

NETCODE TOOLKIT

MONITORING THE MARKETING OF BREAST-MILK SUBSTITUTES: **PROTOCOL FOR ONGOING MONITORING SYSTEMS**



World Health
Organization



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Developed by the 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)



World Health
Organization

unicef 

The UNICEF logo, which consists of a stylized figure of a mother holding her child, set against a background of a map of the world, all enclosed within a laurel wreath.

NetCode toolkit. Monitoring the marketing of breast-milk substitutes: protocol for ongoing monitoring systems.

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CONTENTS

BACKGROUND		1
	<i>Understanding the Code</i>	3
	<i>A toolkit for ongoing monitoring and periodic assessment of the Code</i>	6
	<i>How to choose which protocol to use</i>	7
	<i>Intended users</i>	7
A STEP-BY-STEP GUIDE TO SETTING UP A NATIONAL MONITORING SYSTEM		9
	A. <i>Negotiating the political and bureaucratic environment</i>	12
	B. <i>Determining the coverage and extent of monitoring</i>	15
	C. <i>Building a national monitoring team</i>	18
	D. <i>Costing and budgeting monitoring</i>	24
	E. <i>Developing standard monitoring tools and a database</i>	27
	F. <i>Building the capacity of monitors</i>	32
	G. <i>Monitoring and enforcement</i>	35
	H. <i>Evaluation and assessment</i>	39
ANNEX 1	WHAT TO MONITOR	42
ANNEX 2	DATA ENTRY FOR THE UNIVERSAL FORM	44
ANNEX 3	DATABASE FOR RECORDING MONITORING ACTIVITIES	45
ANNEX 4	ESTABLISHING A CENTRAL DATABASE	47
ANNEX 5	TRAINING RESOURCES	49
ANNEX 6	OUTLINE FOR ANNUAL MONITORING REPORT	52



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ABOUT NETCODE



In 2014, WHO in collaboration with UNICEF, established 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). Civil society member organizations include IBFAN, Helen Keller International, Save the Children Foundation, World Alliance for Breastfeeding Action and the WHO Collaborating Centre at Metropol University. The following countries participate in NetCode: Armenia, Bahrain, Bangladesh, Cambodia, Chile, Ghana, India, Kenya, Lao's People's Democratic Republic, Mexico, Oman and Poland.

The vision of NetCode is a world in which all sectors of society are protected from the inappropriate and unethical marketing of breast-milk substitutes and other products covered by the scope of the Code. The goals are to strengthen Member States' and civil society capacity to monitor the Code; and to facilitate the development, monitoring and enforcement of national Code laws by Member States, by bringing together a group of committed actors to support these processes.

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The Monitoring and Assessment Toolkit was developed by the World Health Organization (WHO), in collaboration with UNICEF and the 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).

The initial draft was prepared by Alessandro Iellamo in close collaboration with a protocol design committee, including David Clark, UNICEF; Yeong Joo Kean, International Breastfeeding Action Network (IBFAN); Elizabeth Zehner and Alissa Pries, Helen Keller International (HKI); and Ye Shen, Johns Hopkins University. Substantial comments on the protocol were received from Lida Lotszka, IBFAN; Rukhsana Haider, World Alliance for Breastfeeding Action (WABA); Aileen Robertson, Metropol University, and Chessa Lutter, USA. During the piloting of the protocol, extensive feedback was provided by Sonia Hernández Cordero and Ana Lilia Lozada-Tequeanes, Centro de Investigación en Nutrición y Salud, Instituto Nacional de Salud Pública, Mexico; Anna Christina Pinheiro Fernandes and Fernanda Mediano Stoltze, Ministry of Health, Chile; Mackenzie Green, HKI Cambodia; James Rarick and Sano Phal, WHO Country Office, Cambodia; Gladys Mugambi and Betty Samburu, Ministry of Health, Kenya; Isabella Sagoe-Moses, Ghana Health Service, Ghana; Gabriel Y.K. Ganyaglo, Korle Bu Teaching Hospital, Ghana. Karen McColl, France, provided significant writing assistance and helped to structure the final toolkit.

The development process of the Monitoring and Assessment Toolkit was coordinated by Laurence Grummer-Strawn, Department of Nutrition for Health and Development (NHD), and Marcus Stahlhofer, Department of Maternal, Newborn, Child and Adolescent Health (MCA), under the supervision of Francesco Branca, Director, NHD.

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ABBREVIATIONS

BFHI	Baby-friendly Hospital Initiative
FDA	food and drug authority
IBFAN	International Baby Food Action Network
ICDC	International Code Documentation Centre
IYCN	infant and young child nutrition
MCHN	maternal and child health and nutrition
NGO	nongovernmental organization
WHA	World Health Assembly
WHO	World Health Organization



BACKGROUND TO THE NETCODE MONITORING AND ASSESSMENT TOOLKIT

BACKGROUND

Breastfeeding is the cornerstone of child survival, preventing more than 800,000 deaths a year among children under 5 years of age. It helps children thrive by preventing acute and chronic illnesses and contributing to their intellectual development, educational achievement and adult earnings. Breastfeeding also saves women's lives by reducing their risk of breast and ovarian cancers and some cardiovascular diseases. Its benefits are universal; as relevant to mothers and children living in high-income countries as to those in living in middle- and low-income countries.¹

To protect, promote and support breastfeeding, measures at many levels are needed. These include legal and policy directives, supportive social attitudes and values, maternity protection and worksite breastfeeding policies, along with health-care services that foster and enable women to breastfeed. In addition, women and their families need protection from inappropriate and unethical marketing of breast-milk substitutes.

The *International Code of Marketing of Breast-milk Substitutes* (International Code), adopted at the Thirty-fourth World Health Assembly in 1981, came about because of compelling accounts of severe malnutrition and death among infants and young children resulting from the consumption of contaminated or diluted infant formula. In the years since adoption, a number of relevant subsequent resolutions have been endorsed providing clarification and guidance for its effective implementation.² Adopted by the World Health Assembly as a recommendation, it is not binding and thus dependent on individual Member States to legislate into their national laws,³ monitor and enforce. Nonetheless, manufacturers, distributors, retail outlets, health-care systems and health-care workers have a responsibility to comply.

While the vast majority of countries have legal measures in place covering some provisions of the Code, very few have functioning implementation and monitoring systems. Just a handful have a dedicated budget or funding for monitoring and enforcement.⁴ As a result, unethical and inappropriate marketing of breast-milk substitutes continues, as documented by International Baby Food Action Network International Code Documentation Centre (IBFAN-ICDC) in its periodic global monitoring report *Breaking the Rules, Stretching the rules*.⁵

BOX 1. AS BABY MILK SALES CONTINUE TO GROW THE CODE IS AS RELEVANT AS EVER

Today, the Code is as relevant as ever, as the commercial market for breast-milk substitutes is large, growing and resilient to market downturns. In 2014, global sales of all baby milk formula were about US\$44.8 billion and projected to reach \$70.6 billion by 2019.⁶ Aggressive and inappropriate marketing of breast-milk substitutes, and other food products that compete with breastfeeding, continue to undermine efforts to improve breastfeeding rates. As such, Code implementation, monitoring and enforcement remains a vital tool to ensure mothers are able to make infant feeding decisions free of market influences.

¹ WHO recommends that infants are exclusively breastfed for 6 months and continue to be breastfed for 2 years or more with complementary foods introduced at 6 months.

² The International Code and subsequent resolutions are collectively referred to as 'the Code'.

³ The term 'national laws' is used to cover all national measures intended to implement the Code, including primary legislation (Acts) and secondary legislation (regulations). Although voluntary codes are not considered adequate for full implementation of the Code, this toolkit can still be used for the monitoring and assessment of voluntary measures.

⁴ WHO, UNICEF, IBFAN. *Marketing of Breast-milk Substitutes: National Implementation of the International Code Status Report 2016*. Geneva: World Health Organization; 2016.

⁵ *Breaking the Rules, Stretching the Rules 2017*. Penang: IBFAN-ICDC; 2017. (<https://www.ibfan-icdc.org/ibfan-icdc-launches-its-11th-global-monitoring-report-breaking-the-rules-stretching-the-rules-2017/>, accessed 18 September 2017).

⁶ Rollins NC, Bhandari N, Hajeerhoy N, et al. Why invest, and what it will take to improve breastfeeding practices? *Lancet*. 2016;387:491-504. DOI: [http://dx.doi.org/10.1016/S0140-6736\(15\)01044-2](http://dx.doi.org/10.1016/S0140-6736(15)01044-2)

Monitoring of the Code is essential to detect violations, report them to the appropriate adjudicating body and enable existing enforcement mechanisms to effectively intervene to stop actions that do not comply with the Code and national laws. Therefore, the 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) has developed this toolkit for an ongoing monitoring system. Its purpose is to reinvigorate and reinforce ongoing monitoring of the Code and national laws by providing protocols, guidance and tools.

BOX 2. INTERNATIONAL COMMITMENTS, HUMAN RIGHTS LAW AND THE CODE

Multiple international commitments, declarations and recommendations have reinforced the importance of protecting breastfeeding through Code implementation, monitoring and enforcement. These include the *Innocenti Declaration (1990)*, the WHO/UNICEF *Baby Friendly Hospital Initiative (1991)*, the WHO/UNICEF *Global Strategy for Infant and Young Child Nutrition (2002)*, the World Health Organization *Comprehensive Implementation Plan for Maternal Infant and Young Child Nutrition (2012)* and the *Second International Conference on Nutrition Framework for Action (2014)*. Breastfeeding also contributes to many of the Sustainable Development Goals adopted by the United Nations in 2015.

The Code protects human rights, including children's rights to life, survival and development, the right to health, the rights to safe and adequate food and nutrition and the right of women to full and accurate information on which to base decisions affecting their children's health. These rights are set out in international human rights treaties, such as the *Convention on the Rights of the Child*, the *Convention on the Elimination of All Forms of Discrimination Against Women* and the *Covenant on Economic, Social and Cultural Rights*. Implementation of the Code will help Member States, as parties to these treaties, meet their obligations to respect, protect and fulfill the rights set out in these instruments. In 2016, the United Nations Office of the High Commissioner for Human Rights referred to breastfeeding a matter of human rights, urging action on formula milk.^{7, 8}

UNDERSTANDING THE CODE

The Code prohibits any form of promotional activity, including advertising, of products within its scope. It also promotes appropriate infant and young child feeding practices with the protection of breastfeeding (See Box 3 for a 10-point summary of the Code).

⁷ Joint statement by the UN Special Rapporteurs on the Right to Food, Right to Health, the Working Group on Discrimination against Women in law and in practice, and the Committee on the Rights of the Child in support of increased efforts to promote, support and protect breast-feeding. Geneva: Office of the UN High Commissioner on Human Rights; 2016. (<http://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=20871&LangID=E>, accessed 18 September 2017).

⁸ See <http://www.who.int/nutrition/netcode/en/> for more information on how the Code relates to international human rights law.

BOX 3. THE CODE: A 10-POINT SUMMARY (ADAPTED FROM IBFAN-ICDC'S SUMMARY⁹)

- 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 breast-milk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution.
- 2. Scope** Applies to **breast-milk substitutes** or any food being marketed or otherwise represented as a partial or total replacement for breast milk. This includes:
 - Infant formula
 - Follow-up formula (sometimes referred to as 'follow-on milk')
 - Growing-up milk
 - Any other milk for children 0 to < 36 months
 - Any other food or liquid targeted for infants under 6 months of age
 - Feeding bottles and teats
- 3. Promotion** No advertising or promotion of above products to the public. No nutrition or health claims on products.
- 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 use of 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.
- 7. Supplies** No free or low-cost supplies of breast-milk substitutes to any part of the health-care system.
- 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 companies.
- 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 contain the warning that powdered infant formula may contain pathogenic microorganisms and must be prepared and used appropriately. Labels on complementary foods should not cross-promote breast-milk substitutes, should not promote bottle feeding, and should state the importance of continued breastfeeding.
- 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.

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

⁹ Breaking the Rules, Stretching the Rules 2017. Penang: IBFAN-ICDC; 2017. (<https://www.ibfan-icdc.org/ibfan-icdc-launches-its-11th-global-monitoring-report-breaking-the-rules-stretching-the-rules-2017/>, accessed 18 September 2017).

The scope of the Code is set out in Article 2, which explains that, beside breast-milk substitutes, other milk products, foods and beverages fall under the scope if they are promoted or marketed in a way to undermine breastfeeding. Over the years this has been clarified by various World Health Assembly Resolutions and, most recently, by WHO *Guidance on ending the inappropriate promotion of foods for infants and young children*¹⁰ approved by the Sixty-ninth World Health Assembly in Resolution WHA69.9 in 2016.

The list of relevant products covered by the Code includes:

a. Infant formula

This includes milk or milk-like formulation that can be fed to infants from birth and prepared in accordance with relevant international or national standards. The upper age indication on the product label varies from country to country but is usually between 6 and 12 months. There are various types of infant formula. These include “special” formulas such as soy formula, lactose-free formula, low-birth-weight/premature formula and therapeutic milks.

b. Follow-up formula (sometimes referred to as “follow-on milk”)

This includes milk or milk-like formulations commonly marketed for babies from 6 months of age and prepared in accordance with relevant international or national standards. The upper age indication on the product label varies from country to country but is usually between 12 and 24 months. WHO’s *Guidance on ending the inappropriate promotion of foods for infants and young children* is clear that follow-up formula is covered by the Code and should not be promoted. Since breastfeeding is recommended to continue for 2 years or beyond, this product always replaces breast milk.

c. Growing-up milk (sometimes called “growing-up formula”, “toddler milk” or “formulated milk”)

These products are targeted at infants and young children from 1 year old (sometimes younger) to 3 years old. Often, the product name is similar to a company’s formula products, with a figure “3” added on. Where growing-up milks are marketed as suitable for feeding young children up to the age of 36 months, they fall under the Code definition of breast-milk substitute, as set out in WHO Guidance, since WHO recommends that breastfeeding should continue for up to 2 years or beyond.

d. Any other milk for children 0 to < 36 months

The Guidance approved by WHA 69.9 clarifies that any other milk (or products that could be used to replace milk, such as fortified soy milk), in either liquid or powdered form, that may be available in the country and are specifically marketed for feeding infants and young children (0 to < 36 months) should be considered as breast-milk substitutes and will be covered by the Code.¹¹

e. Any other food or liquid targeted for infants under 6 months of age

Since resolution WHA 54.2, from 2001, recommends exclusive breastfeeding for 6 months followed by safe and appropriate complementary foods with continued breastfeeding for up to 2 years or beyond, any food product represented as suitable for infants under 6 months necessarily replaces breast milk. This would include complementary foods marketed as suitable from 4 months. All such products are within the scope of the Code.

f. Feeding bottles and teats are also covered by the Code

This includes feeding bottles attached to breast pumps and other types of vessels for feeding of infants comprising of a container and a teat.

¹⁰ Guidance on ending the inappropriate promotion of foods for infants and young children. Geneva: World Health Organization; 2016. (See <http://www.who.int/nutrition/topics/guidance-inappropriate-food-promotion-iyf/en/>)

¹¹ Guidance on ending the inappropriate promotion of foods for infants and young children. Geneva: World Health Organization; 2016. (See <http://www.who.int/nutrition/topics/guidance-inappropriate-food-promotion-iyf/en/>) as approved by WHA Resolution 69.9

g. Complementary foods or liquids for infants and children from 6 to 36 months

Complementary foods marketed for use after the age of 6 months generally fall outside the scope of the Code. At the same time, WHA 69.9 calls on Member States to implement WHO's *Guidance on ending the inappropriate promotion of foods for infants and young children*, which covers foods that are marketed as being suitable for infants and young children from the age of 6 months to 36 months. It is also important, therefore, to monitor how marketing of these products is done. The Guidance stipulates that complementary foods should not be promoted in a way to cross-promote breast-milk substitutes, should not recommend or promote bottle feeding, should state the importance of continued breastfeeding for up to 2 years and beyond, and should not discourage breastfeeding.

A TOOLKIT FOR ONGOING MONITORING AND PERIODIC ASSESSMENT OF THE CODE

The toolkit for ongoing monitoring and periodic assessment of the Code is comprised of two protocols.¹²

Ongoing Monitoring System Protocol

The protocol described in this document describes the process of setting up an ongoing government-run monitoring system, ideally integrated into existing regulatory and enforcement systems, to continuously monitor adherence to the Code in a systematic and sustainable way so as to take immediate enforcement action. The specific objectives of the ongoing monitoring system are to:

- detect violations of the national laws 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; and
- hold manufacturers, distributors, retail outlets, the health-care system and health-care workers to account for their breaches of national laws and/or the Code.

Periodic Assessment Protocol

The protocol for conducting a periodic assessment is described in a separate document available at <http://www.who.int/nutrition/publications/infantfeeding/netcode-toolkit-periodic-assessment/en/>. The periodic assessment would quantify the level of compliance with national laws and the Code, and identify gaps and issues that will need to be addressed through policy and legislative measures, programming and investments (every 3 to 5 years). The specific objectives of the periodic assessment are to:

- assess quantitatively the level of compliance with the provisions of the Code and national measures;
- assess trends and changes in compliance over time;
- identify priority areas for Code implementation and enforcement work; and
- reveal gaps and limitations of national laws. Findings and results from implementation of either protocol can be used to advocate for the strengthening of existing legislative and regulatory frameworks. They can also be used to identify and make public information on manufacturers, distributors, retail outlets and health care facilities that fail to comply with the Code and national laws.

¹² Several protocols have been used to monitor the adherence to the Code. In 1999, a Standard IBFAN Monitoring Kit (SIM) was developed by IBFAN and has been widely used globally. In 2003, SIM evolved into its current form – the Code Monitoring Kit (CMK), with the latest edition launched in August 2015. In 1996, WHO published a Common Review and Evaluation Framework (CREF). The Interagency Group on Breastfeeding Monitoring (IGBM) has also developed a protocol for systematic monitoring of the Code. This Tool Kit is intended to replace both the CREF and IGBM protocols.

Each protocol is accompanied by a set of guidelines and tools to support implementation. This toolkit is intended to evolve over time and new tools will be added, so visit the site regularly for the latest updates and additions.

HOW TO CHOOSE WHICH PROTOCOL TO USE

The two protocols in this toolkit, while complementary, are designed to be used independently. While they can both be used at the same time, it is more likely that countries will decide initially to implement one or the other. Which one to initially implement will differ from country to country, depending on their specific context, resources and need for information.

Implementation of *ongoing monitoring* has the advantage that it can lead to immediate results, if violations are identified, verified and enforcement action taken. It also requires active government involvement at the onset as, by default, it must be embedded within existing systems related to the control and regulation of customs, food and advertising, among others. When government officials are involved in data collection they are more empowered to act when violations are identified and verified. In many countries, food and health inspectors are able to take immediate action, such as removal of a product or promotional material when observing a violation. Setting up ongoing monitoring will entail investment of time and resources at the onset in order to get the system up and running; however, it has the advantage of being sustainable once it becomes part of a government's core function. Another advantage is that ongoing monitoring may improve compliance with the Code and national laws by manufacturers, distributors and the health sector as they become aware of its existence. For countries that are just adopting national laws, it is good practice to plan and set up an ongoing monitoring system as part of the initial implementation of the legislation.

Implementation of *periodic assessment* has the advantage of providing quantitative estimates of violations so as to get an overall picture of the situation with respect to Code compliance. This snapshot of compliance—or lack of compliance—with the Code can be used to advocate to national authorities for strengthening Code laws and enforcement and/or budgets to strengthen ongoing monitoring. In addition, by using consistent methods, periodic assessments enable trends in Code compliance to be tracked over time. Periodic assessments can be useful to establish a baseline at the time of new laws being introduced. Periodic assessments typically require the presence of an academic institution or non-governmental organization (NGO) with experience in conducting field assessments. Use of the periodic assessment protocol is likely to be particularly useful when a country does not have national legislation, as the report generated can be used to advocate for a Code law.

It is recommended that countries have an ongoing monitoring system accompanied by periodic assessments, since they serve different purposes. Even when an ongoing monitoring system is fully functional, periodic assessments can provide a broader picture of compliance with the Code and national laws, as well as inform on the extent to which the ongoing system is working as planned.

INTENDED USERS

The toolkit is primarily 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 infants 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.

A STEP-BY-STEP GUIDE TO SETTING UP A NATIONAL MONITORING SYSTEM

Monitoring is essential in countries that have implemented the Code as national laws to detect violations and to enable effective interventions to stop or eliminate non-compliant actions.

This 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 (See Page 6 for the specific objectives). This enables relevant enforcement actions to be taken, so that violators can be held accountable for behaviour and practices that undermine breastfeeding and place the health of infants and young children at risk. The very existence of functioning national monitoring systems sends a strong message that potential violators are under continuous scrutiny, and this in itself will improve compliance with national laws.

BOX 4. IMPLEMENTATION AND MONITORING OF THE CODE—RELEVANT CLAUSES FROM ARTICLE 11

Art. 11.1 of the Code states that the 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, regulation or other suitable measures...

Art. 11.2 of the Code states that the responsibility for monitoring the implementation of the Code rests with governments, both individually and in collaboration with other parties (e.g. WHO, NGOs and professional groups).

Art. 11.3 of the Code made clear to the Manufacturers and distributors that: ...Independently of any other measures taken for the 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 the aim of this Code, and for taking steps to ensure that their conduct at every level conforms to them.

Art. 11.4 of the Code calls for NGOs, professional groups, institutions and individuals, to draw the attention of manufacturers or distributors to activities that are incompatible with the principles and aim of the Code.

It is important to stress at the outset that Article 11.2 of the Code has been clarified by Resolution WHA49.15 [1996] which urges governments to ensure that monitoring is carried out in a transparent and independent manner, free from commercial influence.

This requires, among other things, the establishment of a monitoring system that:

- (1) enables the government to perform its duties and tasks without external pressure, fear or influence;
- (2) gives the government the authority and sufficient resources to investigate Code violations;
- (3) empowers the government to take remedial action in line with its national laws and regulations following investigation and verification of alleged violations;
- (4) makes information related to monitoring activities, final results and remedial actions taken publicly available and accessible; and
- (5) has safeguards to detect and exclude persons or bodies that have a conflict of interest and thus preserve its independence, integrity, trustworthiness and credibility.

While **Article 11.3** calls for manufacturers and distributors to monitor their own marketing practices, they should not be part of the government monitoring bodies, in order to prevent conflict of interest. Anyone with a perceived/apparent interest in, or ties to, the business of baby milks or foods, feeding bottles and teats should not be part of any government monitoring body.

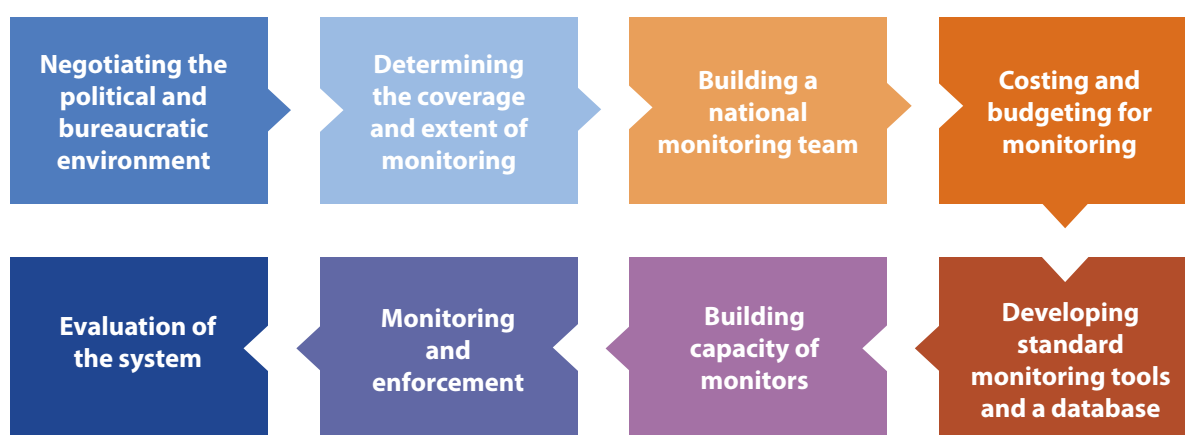
There should be safeguards in place to identify and exclude persons or bodies that have a conflict of interest.

A STEP-BY-STEP GUIDE TO SETTING UP A NATIONAL MONITORING SYSTEM

The establishment of an effective and sustainable monitoring system requires the following steps:

- A** Negotiate the political and bureaucratic environment;
- B** Determine the coverage and extent of monitoring activities based on the provisions of national laws (What and where and when to monitor);
- C** Build a national monitoring team to monitor, report and act upon violations of national laws (Who should monitor, including through identified existing monitoring mechanisms);
- D** Determine the cost of establishing and maintaining a national monitoring system, and budget for, and allocate resources, accordingly (including identification of existing resources, where possible);
- E** Develop standard monitoring tools and a database, based on the NetCode universal monitoring form;
- F** Build the capacity of monitors;
- G** Monitor and enforce to capture and act upon violations of national laws; and
- H** Evaluate and assess effectiveness of the monitoring system.

Figure 1. Establishing and operationalizing an ongoing national monitoring system



A – NEGOTIATING
THE POLITICAL AND
BUREAUCRATIC
ENVIRONMENT

To establish a well-functioning monitoring and enforcement system, it is critical to identify and understand the political forces that can streamline or impede action on the Code. Eliciting the support of key leaders and managing entities that are resistant to controlling marketing will help to ensure that the system can function as intended.

1 Obtaining high-level commitment. It is important to have the full backing of high-level officials in the Ministry of Health. In many countries, the Minister of Health or Director General is highly committed to improving maternal, newborn and child health, and sees full compliance with the Code as central to this agenda. However, other health priorities are a greater focus in other countries and so it may be necessary to convince high-level officials on the importance of the Code and national laws. Offices aiming to build a stronger ongoing monitoring system might advocate for it by:

- a. showing how the Code and national laws fit into the Minister's top priorities;
- b. articulating the public health and economic significance of breastfeeding in the country;
- c. sharing data from previous Code monitoring exercises or periodic assessments;
- d. pointing to World Health Assembly resolutions approved by Ministers of Health;
- e. highlighting legislative mandates for Code monitoring;
- f. reaching out to a new Minister of Health early in his/her tenure; and
- g. partnering with WHO and UNICEF to convene a meeting with the Minister on the Code.

2 Engaging relevant offices. Often, the departments most interested in ensuring that national legislation on the Code is fully enforced are in nutrition, family health, or maternal and child health. Other departments that should have a key role in Code monitoring and enforcement may have broad mandates and are less focused on ensuring an optimal environment for breastfeeding. It is important to conduct a stakeholder analysis to understand not only who can contribute to Code monitoring but also how supportive they will be.

Bureaucratic constraints can sometimes make it difficult to collaborate across multiple departments, especially if they are in separate organizational units or are not located in the same place. Turf battles of department managers protecting their own areas of responsibility can get in the way of joint monitoring activities and efficient information flow. It is important to recognize these barriers and identify solutions.

Some government departments are naturally more aligned with the interests of manufacturers and distributors of breast-milk substitutes. For example, agencies tasked with overseeing the quality of breast-milk substitutes may need to interact closely with the manufacturers that they regulate. Conflicts of interest may arise from such situations due to the regular engagement with industry. These conflicts of interest need to be identified and addressed openly. A key principle in avoiding conflicts of interest is that industry should not be involved in policy-setting or monitoring activities.

3 Identifying external supporters. Individuals and organizations outside of the government may be important allies in advocating for a strong monitoring and enforcement system. They may be able to exert pressure on key government officials or offices to encourage their participation in the system. External advocates may be able to develop advocacy materials to build the necessary case for monitoring and enforcement. Such advocates may be able to use their public voice to call for action by the government.

Key advocates might include civil society organizations that support maternal and child health or consumers' rights. Parliamentarians, including individuals who supported the original Code legislation, may be particularly effective in pressuring the government to develop robust monitoring systems for the legislation. Health professional associations can sometimes be an important force fighting for the health of women and children.

- 4 *Anticipating and addressing opposition.*** Because enforcement implies that certain groups will be penalized for actions taken, it is natural to expect that there will be groups concerned about implementation of a strong monitoring and enforcement system. It is important to anticipate these concerns and address them head-on.

Manufacturers and distributors of breast-milk substitutes have an interest in avoiding full compliance with the law to allow them additional channels for marketing their products. However, as stated above, industry should not play a role in designing the monitoring system. There may be a need to hear the concerns of industry, but this should be done through public hearings involving multiple industry representatives, not in private meetings. It may be advisable to invite industry to put their concerns in writing, so that the concerns can be dealt with rationally and in a public way. Strong monitoring and enforcement can actually benefit industry by establishing a level-playing field in which all companies are held to the same standards, with no individual companies being able to get away with breaking the law.

While health professional associations have an interest in fighting for strong implementation of the Code, they also have an interest in protecting their members from harsh penalties that could be imposed when violating the Code. Health professional associations also may be closely aligned with the interests of manufacturers of breast-milk substitutes because of meeting sponsorship, research funding, training fellowships, etc. As such, caution should be exercised in partnering with associations that have conflicts of interest.

B – DETERMINING THE COVERAGE AND EXTENT OF MONITORING

Establishing the scope of monitoring means identifying what to monitor, where to monitor, and when to do so.

1 What to monitor?

Monitoring should cover promotional and marketing materials, activities and 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 relevant products.

Monitoring activities should cover the following (for examples see Annex 1):

- *Media advertisements (TV, radio, online, print materials)*
- *Promotion in shops and pharmacies*
- *Free samples*
- *Information or educational materials for the general public*
- *Information from the manufacturer or distributor for health professionals*
- *Promotion in health facilities*
- *Health worker promotion*
- *Scholarships*
- *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*

2 Where to monitor?

Monitoring activities should be conducted where relevant products enter the country and in settings where the main targets of promotional and marketing efforts are to be found.

BOX 5 KEY SETTINGS FOR MONITORING ACTIVITIES

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

Some 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.

3 **When to monitor?**

Marketing and promotional activities happen at any time of the day and in a variety of settings, depending on the specific marketing target of the baby food manufacturers and distributors. Code monitoring should be an ongoing process designed to identify violations as and when they occur. It is thus recommended that Code monitoring be integrated into existing monitoring processes, which may or may not be under the jurisdiction of the Ministry of Health.

BOX 6. EXAMPLES OF EXISTING MONITORING PROCESSES

Existing monitoring processes may include:

- Product Registration
- Customs and border controls
- Food and drug inspection activities at point of sale
- Media monitoring
- Health facility monitoring and assessments
- Monitoring health and nutrition programmes at community level

C – BUILDING
A NATIONAL
MONITORING TEAM

It is important to identify existing monitoring mechanisms and processes with the potential to incorporate Code monitoring elements. Identification of existing monitoring opportunities helps to determine which key agencies and departments should be engaged in the development and operationalization of the Code monitoring system. This requires inter-sectoral collaboration between government agencies and partners.

1 **Identifying existing monitoring mechanisms and processes**

It is important to identify existing monitoring mechanisms and processes with the potential to incorporate Code monitoring elements. Identification of existing monitoring opportunities helps to determine which key agencies and departments should be engaged in the development and operationalization of the Code monitoring system. This requires inter-sectoral collaboration between government agencies and partners. Consider to what extent the following activities provide opportunities for the integration of Code monitoring:

Product registration	Registration/licensing of relevant products provides an opportunity to ensure that labels of relevant products adhere to the provisions of the Code and/or the provisions of the national measure. In general, products that do not comply with the Code and/or national laws should not be given a product registration or license for importation.
Customs and border control	Product inspections and requirements for importation should include the requirements set by the Code and/or national laws related to labels and product quality. Products that do not comply with requirements should not be allowed to enter the country.
Food and drug inspection activities at point of sale	Agencies tasked to conduct routine monitoring and inspection of food products at point of sale (Ministry of Trade and Commerce, The Ministry of Health, Food and Drug Administration, etc.), should ensure that products covered by the Code are also integrated in their monitoring efforts. Monitoring will focus on whether they are marketed in line with the provisions of the Code and/or national laws.
Media monitoring	Monitoring of media channels (TV, radio, printed materials, internet) for Code violations may be conducted by government agencies, such as the Ministry of Information and Communication (or its equivalent), Ministry of Social Welfare and Development, and the Food and Drug Administration of the Ministry of Health. Advertising and promotion using media channels should be integrated into existing monitoring activities.
Health facility monitoring and assessments	Teams in charge of monitoring the implementation of public health programmes like maternal and child health and nutrition (MCHN) have the opportunity to monitor compliance by health facilities and health workers (public and private) with the provisions of the Code and national laws. Monitoring can also be done during hospital licensing and accreditation processes, for national health insurance programmes, or other national programmes, such as the Baby Friendly Hospital Initiative.
Monitoring health and nutrition programmes at community level	Registration/licensing of relevant products provides an opportunity to ensure that labels of relevant products adhere to the provisions of the Code and/or the provisions of the national measure. In general, products that do not comply with the Code and/or national laws should not be given a product registration or license for importation.

2 Building a national monitoring team

When national laws 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. For an efficient use of resources, it is recommended that a monitoring system generally be set up at the central level, with clear roles and responsibilities for local actors.

The following is a suggested process for the identification and establishment of a national monitoring team.

Designating a lead agency

Generally, one of the departments in the Ministry of Health is best situated to be the lead monitoring agency for the government. This will often be the **Maternal and Child Health** or **Nutrition Department**. Other departments within the Ministry of Health may have an important role to contribute to the monitoring and enforcement process, such as the food and drug regulatory authority, the health facility licensing, accreditation and development department and the legal office of the Ministry of Health (or their equivalent).

Who should be part of the national monitoring team?

It is recommended that the Ministry of Health set up an **inter-ministerial monitoring team**, composed of representatives from the different ministries, agencies and departments that have a direct responsibility over the marketing, availability and promotion of relevant products.

Table 1 Potential monitoring agencies for different areas of monitoring

Area of Monitoring	Potential Monitoring Agencies
1. Product registration	<ul style="list-style-type: none">• Licensing departments and agencies,• Inspectors and monitors of the food and drug authority (FDA)
2. Customs and border controls	<ul style="list-style-type: none">• Custom and border inspectors
3. Food and drug inspection activities at point of sale	<ul style="list-style-type: none">• Ministry of Trade and Commerce,• Ministry of Health, FDA
4. Media monitoring	<ul style="list-style-type: none">• Advertising boards• Ministry of Trade and Commerce• Ministry of Health• Ministry of Information and Communication
5. Health facility monitoring and assessments	<ul style="list-style-type: none">• Ministry of Health (FDA, MCHN, Hospital Licensing and Accreditation, National Health Insurance Programme, BFHI monitoring)
6. Monitoring health and nutrition programmes at community level	<ul style="list-style-type: none">• Ministry of Health (FDA, MCHN)

COUNTRY EXAMPLE: DEVELOPING A NATIONAL TEAM IN CAMBODIA

When Cambodia initiated a multi-sectoral process to monitor implementation of its Code laws, it established an Oversight Board and an Executive Working Group. The Oversight Board brings together the ministries of health, commerce, industry and handicrafts, and information. Following this, the different parties got together to understand each agency's current role in relation to the Code law and to build consensus on future structures, roles and responsibilities for monitoring and enforcement. Using new tools that were developed collectively, the different agencies—particularly the Ministry of Health and the Ministry of Commerce—then worked together on a rapid assessment in four locations to test the new monitoring arrangements.

Participation by NGOs, public-interest civil society groups and the general public

Nongovernmental organizations, consumer organizations, religious groups and other development organizations can assist governments in monitoring adherence to the Code and/or national laws, and report violations to the designated agency. In selecting civil society groups with which to collaborate on monitoring, the following characteristics should be considered:

- previous experience in Code and/or national laws monitoring activities;
- involvement in other activities on the promotion, protection and support of breastfeeding and infant and young child feeding;
- wide presence throughout the country (directly and/or through partners' networks); and
- free from commercial influence and conflicts of interest.

COUNTRY EXAMPLE: GOVERNMENT WORKING WITH VOLUNTARY ORGANIZATIONS TO MONITOR AND ENFORCE THE CODE IN INDIA

India's *Infant Milk Substitute, Feeding Bottles and Infant Foods Act* gives the government power to authorize NGOs to undertake monitoring and enforcement activities. For example, the Breastfeeding Promotion Network of India (BPNI) supports the government to implement the Act by regular monitoring of product labelling and promotional activities of manufacturers, periodic reporting to the Ministry of Women and Child Development and initiating legal action through filing cases before a court of law. Although more work in the area of enforcement needs to be done, the approach of working with voluntary organizations has led to a noticeable reduction in harmful promotion of foods for infants and young children in India.

There should also be a channel through which members of the public can report violations.

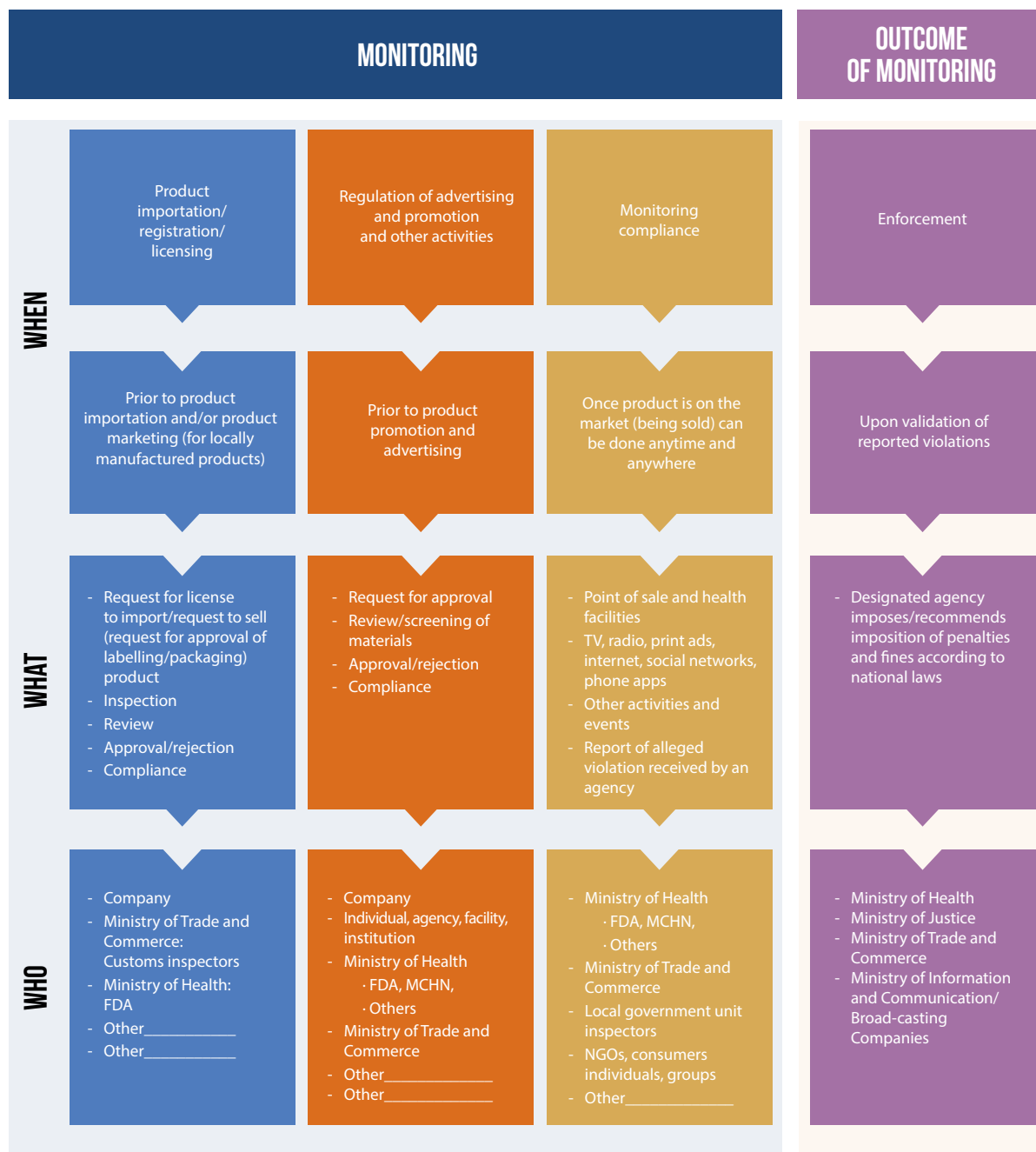
3 Team building and allocation of roles and responsibilities

The lead agency should convene a meeting of representatives of all the potential monitoring agencies identified in page 20 to agree upon areas of responsibilities. Proposed terms of reference for the national government monitoring team are provided below.

Proposed terms of references for the national monitoring team

- Agree on the roles and responsibilities of the monitoring agencies in the ongoing national monitoring system.
- Attend periodic meetings to review reported violations, results of monitoring activities, address issues and concerns relating to the roles and responsibilities of monitoring agencies, discuss the challenges and agree appropriate solutions.
- Oversee and coordinate the monitoring of national laws in line with the existing monitoring procedures and according to the roles and responsibility of each ministry and agency represented.
- Review and investigate all reported violations of the national law, and request action by the relevant authorities.
- Periodically, share a list of reported violations processed, actions taken and other relevant monitoring findings with the lead agency and/or other relevant national agencies.
- Provide technical assistance to sub-national level agencies (provincial/district) in relation to monitoring and enforcement activities.
- Support capacity building on monitoring and enforcing the national law to all relevant officers of the different monitoring agencies, health workers (national and sub-national), NGOs and other interested groups.
- Develop an annual operational plan and budget to guide the activities and operations of the monitoring system.

Figure 2 Outlines the areas, activities and outcomes that need to be achieved and can be used to allocate responsibilities



D – COSTING AND BUDGETING MONITORING

It will be necessary to estimate the cost of operationalizing monitoring activities at the national and sub-national levels. The results of the costing exercise will help the country to:

1. identify available resources (human and financial) that can be allocated for monitoring the Code and/or national laws;
2. estimate resources that need to be requested and/or advocated for at national and/or sub-national levels; and
3. review systems and plans in order to ensure their sustainability and efficiency.

A number of key assumptions are relevant to costing the monitoring system and activities:

- **Government monitors are existing salaried staff** of the different ministries and will integrate monitoring of the Code and/or national laws into their regular monitoring and inspection tasks. In estimating the cost, governments may allocate a proportion of the time that a monitor would dedicate to the monitoring of the Code and/or national laws;
- **Logistical support of government monitors** (transportation and other logistics) is already being provided based on their existing functions and responsibilities;
- **There is no need for additional infrastructure**, such as office space or premises, as the existing office space and buildings of the agencies involved will be used;
- **Existing communication and digital equipment** (PCs, laptops, cell phones, radios) will be used also for monitoring the Code and/or national laws.

Based on the above assumptions, a list of costs (one-off and recurrent costs) that need to be estimated at the country level can be drawn up and options for their implementation identified;

1. Initial training of monitors, evaluating the following options:
 - a. residential;
 - b. non-residential; or
 - c. self-training.
2. Incorporation of Code monitoring into pre- and in-service training for relevant bodies.
3. Development, adaptation and finalization of Standard Operating Procedures and monitoring tools:
 - a. consultancy; or
 - b. in-house development costs, including development and evaluation workshops.
4. Development of centralized monitoring database:
 - a. consultancy; or
 - b. in-house development cost; and
 - c. maintenance costs.
5. Printing and reproduction of recording and reporting forms.
6. Regular meetings of the monitoring team (operation costs, *per diem*, logistical costs).

7. Development of annual national reports:
 - a. consultant; or
 - b. in-house.
8. Publication and dissemination of annual national reports.
9. Development of a web-based reporting system:
 - a. web development (consultant, in-house);
 - b. development process;
 - c. web hosting;
 - d. annual web registration and maintenance; and
 - e. technical support agent/s.

Following costing, resources for Code monitoring should be secured in annual budget allocations.

COUNTRY EXAMPLE: COSTING MONITORING AND ENFORCEMENT OF KENYA'S NEW CODE LAW

In anticipation of the adoption of regulations for the recently passed Kenyan Code law, the Kenyan government prepared a five-year implementation framework to help put the law into practice. The Ministry of Health Nutrition and Dietetics Unit and the National Committee on Infant and Young Child Feeding developed the framework, with the involvement of NGOs, UNICEF, WHO along with the Environmental Health Division and Health Standards, Quality Assurance and Regulation Department within the Ministry of Health, Kenyatta University and Nairobi and Nandi county health department. The development of the implementation framework included a detailed costing of implementation of the law, including the monitoring system. In this way, the necessary resources for monitoring were identified from the outset, enhancing the chances of establishing a viable, sustainable monitoring system.

E – DEVELOPING STANDARD MONITORING TOOLS AND A DATABASE

Governments may already have monitoring tools for their inspectors and monitors. For example, where there are existing tools used to monitor point of sale and health facilities, the integration of additional information on monitoring of marketing and promotional practices for the relevant products is recommended. As a minimum, the following types of information should be integrated into the existing monitoring tools used by government inspectors:

1. date;
2. place or media where monitoring is being conducted;
3. product monitored;
4. type of violation observed/documented;
5. brand;
6. company name;
7. sample or picture of violation; and
8. action taken as appropriate.

1 *Using a standard monitoring form*

Where monitoring tools do not already exist, this protocol proposes use of a practical, user-friendly universal monitoring form based on the minimum standards set by the Code (see model form, below).

Countries are encouraged to review the form and adapt it to the provisions of their national laws. The objective of the universal form is to ensure that monitors are able to document the essential information required to report an alleged violation, with a view to triggering investigation and support the enforcement actions.



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UNIVERSAL MONITORING AND REPORTING FORM

Use this form to report any practice that violates national Code laws. 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; web site: 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 or other social media accounts; 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 (describe)

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

- Advertisement (TV, radio, printed materials)
- Online or social media promotion
- Promotion in retail outlets
- Free samples
- Promotional material for health professionals
- Promotion in health facilities
- Gifts or scholarships to health workers
- Sponsorship of health professional associations
- Inadequate labelling
- Health and nutrition claims on labels
- Non-compliant informational/educational materials
- Events/gifts targeting pregnant women or mothers
- Industry 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: Yes/No (circle the answer)

Name of monitor	
Address/Agency	
Contact number	
Email address	

2 **Developing data collection tools**

Of the different tools that can be developed for data collection, the following can be considered:

PAPER FORM: All the monitoring and reporting forms can be submitted using existing media. Hard copies can be sent by post, by fax and/or hand delivered. Scanned copies can be emailed and submitted to the designated agency. All reports should be secure with the designated authority, and information should be stored in a database as discussed later.

WEB BASED: Government may explore the possibility of developing web-based reporting tools with the following basic features:

- Desktop and mobile versions;
- Online uploading and filing of reports of alleged violation with supportive documentation (e.g., pictures, scanned documents, videos).

The tools may also be designed to:

- Include a built-in feedback mechanism that should provide concrete updates on the status of the filed alleged violation (assigning each complainant with a unique tracking number); and
- Generate regular reports for government and the public on the progress made in acting upon the reports of violations submitted.

Adequate safeguards must be in place to ensure the security and viability of the system. It is proposed, therefore, that a security system should be installed, through the procurement of branded hardware and professional services of security experts to set up an in-house web-hosting system.

For countries with existing web-based consumer reporting systems, these systems should be expanded to integrate information and reports related to the products and activities covered by the Code and/or national laws.

A data entry form for application of the Universal Monitoring and Reporting Form is available as Annex 2. on the webpage for the NetCode Toolkit protocol for ongoing monitoring systems:

<http://www.who.int/nutrition/publications/infantfeeding/netcode-toolkit-monitoring-systems/en/>

This Excel file is a template XLSForm, which also includes information about integration of the data into popular data collection platforms (e.g., KoBo ToolBox). Further information and instructions on how to enter data can be found in Annex 2 of this protocol.

COUNTRY EXAMPLE: DEVELOPMENT OF A SMARTPHONE APPLICATION FOR MONITORING IN MYANMAR

In Myanmar, the NGO Save the Children developed a mobile application (an 'app') for monitoring the country's *Order of Marketing of Formulated Food for Infant and Young Child*. To produce the app, the Myanmar Nutrition Technical Network took the IBFAN-ICDC's existing monitoring form and turned it into an app using Kobo Collect open source software. The app has been adopted by the Department of Health and the National Nutrition Centre and is reported to be widely used across the country to monitor and report violations.¹² The app allows users to report violations by taking a photograph or a screen shot and filling in some key information and then sending the data directly to the National Nutrition Centre, which then verifies and takes action on violations. In this way, various different types of violations have been captured and reported.

3 **Setting up a database for monitoring activities**

Information on violations and action taken should be stored in databases maintained by individual monitoring bodies, in addition to a central database managed by the national monitoring team.

Templates for collection and storage of data can be found in Annexes 3 and 4 on the webpage for the NetCode Toolkit protocol for ongoing monitoring systems:
<http://www.who.int/nutrition/publications/infantfeeding/netcode-toolkit-monitoring-systems/en/>

Annex 3 provides a simple excel template that can be used by the different monitoring bodies at the national and sub-national levels to collate the results of the monitoring activities, including actions taken.

All verified reports of violations should be entered in the central database that will help track the different reports made, type of products and violations being reported and all the key information contained in the universal monitoring and reporting form. The database will also allow the tracking of actions taken, as appropriate, in response to the reported violations and the status of the specific complaint.

Annex 4 provides a template for the development of the central database, which will provide relevant information on the frequency, volume, and coverage of the monitoring efforts, as well as some qualitative information on how companies are violating national laws.

¹² Ending malnutrition for every last child in Myanmar. Save the Children; 2016. (Available from <https://campaigns.savethechildren.net/publications?page=1>, accessed 19 September 2017).

F – BUILDING THE CAPACITY OF MONITORS

Once the key members of the monitoring team have been identified, and the monitoring tools have been developed, the different agencies should complete a hands-on training that will help them understand:

1. Why breastfeeding is important and the state of Infant and young child nutrition in the country;
2. The importance of regulating the marketing of breast-milk substitutes for the protection of infant and young child nutrition;
3. The aim, scope and major provisions of the Code and the national law;
4. Functions, roles and responsibilities for monitoring and enforcement;
5. What, where and when to monitor;
6. How to monitor (*vis a vis* their existing monitoring roles and responsibilities);
7. The monitoring protocols and procedures to follow;
8. Reporting and enforcement mechanisms.

The importance of building the capacity of all monitors is crucial to ensure the effective implementation of monitoring activities.

TRAINING PLAN AND PROGRAMME OUTLINE

It is important to bear in mind that some of the monitors identified may have no prior knowledge of the importance of breastfeeding for child health and development. This needs to be part of the training curriculum.

Identified monitors should also be familiarized with the provisions of the national laws, so they will be able to identify violations, document them and report them using the appropriate reporting tools.

Having identified the monitors – and having clarified their roles and responsibilities, scope and coverage – it is time to provide them with a basic, hands-on training to prepare them for the work ahead. The monitoring team should consider whether all monitoring agencies should be trained together or whether training should be tailored to individual agencies.

While initial training will be necessary in order to initiate the monitoring system, capacity building on monitoring the national law should be integrated into induction and in-service training, where appropriate. In addition, monitoring responsibilities should be included in job descriptions of relevant monitors.

For the purpose of this protocol, a minimum of two days is required for the initial training of monitors. At the same time, similar training can be offered to NGO staff and workers that may want to contribute to government monitoring efforts.

As the main objective of the monitoring system is to detect, report and act on violations committed, it is envisaged that the focus of the training will be the existing relevant national measure and its enforcement mechanisms. A two-module training programme, which can be adapted and enhanced according to the country's context and legal and regulatory framework, is available in Annex 5, which also provides a list of references related to existing training resources that can be accessed and adapted to the country's needs.

COUNTRY EXAMPLE: TRAINING OF INSPECTORS IN ADVANCE OF NEW CODE REGULATIONS IN NAMIBIA

From the very outset, Namibia identified and trained the people who would eventually be responsible for monitoring and enforcing its anticipated regulations on marketing of foods for infants and young children. The relevant inspectors, district environmental health managers, participated in a week-long training course on Code implementation and monitoring, helping to design relevant monitoring protocols. This helped to establish a solid foundation for systematic monitoring and enforcement in advance of the regulations coming into effect.



G – MONITORING AND ENFORCEMENT

MONITORING AND ENFORCEMENT

1 *Identifying violations*

The main purpose of the ongoing monitoring system is to identify violations and, where these are verified to be actionable offences, the relevant agency can be called upon to take enforcement actions. Using the universal monitoring form (see **Developing standard monitoring tools and a database**), monitoring agencies should be able to identify violations that fall under their remit.

NGOs, civil society, consumers and citizens should also be provided with information on how to identify and report alleged violations. Confidentiality of the informants should be respected and protected, as much as possible.

2 *Reporting on violations*

Information and reports of alleged violations gathered during monitoring activities need to be reported to the relevant designated government authority in accordance with the national measure or procedures laid down by the lead agency or other relevant authority. Details of how and where to report violations should be available and accessible to all concerned parties.

A variety of methods can be used for submission of reports of violations (see **Developing standard monitoring tools and a database**).

The Ministry of Health, through its food and drug authority (or equivalent regulatory body), in general handles consumer complaints and feedback for other food and non-food products, and may integrate complaints of violations of national laws in its existing reporting, processing and enforcement procedures.

3 *Verifying and acting on violations*

In most cases, monitoring agencies will have to report the suspected violation to the appropriate authority, which will have to verify the completeness of the information provided, and if necessary, obtain further information to validate the complaint. In this case, the authority concerned may request the monitors to verify the report by:

- Inspecting venues where violations have been reported;
- Collecting samples of the products, labels or promotional materials which are being questioned/ reported as being in violation; and
- Visiting and documenting promotional activities deemed to be in violation at the community, health facility or point of sale.

Once verified and confirmed as a violation, the designated agency will trigger the appropriate enforcement process.

In other cases, monitors may have the authority to take immediate action to stop the offending practice through a variety of penalties, such as warnings, cease and desist orders or fines.

In either case, enforcement actions send a clear message to potential violators that they are being watched, and that infringements of the national law will not be tolerated.

COUNTRY EXAMPLE: CODE MONITORING IS EMBEDDED INTO EXISTING SYSTEMS IN MALAYSIA

In Malaysia the government-led system for monitoring Code violations has been evolving over many years and is well embedded in the country's systems. Although Malaysia has only adopted a voluntary measure to implement the Code, monitoring for violations is done continuously at the implementation level. Suspected violations are reported to the Disciplinary Committee on the Code of Ethics for the Marketing of Infant Foods and Related Products and actions are taken on those violating the Code. This example illustrates that Code monitoring can be incorporated into existing systems and sustained in the long term.

4 *Disseminating monitoring findings*

Feedback on action taken on the case should be provided at appropriate intervals to the complainant. Certain information should be included in that feedback.

- a) Acknowledgement of receipt of the report;
- b) Action taken following the reported violation(s) (e.g., investigation, notice to company, etc.);
- c) Status update on processing of the report:
 - Investigation and stepping up of monitoring on specific areas of concern raised;
 - Violations confirmed with enforcement agency;
 - Information/Warning issued to concerned companies/individuals;
 - Action taken against the violation/violator in line with existing laws and regulations.

An annual monitoring report can be instrumental in ensuring increased attention, awareness and support to the protection, promotion and support of appropriate infant and young child feeding practices. It also provides an opportunity for the lead agency and its partners to highlight loopholes and weaknesses in the system and /or the national laws in place.

Target users of the annual report are legislators, policy-makers and decision-makers, who will thus be informed of priority areas that will need to be strengthened. The annual report will also provide guidance and information to national and international organizations, as well as partners working in the area of infant and young child nutrition and maternal and child health, on the type of violations being committed, actions taken and, potentially, recommendations to improve the monitoring system.

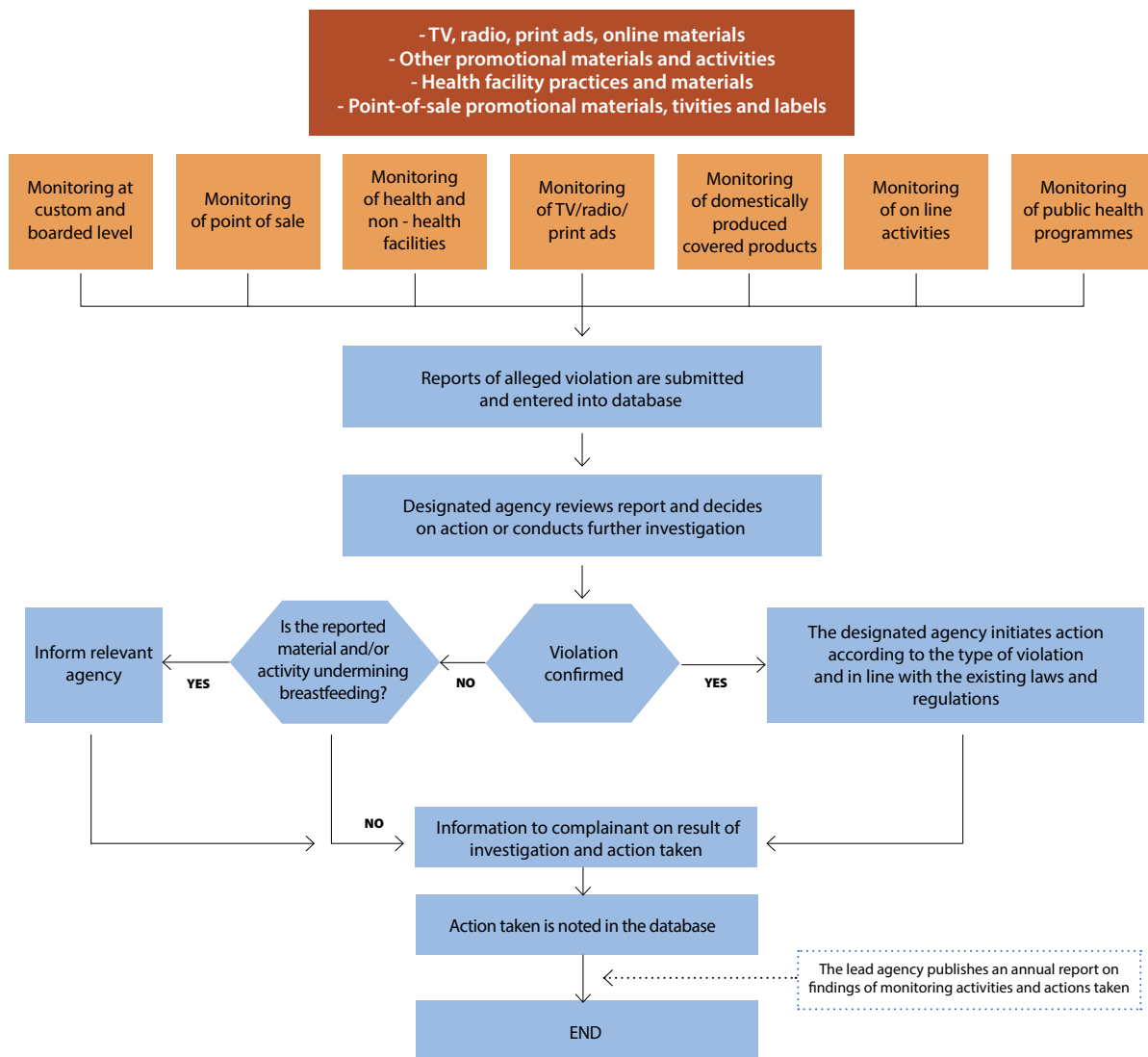
The annual report will support information and dissemination campaigns intended to highlight inappropriate marketing activities and violations committed by companies in the country. Formal reports can be submitted to international agencies – such as UNICEF and WHO – to bring renewed attention to company behaviour. They can also be shared with international organizations that compile reports of violations from all over the world (such as IBFAN-ICDC), to engage company headquarters and call their attention to country-level behaviours of their representatives and distributors.

A template for an annual report is presented in Annex 6.

Visualizing the monitoring flow

The overall monitoring flow described above is reflected in Figure 3, showing the various monitoring and reporting activities.

Figure 3 Flow Chart for monitoring, reporting and acting on violations



H – EVALUATION OF THE SYSTEM

The ongoing monitoring should be evaluated approximately every 3 to 5 years to determine whether it is effectively ensuring full compliance with national laws and/or the Code. The evaluation should aim to determine that the system is still relevant, efficient, effective, making an impact and sustainable.

So as to ensure an unbiased process and outcome of the evaluation, it is recommended that the evaluation be conducted by an external entity that is not involved in the regular operations of the system. An independent contractor or an NGO should be identified from the beginning of the programme to carry out the evaluation.

The evaluation should include both qualitative and quantitative information collection. Interviews with key personnel in the lead agency and other members of the monitoring team are important. Additional interviews with staff responsible for reporting violations in relevant settings will be needed to determine whether they have the required knowledge, time, and political/bureaucratic support to identify violations and report on what they find. Interviews with key NGOs that work in maternal and child health and nutrition may indicate where there are perceived gaps or inefficiencies in the system. The evaluation findings and recommendations should be written up in a report, and a publicly available summary should be considered. This should be made known to both evaluators and evaluates prior to the interviews.

Reviews of the monitoring databases will be valuable to evaluate what types of violations are being reported, how they are being followed up, and whether they are increasing or decreasing. Examination of reports to the system that do not ultimately end in sanctions may be especially important. These may point to aspects of the Code that are not adequately covered by existing national laws or where the national laws are not clearly written. Alternatively, they may indicate poor training of monitors who do not adequately understand the Code and national laws.

The periodic assessment, which is also part of the NetCode Monitoring and Assessment Toolkit, provides an excellent mechanism for evaluating whether the ongoing monitoring system is achieving its objectives. It will highlight areas in which national laws and/or the Code are being violated in ways that are not captured by the ongoing monitoring system. It can point out where additional monitoring is needed. It may also identify new modes of marketing that were not envisioned when the system was created. These may require the involvement of additional governmental departments or new systems to detect violations.

Following an evaluation, it will be important to return to the steps described earlier in this document to make improvements to the ongoing monitoring system. The evaluation will likely point to the need for new measures to deal with political and bureaucratic pressures, reconsider the scope of products covered by the system and who should be involved, refine tools, and retrain key staff in the monitoring system. Those responsible for the monitoring system should address key findings and recommendations in a written document to be provided along with the publically available evaluation summary report.

COUNTRY EXPERIENCE: ASSESSING MONITORING AND ENFORCEMENT IN ALBANIA

Following identification of a clear violation of the Albanian law on marketing of breast-milk substitutes, the State Health Inspectorate – a body that had been established relatively recently – initiated a country-wide assessment of monitoring and enforcement. It found that there were gaps in the capacity of the Inspectorate to identify violations of the Code and/or the Albanian law. As a result, Albania, with support from UNICEF, revised its legislative framework and organized capacity building training for monitoring and enforcement of the law.

ANNEXES

ANNEX 1 WHAT TO MONITOR

MEDIA ADVERTISEMENTS (TV, RADIO, ONLINE, PRINT MATERIALS)

Any audio-visual material meant to promote relevant products using TV/radio/print as a mean of dissemination, including but not limited to:

- television/radio commercials;
- billboard, posters, banners, newsletters, flyers, pamphlets, books, magazines, journals, and newspaper promoting relevant products; and
- online promotions on the internet, including Facebook, Twitter and other social media.

PROMOTION IN SHOPS AND PHARMACIES

Any form of promotion or sales inducement that takes place in the location/place where relevant products are being sold, including, but not limited to, supermarkets, shops, groceries and pharmacies.

FREE SAMPLES

Samples of relevant products given to the general public – including mothers and pregnant women – and health workers.

INFORMATION OR EDUCATIONAL MATERIALS FOR THE GENERAL PUBLIC

Materials produced by manufacturers that are meant to provide information for the general public on infant and young child feeding.

INFORMATION FROM THE MANUFACTURER/DISTRIBUTOR FOR HEALTH PROFESSIONALS

Materials for health workers produced by manufactures and distributors that are meant to provide scientific and factual information on relevant products.

PROMOTION IN HEALTH FACILITIES

Promotion of relevant products in health facilities, including the presence of printed materials, samples, gifts, branded materials, posters, placards or other materials that refer to such products.

HEALTH WORKER PROMOTION

Activities and materials aimed at promoting products directly to health workers, and informational and scientific materials that may be distributed within the health-care system.

SCHOLARSHIPS

Grants or payments made to support activities including, but not limited to, a person's education, continuing education, studies and training by manufacturers or distributors of relevant products.

SPONSORSHIPS

Help given to support an event, activity, person or organization financially or through the provision of products or services by companies producing, importing and/or distributing relevant products.

GIFTS OF ANY SORT (BRANDED GIFTS) FOR HEALTH WORKERS, HEALTH ASSOCIATIONS AND MOTHERS

Free items like bags, pens, calendars, posters, note-books, growth charts, toys and other gifts etc., which may promote the use of a relevant product and are given to mothers, pregnant women, the general public or health workers.

LABELS

Means any tag, brand, mark, picture or other description whether written, printed, stencilled or impressed on, or affixed to a container of any relevant product.

COMPANY/MANUFACTURER/DISTRIBUTOR REPRESENTATIVE CONTACT

Activities conducted by company representatives aimed at contacting mothers and pregnant women and promoting/presenting relevant products.

SALES INCENTIVES/SALES QUOTAS

Practices set by manufacturers and distributors to reward their sales representatives with incentives based on the amount/volume of relevant products actually sold.

DONATIONS

Free provision of goods and services including, but not limited to, informational or educational materials related to infant and young child feeding, materials, samples or regulated products, equipment, documents and services.

ANY OTHER MARKETING OR PROMOTIONAL MATERIALS AND ACTIVITIES THAT MAY UNDERMINE BREASTFEEDING IN THE COUNTRY

This could include any promotional activity or events conducted in public places (plazas, streets, open areas, parks, etc.) and in communities and villages, or other public places such as airports, train stations, bus stations, etc. It could also encompass baby food promotional activities that directly or indirectly support, among others, trainings, workshops, events, raffles, contests, discounts, coupons, displays, community social activities that promote relevant products. This list is not exhaustive and monitoring bodies need to be attuned to new marketing strategies invented in the future.

ANNEX 2 DATA ENTRY FOR THE UNIVERSAL FORM

An Excel file is provided as a template for entering data collected using the Universal Form. The instructions given with the file are shown below. THE EXCEL FILE IS AVAILABLE IN THE ONLINE TOOLKIT.

UNIVERSAL MONITORING AND REPORTING FORM

This spreadsheet provides the raw information for creating a data entry package for the Universal Monitoring and Reporting Form. A number of data entry programs can read an .XLS file of this type to create forms. The instructions here are developed for KoboToolBox.

Go to www.kobotoolbox.org. If you do not already have an account with KoboToolBox, create one. For the purposes for monitoring the Code, it is appropriate to establish an account as a humanitarian organization. You can login or create an account on the Get Started page.

Once logged into KoboToolBox, select Add Form. You can then choose Import Form and browse to the location of this .XLS file. If you need to make changes to the form, it is generally easier to do so within the package. After changes are made, you can test to see that the form works as expected by clicking on Preview Form. It is also possible to make changes directly in this .XLS file before importing, but this should only be done by an experienced programmer, since errors may make the form unusable or lead to unpredictable results. Once changes have been made, select Save and Exit.

To actually create a project for data entry, on the Form Drafts page, select Deploy Form as New Survey Project. Under Share Project with Other Users, select Turn On. This will generate a website address (URL) that can be sent to any potential users who would be entering violations into the form.

Once violations have been entered, you can see the reports by going to the Projects page from the top menu button. Click on the project name to see the data that have been entered. You can view the data in a table, download the data, create tables, or view photos that have been uploaded.

See Excel file (Annex 2 Universal Form Data Entry Code) in the online NetCode Monitoring and Assessment Toolkit (<http://www.who.int/nutrition/publications/infantfeeding/netcode-toolkit-monitoring-systems/en/>).

ANNEX 3 DATABASE FOR RECORDING MONITORING ACTIVITIES

An Excel file is provided as a template for a database to record monitoring activities. Snapshots of the form (which follow-on from one another horizontally on the screen in the actual Excel file) are shown below and over. the Excel file (Annex I.3 Database monitoring activities) is available in the online toolkit.

Ministry of Health		DATABASE OF MONITORING ACTIVITIES			
Period Covered		From	(dd/mm/yyyy)		
No	Date of observation (type/write the date when the complaint was submitted/monitoring visit was made dd/mm/yyyy)	Description of activity (type/write the key words to describe the activity conducted) e.g. control of labels, review of promotional materials in supermarket, monitoring of TV ads, monitoring in hospitals, monitoring a workkshop, etc.)*	Location of monitoring activity (type/write the name of the locality where the activity was conducted)	Name of store/shop/hospital/health facility/community/ where monitoring was conducted (type write the key words to describe the activity conducted)	
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8					
9					
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11					
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15					
16					
17					
18					
19					
20					

Continued over

VIOLATIONS				
To		(dd/mm/yyyy)		
Key findings of the monitoring (select the finding)	List of products found non-compliant (type/write the name/name(s) of product(s) found non-compliant)	Action taken (select action taken)	Date when action was taken (type/write the date when the action was taken dd/mm/yyyy)	Received any feedback on the action (Select the answer)

See the Excel file (Annex I.3 Database monitoring activities) in the online NetCode Monitoring and Assessment Toolkit <http://www.who.int/nutrition/netcode/en/>.

ANNEX 4 ESTABLISHING A CENTRAL DATABASE

An Excel file is provided as a template for a central database to record potential violations reported and follow-up action. Snapshots of the form (which follow-on from one another horizontally on the screen in the actual Excel file) are shown below and on the following pages. THE EXCEL FILE (ANNEX I.4 DATABASE VIOLATIONS) IS AVAILABLE IN THE ONLINE TOOLKIT.

Ministry of Health		DATABASE ON REPORTED VIOLATIONS		
Period Covered		From	(dd/mm/yyyy)	
No	Date submitted (Enter Date when report was submitted dd/mm/yyyy)	Where was the violation observed (Enter the name of the place where the violation was observed)	Company name (Enter the name of the company as per report)	Brand name, or logo if any (Enter the name of the brand as per report)
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Continued over

ANNEX 5 TRAINING RESOURCES

Suggested modules

MODULE I: UNDERSTANDING THE CODE AND THE RELEVANT NATIONAL LAWS

Session 1: Context (60 minutes)

Why is breastfeeding important in (Country Name)

Current infant and young child nutrition indicators (IYCN) and current programmes in (country name)

Session 2: The importance of regulating the marketing of breast-milk substitutes for the protection of IYCN: A brief history of breastfeeding protection and the International Code of Marketing for Breast-milk Substitutes and WHA resolutions (The Code) and relevant national laws (30 minutes)

Session 3: The “AIM” and the “SCOPE” of the Code and the national laws (45 minutes with exercise)

Session 4: Major Code provisions (240 minutes with exercise)

- Information to the public
- Promotion to the public
- Promotion in health-care systems and to health workers
- Labelling

Session 5: Introduction to monitoring and enforcement (25 minutes)

MODULE II: THE CODE/NATIONAL MEASURE: MONITORING AND REPORTING OF VIOLATIONS

Session 1: Recap Day 1 – The DOs and DON'Ts of the Code/national law (15 minutes)

Session 2: Monitoring of the national law (120 minutes):

- Who monitors?
- What to monitor?
- When to monitor?
- How to monitor? (existing monitoring roles and responsibilities)

Session 3: Introduction to the monitoring protocols and procedures to follow

Session 4: Monitoring: Field exercise (1/2 day)

Session 5: Presentation of results from field exercise (80 minutes)

Session 6: Reporting and enforcement mechanisms (45 minutes)

- How to report?
- Where to report to initiate enforcement mechanism and application of sanctions?

Session 7: Planning (60 minutes)

Session 8: Recap: Conclusion (30 minutes)

Additional training resources

WHO/UNICEF ONLINE TRAINING COURSE ON THE CODE

The World Health Organization and UNICEF have developed an online course on Code implementation and monitoring. The course helps the participants to understand the key articles of the Code, their interpretation and application at the country level. At the same time, discussions on monitoring activities, and identification of violations at the country level, enable participants to have better understanding the importance of the Code and its implication for child survival and development. The online course can be requested from NetCode.

IBFAN INTERNATIONAL CODE DOCUMENTATION CENTRE (ICDC) COURSES ON CODE IMPLEMENTATION AND CODE MONITORING

IBFAN-ICDC has more than 20 years of experience in developing and delivering Code training courses at international, regional and national levels. (See <http://www.ibfan-icdc.org/index.php/what-we-do#ct>)

The aims of IBFAN-ICDC Code courses are to:

1. encourage countries with no or limited national legislation or a voluntary code to implement the Code or to strengthen existing legislation;
2. build capacity of government officials and civil society groups to monitor the Code at all levels so that companies can be held to account for their marketing behaviour;
3. empower health workers to take appropriate steps to protect mothers and infants from unethical marketing practices within the health system; and
4. encourage regulators and enforcement officials to ensure compliance with national laws through systematic monitoring and enforcement of national laws.

The courses target policy-makers, regulators, enforcement officials, civil society groups and lawyers, and their duration varies between five and 10 days, according to specific needs and objectives.

BABY MILK ACTION CODE TRAINING (IBFAN UK)

The Baby Milk Action group (IBFAN UK), conducts an online training course on monitoring baby food manufacturers and distributors. Two initial modules are available for all the members and subscribers of the group:

- **Module 1:** Introduction to the *International Code of Marketing of Breast-milk Substitutes*.
- **Module 2:** History and current state of the Code.

See <http://www.babymilkaction.org/training>

OTHER CAPACITY-BUILDING OPPORTUNITIES

Implementation and monitoring of the Code and/or national laws should remain important topics for discussion in several other training courses. Health workers, for example, should be refreshed and reminded on the importance of the Code and/or national measure, in their efforts to protect, promote and support breastfeeding in the country. A module on the Code and/or national laws is included (and may be adapted) in the following existing training courses:

Baby Friendly Hospital Initiative Training Course:

(http://www.who.int/nutrition/publications/infantfeeding/bfhi_trainingcourse/en/)

Infant and Young Child Feeding Counselling and Integrated Course:

(<http://www.who.int/nutrition/publications/infantfeeding/9789241594745/en/>)

Infant and Young Child Feeding Community Training Modules:

(http://www.unicef.org/nutrition/index_58362.html)

Infant and Young Child Feeding in Emergencies:

(<http://www.enonline.net/ourwork/capacitydevelopment/iycflearning>)

ANNEX 6 OUTLINE FOR ANNUAL MONITORING REPORT

- Executive summary
- Background
- Introduction
- Objectives
- Methodology
- Monitoring results/findings/actions taken:
 - i. presentation of the monitoring activities conducted during the period
 - ii. presentation of monitoring findings and actions taken
 - iii. media
 - iv. health facilities and health workers
 - v. point of sale
 - vi. other (s).
- Analysis of results:
 - i. Situation compared to the recommendations of the Code and/or compared to the provisions of the national laws
- Conclusions
- Programmatic and policy recommendations
- References (Bibliography)
- Annexes:
 - 1. tools
 - 2. database of violations
 - 3. pictures of examples of violations
 - 4. other.



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