associated with artificial feeding and instructions for the proper use of infant formula.

# Q. WHAT ARE THE LIMITS SET BY THE CODE ON THE PROMOTION OF BREAST-MILK SUBSTITUTES TO THE GENERAL PUBLIC AND MOTHERS?

The Code explicitly states that there should be no advertising or other form of promotion to the general public. This would include any advertising through mass media outlets such as television, magazine, billboards, websites, or social media.

In addition, manufacturers and distributors of breast milk substitutes should not provide samples of their products to pregnant women, mothers or members of their families. Promotion through other means, such as special displays, discount coupons, price reductions, or special sales, is also prohibited. Furthermore, no company personnel should seek direct or indirect contact with, or provide advice to, pregnant women or mothers, whether this is in retail outlets or through social media channels.

# Q. DOES THE CODE RESTRICT PROMOTIONAL ACTIVITIES TO HEALTH WORKERS AND IN HEALTH CARE SETTINGS?

Yes. The Code and subsequent relevant WHA resolutions call for a total prohibition of any type of promotion of breast-milk substitutes, bottles, or nipples in health services.

Furthermore, donations of free or subsidized supplies of breast-milk substitutes or other products, as well as gifts or personal samples to health workers, are not allowed in any part of the health care system. Even for medical institutions dealing with infants who have a medical indication not to breastfeed, they should not accept free or low-cost supplies or give out samples of those products. WHA Resolution 39.28 clearly stated that infant formula needed for infants with medical reasons for its use should be obtained through normal procurement channels.

Information provided by manufacturers and distributors to health professionals regarding products should be restricted to scientific and factual matters.

# Q. WHAT DOES THE CODE SAY ABOUT LABELLING AND QUALITY OF BREAST-MILK SUBSTITUTES?

No pictures of infants or other pictures idealizing the use of breastmilk substitutes are permitted on the labels of the products.

Information on artificial feeding, including that on labels, should explain the benefits of breastfeeding and the costs and dangers associated with the unnecessary or improper use of infant formula and other breast-milk substitutes.

Unsuitable products for feeding infants, such as sweetened condensed milk, should not be promoted.

### Q. WHAT ARE THE ACTIONS REQUIRED FOR IMPLEMENTATION OF THE CODE?

The Code requires that action should be taken to give effect to its principles and aim, including the adoption of national legislation, regulation or other suitable measures. All measures should be made public. As the Code is a minimum requirement, additional, possibly more stringent, measures than those set out in the Code can be taken by governments, and make them legally binding.

Comprehensive and enforceable legislation which covers all provisions of the Code and relevant subsequent WHA resolutions is the most effective means of regulating the inappropriate marketing of breast-milk substitutes and other products covered by the scope of the Code.

# Q. WHO SHOULD BE INVOLVED TO MAKE IMPLEMENTATION OF THE CODE A REALITY?

Governments should act on the Code, taking into consideration subsequent relevant WHA resolutions. In the WHA resolution that adopted the Code, Member States were urged to translate the Code into national legislation, regulation or other suitable measures.

While governments have a responsibility to take action on the International Code, food manufacturers and distributors, health care professionals, nongovernmental organizations and consumer organizations also have key roles to play.

Non-governmental organizations, professional groups, including health professional organizations, and other relevant actors have a responsibility to call manufacturers and distributors of breast-milk substitutes to account for actions that are in violation of the Code. They should also inform the relevant government body about violations identified.

Manufacturers and distributors of breast-milk substitutes are responsible for adherence to the Code "independently of any other measures taken for implementation." This means that even if a government has not fully implemented the Code in national legislation, manufacturers and distributers still must comply.

# Q. IS THE IMPLEMENTATION OF THE CODE SUFFICIENT FOR THE IMPROVEMENT OF INFANT AND YOUNG CHILD FEEDING?

No, additional measures are needed to support optimal infant and young child feeding. The Breastfeeding Advocacy Initiative<sup>11</sup>, led by WHO and UNICEF, aims to increase global commitment to breastfeeding. In addition to full implementation of the Code through strong enforceable legal measures, the Initiative's Call for Action<sup>12</sup> calls upon governments, donors and development partners to:

- increase funding for breastfeeding;
- enact better family leave and workplace breastfeeding policies;
- improve the quality of maternity facilities, especially for sick and vulnerable newborns:
- improve access to skilled lactation counselling;

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<sup>&</sup>lt;sup>11</sup> WHO, UNICEF. Breastfeeding Advocacy Initiative, Geneva, 2015.

<sup>&</sup>lt;sup>12</sup> UNICEF. Breastfeeding Advocacy Initiative, A call for Action. New York, 2016.

- strengthen community networks that protect, promote, and support breastfeeding;
- create monitoring systems that track the progress of policies, programmes, and funding.

The action points above are called for within the ICN2 framework for action<sup>13</sup> and its relevant recommendations.

# Q. WHAT ARE THE REQUIREMENTS FOR MONITORING OF NATIONAL MEASURES?

It's not enough to simply translate the provisions of Code into national legislation. Monitoring of such legislation is necessary to ensure that its provisions are complied with and are effective, and that achievements are not eroded. Monitoring also provides information on the quality of the legislation, including possible weaknesses and loopholes.

Monitoring mechanisms need to be transparent, independent, and free from commercial influence and should address labelling, all forms of advertising and commercial promotion across all media. Responsible bodies should be able to impose appropriate sanctions according to existing legal systems.

# Q. WHO IS RESPONSIBLE FOR MONITORING THE IMPLEMENTATION OF THE INTERNATIONAL CODE?

Primary responsibility for monitoring of the Code lies with governments. Monitoring is more effective when responsibility is

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<sup>&</sup>lt;sup>13</sup> FAO, WHO. ICN2 2014/3 Corr.1, Framework for Action. Rome, 2014.

shared among key government agencies that have a role during the different phases of marketing and of relevant products. National Code legislation should indicate which government agency or agencies should lead the monitoring, and how monitoring should be conducted.

Manufacturers and distributors of breast-milk substitutes should monitor their marketing practices at all levels. Similarly, health professionals and health managers have a responsibility for monitoring their practices in health care settings, ensuring that no marketing takes place in facilities.

Nongovernmental organizations, institutions and individuals can draw the attention of manufacturers and distributors to activities which are incompatible with the Code, and inform the government so that action can be taken.

# Q. WHAT IS WHO DOING TO HELP COUNTRIES IMPLEMENT AND MONITOR THE CODE?

In 2014, WHO and UNICEF created a Network for Global Monitoring and Support for Implementation of the International Code of Marketing of Breast-milk Substitutes and Subsequent relevant World Health Assembly Resolutions (NetCode).

NetCode combines the efforts of civil society organizations, academics, and selected countries to establish standards for Code monitoring. NetCode has developed a protocol for monitoring that is composed of two main components: ongoing monitoring to detect, investigate and act on alleged violations of existing national measures and the Code, and periodic assessment, to verify the level

of adherence with the national measures and the Code, and identify gaps and issues that need to be addressed through policy and legislative measures. WHO is working with a number of countries to implement the monitoring protocol.

In addition, NetCode provides countries with further information on implementation of the Code in the context of the Codex Alimentarius Commission, matters concerning international trade and the code, as well as on application of international human rights standards for Code monitoring and implementation.

### Q. HOW DOES THE CODE APPLY IN THE CONTEXT OF HIV?

The Code is applicable in all countries, regardless of national policy about the feeding of infants of HIV infected mothers. Code implementation is essential to avoid undermining breastfeeding. Choices about infant feeding need to be made based on unbiased information. For mothers who choose not to breastfeed, a reliable and sustainable source of formula or other replacement must be available so that they are never left without adequate nutrition for their babies. The Code does not restrict the availability of breastmilk substitutes for mothers who make an informed choice to use them.

For countries where environmental and social circumstances are unsafe for, or cannot fully support, replacement feeding, WHO recommends that mothers living with HIV should breastfeed for at least 12 months, and may continue breastfeeding for up to 24 months or longer.

In other countries, where the national policy is that HIV infected mothers should avoid breastfeeding altogether, it is still the case that general promotion of breast-milk substitutes would be inappropriate. Governments, social welfare agencies or health care facilities can provide breast-milk substitutes to HIV-positive mothers. However, breast-milk substitutes should be obtained through <u>normal</u> procurement channels, through donations from and not manufacturers (WHA 39.28. 1986).

### Q. HOW DOES THE CODE APPLY IN COMPLEX EMERGENCIES?

The International Code and relevant WHA resolutions are important in all situations for protecting infants and caregivers from inappropriate marketing of breast-milk substitutes. The Code prohibits advertising and other forms of promotion of infant formula and other breast-milk substitutes as well as feeding bottles and teats.

In emergency situations, the Code is particularly important for controlling donations and distribution of these products. In these situations, there will always be infants who cannot be breastfed such as infants who have been separated from their mothers, infants whose mothers are ill or have died, or those who were not-being breastfed prior to the emergency. In the absence of other sources of breast milk, these infants will need to be fed with breast-milk substitutes. Mothers of infants below six months who were mixed feeding prior to the emergency should be supported to revert to exclusive breastfeeding.

The Code protects infants who are artificially fed by ensuring that product labels carry the necessary warnings and instructions for safe preparation and use. In addition, according to Article 6.5, when formula feeding is necessary, it should be demonstrated only by

health workers or community workers and only to the mothers who need to use it. Mothers must be clearly informed of the hazards associated with improper use.

# Q. IS THE CODE CONSISTENT WITH INTERNATIONAL HUMAN RIGHTS INSTRUMENTS?

The Code in itself was not adopted as a legally binding document, but rather as a set of recommendations. However, its implementation is generally regarded as a key measure under the right to health as stipulated by a number of international human rights treaties. These treaties establish legal obligations for countries.

The United Nations Convention on the Rights of the Child (CRC) is the most comprehensive international human rights framework in this regard. Numerous articles of the CRC are supportive of the aim of the Code, particularly the right of children to the highest attainable standard of health, by, inter alia, reducing infant mortality, and promoting breastfeeding.

The UN Committee on the Rights of the Child, the independent expert body monitoring government compliance with the provisions of the CRC, has explicitly recognized implementation of the Code as an appropriate measure for the fulfilment of government obligations to realize the right to health and health care of children (Article 24).

The Committee has recommended to specific governments that they should enact legislation to implement the Code or to strengthen and sustain enforcement of existing legislation as an appropriate measure towards implementing the CRC.



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