

---

# NET CODE PROTOCOL

## PROTOCOL FOR THE ASSESSMENT AND MONITORING OF “THE CODE” AND RELEVANT NATIONAL MEASURES

### SUMMARY

## INTRODUCTION

Optimal and appropriate infant and young child feeding (IYCF), access to health services, and proper child care practices are essential elements for the prevention of malnutrition (under-nutrition and overweight and obesity), mortality and illness among infants and young children.

The World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) recommend optimal infant and young child feeding<sup>1</sup> as:

1. initiation of breastfeeding within one hour of birth;
2. exclusive breastfeeding<sup>2</sup> for the first 6 months of life;
3. continued breastfeeding for 2 years or beyond;
4. introduction of adequate and appropriate complementary foods<sup>3</sup> from 6 months onwards.

Every year more than 800,000 deaths in children under the age of five could be prevented by breastfeeding. Evidence shows that breastfeeding provides protection against acute childhood diseases as well as against chronic diseases later in life. Published articles also report that children who are breastfed for 12 months or more had statistically significantly higher IQ scores, more years of education and higher monthly incomes than did those who were breastfed for less than one month.<sup>4</sup> Breastfeeding needs to be protected, promoted, and supported.

Nearly all mothers are able to breastfeed and will do so if they have accurate information and support. However, direct influence of breast-milk substitute manufacturers and distributors – through marketing strategies such as advertisements, information packs and sales representatives – and indirect influence through public and private health systems inundate mothers with incorrect and biased information that undermines breastfeeding.

Global marketing of breast-milk substitutes contributes to the reduction of exclusive and sustained breastfeeding. The development and adoption of the *International Code of Marketing of Breast-Milk Substitutes* by the World Health Assembly (WHA) in May 1981<sup>5</sup> marked an historical step in the efforts to protect breastfeeding and to establish and support appropriate infant and young child feeding practices.

Recognizing the "vulnerability of infants in the early months of life and the risk involved in inappropriate feeding practices", the Code and its subsequent relevant WHA resolutions (hereafter referred to as 'the Code'), are the world's first real attempt to tackle the harmful effects of marketing of breast-milk substitutes, feeding bottles and teats on global scale.

---

<sup>1</sup> WHO/UNICEF, Global Strategy for Infant and Young Child Feeding. Available from [http://www.who.int/nutrition/topics/global\\_strategy/en/](http://www.who.int/nutrition/topics/global_strategy/en/). Published Geneva 2002.

<sup>2</sup> Exclusive breastfeeding means that the infant receives only breast milk. No other liquids or solids are given – not even water – with the exception of oral rehydration solution, or drops/syrups of vitamins, minerals or medicines.

<sup>3</sup> Complementary foods: means giving other foods **in addition** to breast milk. These other foods are called **complementary foods**. During the period of complementary feeding, a baby **gradually** becomes accustomed to eating family foods.

<sup>4</sup> Cesar G Victora, et al. Association between breastfeeding and intelligence, educational attainment, and income at 30 years of age: a prospective birth cohort study from Brazil. *Lancet Glob Health* 2015; 3: e199–205

<sup>5</sup> WHA Resolution 34.22

Implementation, monitoring and enforcement have been inadequate to ensure Code adherence by manufacturers and distributors in many countries. As of 2011, only 37 out of 199 countries (19%) had passed laws reflecting all of the provisions of the Code. An additional 47 countries (24%) had passed laws that reflect many of the provisions. However, only 45 countries (23%) reported having a functioning implementation and monitoring system (see Annex 3 for more information on progress in implementation).<sup>6</sup>

## BACKGROUND TO CODE MONITORING

Internationally, a number of frameworks have been used to monitor the adherence to the Code in Member States. In 1996, WHO published a *Common Review and Evaluation Framework* (CREF). The Interagency Group on Breastfeeding Monitoring (IGBM) developed a protocol for systematic monitoring of the Code, updated in 2007. The International Baby Food Action Network (IBFAN) has routinely collected evidence on violations of the Code. Monitoring by IBFAN began before the Code was adopted and was instrumental in securing some of the provisions found in the Code and subsequent World Health Assembly resolutions. In 1999, a *Standard IBFAN Monitoring Kit* (SIM) was devised for use by IBFAN groups globally. A few governments adopted it for use nationally. In 2003, SIM evolved into its current form - the *Code Monitoring Kit* (CMK). This IBFAN monitoring tool is periodically revised to take into account subsequent World Health Assembly Resolutions and to keep up with latest marketing strategies. The latest edition was launched in August 2015.

In 2014, WHO established a Global Network for Monitoring and Support for Adherence to the Code (hereafter referred to as Net-Code). The aim and objectives of Net-Code are to assist Member States and civil society in:

- i. strengthening their capacity to monitor the Code and all relevant subsequent World Health Assembly resolutions; and
- ii. effective enforcement and monitoring of national Code legislation and regulations.

A monitoring protocol has been developed by NetCode to give effect to these objectives and provide countries with practical tools and guidance to be able to set up effective monitoring systems that will help eliminate inappropriate marketing of foods for infants and young children, as well as regularly assess the level of adherence with the Code and national measures.

## OBJECTIVES OF THE MONITORING PROTOCOL

In line with the request made by Member States to WHO related to the need for practical and concrete guidelines and procedures for Code monitoring, WHO and other Net-Code members are proposing a protocol for Code monitoring and assessment.

The protocol provides Member States and organizations with tools, processes and guidance to be able to:

1. set up, improve and/or strengthen Code monitoring and enforcement mechanisms;

---

<sup>6</sup> WHO. *Country implementation of the International Code of Marketing of Breast-milk Substitutes. Status report 2011*. WHO; Geneva, 2013 <http://www.who.int/nutrition/publications/infantfeeding/statusreport2011/en/index.html>, accessed June 10, 2015

2. implement an effective and efficient monitoring system that will help Member States and organizations in identifying and acting on reported violations of the Code and relevant national measures;
3. regularly assess the level of adherence with the Code and relevant national measures; and
4. advocate for the strengthening of the existing legislative and regulatory systems.

### **Components of the protocol**

This protocol is composed of two main components that provide procedures, guidance and tools for:

*Ongoing Monitoring:* Setting up a monitoring system, to detect, investigate and act on alleged violations of existing national measures and the Code (Chapter 2).

*Assessment:* Conducting a periodic assessment (every 3 to 5 years) to verify the level of adherence with the national measures and the Code, and identify gaps and issues that will need to be addressed through policy and legislative measures, programming and investments (Chapter 3).

The use of both components will ensure a country's ability to act promptly to stop and/or correct any activities contravening international and/or national standards and policies. At the same time, governments will be able to regularly review the effectiveness of existing policies and systems, and take any necessary action to update and enhance them.

### **Intended Users**

The protocol is intended for government agencies and institutions working in the area of maternal infant and young child nutrition and/or regulation of marketing and promotion of breast-milk substitutes and other foods and liquids for infant and young children.

At the same time, it is envisaged that international and national organizations, public-interest civil society groups with no conflicts of interest, working in the area of maternal, infant and young child nutrition will use it for their monitoring activities.

## **ONGOING MONITORING COMPONENT**

The overall goal of this component is to stop all promotional activities related to the marketing of breast-milk substitutes, feeding bottles and teats.

The specific objectives are to:

- Detect violations of the national measures and/or the Code
- Document and report such violations
- Investigate and validate whether the reported activities are indeed violations
- Activate an enforcement mechanism that would stop such violations and deter future violations
- Hold manufacturers and distributors to account for their breaches of national measure(s) and/or the Code.

### **Key principles in setting up a monitoring system**

WHA resolution 49.15 from 1996 urges Member States to ensure that monitoring the application of the Code is carried out in a *transparent, independent* manner, *free from*

*commercial influence*. Government monitoring mechanisms should therefore be based on the following characteristics:

- Independence and transparency.
- Freedom from commercial influence.
- Authority and resources to investigate Code violations.
- Authority to impose legal sanctions/deterrents.

### **Setting up a monitoring system**

To be effective in its operations and efficient at the same time, the monitoring system should be set up with the following basic components:

1. Determining the coverage and extent of monitoring activities based on the provisions of the Code/or the national measures. (*What and where and when to monitor?*)
2. Identification of a designated government agency/agencies to monitor and enforce the laws and regulations. Definition of roles and responsibilities of government agencies, public-interest non-governmental organizations, and consumers. (*Who should monitor?*)
3. Building the capacity of the monitors:
  - a. Knowledge, skills and approaches in detecting and reporting violations.
4. Standardizing monitoring and reporting tools:
  - a. Tools, procedures, processes, communication flow and feedback mechanisms.
5. Issuing and disseminating monitoring guidelines. (*The monitoring procedures*)
6. Documenting and safeguarding monitoring information. (*Monitoring database*)
7. Allocating resources to monitor, identifying existing resources that can be devoted to monitoring activities. (*Financial, Organisational and Human resource requirements*)
8. Evaluating and assessing the monitoring system.

The following sections provide some suggestions and guidance on each of the components listed. It is understood that national governments with their partners may adapt the system to the local context and policy framework, and may expand or reduce the system in response to local needs and requirements.

### **Who should monitor?**

The Code calls for governments to lead monitoring efforts. When national measures are in place, they may already indicate which government agency/agencies should lead the monitoring, and may suggest monitoring procedures and protocols to be followed. In some countries, with decentralized health services, monitoring and enforcement will be a shared responsibility of local government units.

In addition, NGOs, consumer organizations, religious groups and other development organizations play an important role in monitoring adherence with the Code and national measures. They can assist governments in detecting illicit activities and/or products that do not adhere to the Code and/or comply with standards set by national measures, and report such violations to the designated agency. This role is not limited to organizations active in the field of nutrition alone – those working on maternal newborn and child health, for example, can also contribute significantly to enhanced Code monitoring in countries. All NGOs and civil society groups should also lead by example, by ensuring that all their activities and projects comply with the Code and national measures.

Also, consumers and citizen's participation is encouraged, in line with the context and the culture of the country. Information and advocacy campaigns on the Code and the national measure are needed to help sensitize the population, mothers and caregivers on how to protect, promote and support breastfeeding and infant and young child feeding practices. The general public should be encouraged to report activities, products and related incidents that tend to undermine breastfeeding practices.

### **What to monitor?**

Monitoring should cover materials, promotional and marketing activities, events, company personnel, and health care system engagement with manufacturers and distributors and any other form of engagement that manufacturers and distributors may devise to promote and market relevant products.

Monitoring activities should cover the following:

- Media advertisements (TV, radio, online, print materials)
- Promotion in shops and pharmacies
- Free Samples
- Information from the manufacturer for health professionals
- Promotion in health facilities
- Health worker promotion
- Scholarships
- Sponsorships
- Gifts of any sort (branded gifts) for health workers, health associations and mothers
- Labels
- Promotion in communities and public places
- Company/Manufacturer/Distributor representative contact
- Sales incentives/Sales quotas
- Donations
- Any other marketing, promotional materials and activities that may undermine breastfeeding in the country

### **Where to monitor?**

Monitoring activities should be conducted mainly in areas where the main targets of promotional and marketing efforts are to be found. The following are considered key settings where monitoring activities should be carried out regularly:

1. Customs and borders
2. Media channels and social networks
  - a. TV, radio, billboards, other
  - b. Internet (webpages, Facebook, Twitter, Instagram, smartphone apps, etc.)
  - c. Printed materials (magazines, newspapers, flyers, brochures, etc.)
3. Health facilities (public and private)
4. Point of sale (supermarkets, stores, pharmacies, groceries)
5. Public areas (day care centres, parks, theatres, cinemas, open spaces, etc.) and within communities.

### **When to monitor?**

Marketing and promotional activities happen any time of the day and in a variety of settings, depending on the specific marketing target of the baby food manufacturers and distributors.

For government monitoring activities, it is recommended that monitoring activities be integrated into the following regular activities:

1. Customs and border control
2. Food and drug inspection activities at point of sale
3. Media monitoring related to food and drug safety and regulations and monitoring activities related to truth in advertising
4. Health facility monitoring and assessments
5. Programme level monitoring and supportive supervision in public health facilities and communities.

As stated earlier, several monitoring activities can be done at the central level – particularly those related to national broadcasts (national TV and cable channels), internet-based promotion and marketing, printed materials for national editions of magazines, and other materials.

### **Monitoring and reporting tools**

This protocol proposes use of a user-friendly and practical monitoring and reporting tool (See Panel 1). Countries are encouraged to review it and adapt it to their local regulatory and legislative context.

## PANEL 1 UNIVERSAL MONITORING AND REPORTING FORM

Use this form to report any practice that violates the International Code of Marketing of Breast-milk substitutes and subsequent World Health Assembly Resolutions or the relevant national measure. Violations by manufacturers, distributors or by any person who works for or on their behalf must be reported to the designated authority. Please complete the form below, send it together with a copy of the materials, pictures of the same (if any) to the following address: (xxx,xxx), email address: [xxx@xxx.com](mailto:xxx@xxx.com); web site: [www.xxx.com](http://www.xxx.com), sms to: 09xx- xxxxxx.

### Description of Violation

1. When was the violation observed: (dd/mm/yyyy and time): \_\_\_\_\_

### 2. Where (place, town, others) \_\_\_\_\_

(For newspapers and periodicals, indicate the name and date of publication; for TV/Radio indicate channel, or frequency; webpage; Facebook account, name of health facility, shop)

3. Company name: \_\_\_\_\_

4. Brand name (if no brand can be identified please describe logo or any promotional device: \_\_\_\_\_

5. Type of product being promoted: Please indicate the relevant item by ticking (✓) the box.

- ☐ Infant Formula (0+ months)
- ☐ Follow up/on Formula (6 + months)
- ☐ Growing up milk (12 + months)
- ☐ Any other milk for children 0-36 months
- ☐ Any other food or liquid marketed for infants (0-6 months)
- ☐ Commercial complementary food or liquid (6+ months) describe \_\_\_\_\_
- ☐ Feeding bottles or teats
- ☐ Other product (describe) \_\_\_\_\_
- ☐ No specific product (s) promoted, but practice undermines breastfeeding.

6. Type of violations: Please indicate the relevant item by ticking (✓) the box.

- ☐ Advertisement (TV, radio, printed materials)
- ☐ Online promotion (FB, website, photo apps, social media etc.)
- ☐ Promotion in retail outlets
- ☐ Free samples
- ☐ Information for health professionals that is not scientific & factual
- ☐ Promotion in health facilities
- ☐ Promotion to Health workers
- ☐ Scholarships
- ☐ Sponsorship (events, study, research), salary, services etc.
- ☐ Gift or donation to health workers or health association
- ☐ Inadequate labelling
- ☐ Events/Gifts targeting pregnant women, mothers, etc.
- ☐ Promotion in the community and public places (banners, product distribution, company gifts giving)
- ☐ Company/Manufacturer/Distributor representative contact with pregnant women and mothers
- ☐ Sales incentives/ Sales quota for company personnel
- ☐ Donations of relevant products
- ☐ Other(s) \_\_\_\_\_

7. Additional details and observations: (you may want to add details related to the violation you have detected):  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

8. Attached picture/sample materials/sample label/product: Y/N (circle the answer)

9. Name of monitor \_\_\_\_\_  
Address/Agency \_\_\_\_\_  
Contact number \_\_\_\_\_  
Email address \_\_\_\_\_



**The monitoring flow**

Monitors will be equipped with forms that will be filled out during their regular monitoring or when violations are detected. The form(s) may be submitted manually, by fax and/or by email, web site or text/SMS submissions to the relevant office with supporting evidence (picture, copy). Web-based reporting systems with desktop and mobile versions may be particularly useful for filing of reports of alleged violations. Tracking of the status of the filed alleged violations and generation of regular reports for government and the public on the progress made in acting upon the reports of violations submitted can all be incorporated into web-based systems.

A national database that serves as the main repository of the different monitoring activities should be managed by the designated agency. It will provide relevant information on the frequency, volume, and coverage of the monitoring efforts as well as some qualitative information on the way companies violate the Code or national measures and they are being violated.

Once the report of violation is submitted, the designated authority will have to review the reported complaint, verify the completeness of the information provided, validate the complaint, and trigger enforcement mechanisms as per existing national laws and regulations.

**Building the capacity of the monitors**

Once the key members of the monitoring team have been identified, the monitors from the different agencies should complete a hands-on training. Building the capacity of all monitors is crucial to ensure the effective implementation of monitoring activities.

**PERIODIC ASSESSMENT COMPONENT**

The overall goal of the periodic assessment is to stop all promotional activities related to the marketing of breast-milk substitutes, feeding bottles and teats.

The specific objectives are to:

- Assess the level of compliance with the provisions of the Code, subsequent relevant WHA resolutions, and, where in place, national measures.
- Assess changes in compliance over time.
- Identify priority areas for Code implementation work.
- Reveal gaps and limitations of existing national measures.

The results/findings of the assessment will help support and inform national and sub-national policy and legislative development and improvement processes, as well as to plan for policy and legislative reviews and amendments. They will also feed into lobbying and advocacy for coordination and support from other concerned agencies, and for increased resources and attention to breastfeeding promotion, protection and support.

**Frequency**

The full assessment should be conducted every three to five years.

**Location**

It is recommended that the study be conducted in the capital or largest city of the country. This is because marketing of breast-milk substitutes is unlikely to be more common in other

parts of the country than in the major cities. Extending the study to other parts of the country would increase sample size (if there is an intent to compare different areas), drive up costs, and make the study logistics more complex. However, if resources are available, some countries may wish to add additional study sites to demonstrate the widespread nature of the marketing problems.

### **Key channels and/or respondents targeted in the assessment**

There are a four main groups and settings to target with the assessment:

- Mothers of children under 24 months
- Health facilities
- Retail
- Media

## **1. MOTHERS AND HEALTH FACILITIES MODULE**

The first component of this assessment is to measure the level of marketing of breast-milk substitutes and other products covered by the Code as perceived by mothers, the degree of interaction between BMS companies and health professionals, and the presence of promotional materials in health facilities. Assessment of mothers and health facilities are grouped together in this module because of overlap in the study design – mothers are to be sampled at health facilities.

This module assesses:

1. the prevalence of exposure among mothers with 0-23 month-old children to marketing of relevant products through key channels such as health facilities, retailers, media and direct contact with companies.
2. the prevalence of interactions between health professionals and representatives of companies that sell relevant products.
3. the quantity and content of promotional materials, from companies selling relevant products found at health facilities.

### **Sampling procedure**

A two-step approach is recommended to sample health facilities and mothers. Firstly, 33 health facilities that provide well-baby care are selected by probability proportional to size using a list frame that contains all health facilities offering well-child services in the largest city of the country. Facilities that only care for sick children (e.g. hospitalized children, emergency rooms, or sick clinics) are not included. Then, five mothers with children under 6 months and five mothers with children between 6 and 23 months are sampled by stratification from each selected health facility, giving a total sample size of 330 mothers.

### **Data collection**

Three sets of data collection should take place in each facility:

- 1) Interviews with five mothers of children below 6 months old and five mothers of children 6-23 months old
- 2) Interviews with three health facility representatives. These interviews should be conducted separately to ensure independent responses from each person.
- 3) Observation of promotions and informational or educational materials at the health facility as well as equipment or materials bearing the logo or name of manufacturers or brands of products covered by the Code. Each item should either be photographed or a sample taken.

### **Desk Review of Materials**

Promotional and informational or educational materials from health facilities should be analysed in the central office (desk review). A single analyst should examine the pictures and copies of materials obtained during data collection and complete a careful review for each item based on established criteria from the Code and national measures.

### **Data entry and quality control**

Data recording may occur on paper-based data collection forms, with data-entry occurring in the office later. Alternatively, mobile data collection using tablets or smart phones is an option. Data quality control, consistency checking, and documentation of corrections should be in place to reduce errors during data entry. Then transferring, merging, cleaning, and other data preparation should be performed in preparation for data analysis.

## **2. RETAIL AND LABELS MODULE**

The second component of the assessment is to assess the extent of promotions at retail outlets and to assess product labels. This module assesses

1. the extent of promotions related to products covered under the Scope seen at retailers.
2. the compliance of product labels with the Code, subsequent WHA resolutions and relevant national measures.

### **Sampling procedure**

Two separate sampling frames are recommended to sample a total of 43 retail outlets selling products covered under the scope: one for small stores and one for large stores. First, one small store or pharmacy should be chosen in proximity to each of the 33 health facilities selected for the health facility assessment sample. In addition, 10 large stores that sell a high volume and variety of products under the scope are purposively sampled based on local knowledge that they would carry the majority of the covered products available for sale nationally.

### **Data collection**

Data collection procedures include:

- 1) Enumeration of products under the scope being sold through retailers
- 2) Records of any types of promotions related to products covered under the scope at the retailer

Enumeration of products entails listing the products encountered in a series of stores. As additional stores are visited, a master list is built by continuously adding products encountered that had not been found in previous stores. Different package sizes must be counted as distinct products because the details on the labels may differ for different size products. Each product needs to be purchased for subsequent desk analysis. Alternatively, high-quality photos may be taken of each product clearly showing all sides of the labels.

At all retail outlets in the sample, enumerators should photograph all types of promotions observed. Promotional materials being distributed (e.g. pamphlets, coupons) are to be collected. Details of the promotion should be recorded.

### **Desk Review of Labels and Materials**

Two desk review processes should be conducted to analyse the data collected at retailers:

- 1) Desk review of labels on products sold at retail (pictures and products);

- 2) Desk review of promotional materials from retailers (pictures and copies).

Labels in the pictures or the actual products should be closely examined based on a checklist of criteria based on the Code and national measures in the country. Similar to the desk review of promotional materials from health facilities, the desk review of promotional materials from retailers is conducted.

### **Data Entry and Quality Control**

Data recording may occur on paper-based data collection forms, with data-entry occurring in the office later. Alternatively, mobile data collection using tablets or smart phones is an option.

## **3. MEDIA MODULE (TV AND INTERNET)**

The third component of the assessment is to assess the extent of promotion for products covered by the Code in the media. Two elements are assessed separately – television and internet advertising. This module assesses:

1. the number of promotions on television and internet for products covered by the Code
2. frequency of television advertisements (No. of times/day)
3. type of promotional messages being broadcast
4. investment made on a monthly basis
5. health, nutrition and other benefit claims by product category.

### **Sampling and data collection for television promotions**

Media monitoring agencies can be used to collect recordings of TV programming over a six month period. This may already exist in archived files that can be purchased or may require prospective recording. It is recommended to collect recordings on government, private, and cable channels, covering the largest media markets and channels with the largest share/ratings. Advertisements as well as regular programming that may highlight relevant products should be included.

Data should be recorded on total number of TV ads per week for covered products, total number of minutes of advertisements, amount spent, and claims made about products.

### **Sampling and data collection for internet advertising**

Sampling of promotions on the internet is complex given the multifarious nature of the internet. Websites sponsored by a manufacturer, distributor and representative of products listed are an obvious starting point. Websites targeting mothers and/or caregivers of children under 3 years of age are another place where product promotion may be present. Social media sites (e.g. Facebook, Twitter, YouTube, Instagram) targeting this same group of users likewise is a common place to find promotions.

Data should be collected on online information, videos, banner adverts, viral marketing encouraging mothers to contact their peers about a specific product or brand, sweepstakes and promotions, club memberships, and incentives for product purchase.