Strengthening Implementation of the Breast-milk Substitutes Code in Southeast Asia: Putting Child Nutrition First

UNICEF EAST ASIA AND PACIFIC REGION

OCTOBER 2021
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Strengthening Implementation of the Breast-milk Substitutes Code in Southeast Asia: Putting Child Nutrition First

October 2021

UNICEF East Asia and Pacific Region

ABSTRACT

This report presents the main barriers and bottlenecks to implementation of Breast-milk Substitutes Code law monitoring and enforcement systems identified in five ASEAN countries and provides recommendations for action.
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Code law monitoring and enforcement system in Viet Nam

4 Conclusion

Annex A
List of Key Informant Interview (KII) respondents
Abbreviations

A&T  Alive & Thrive
AIMI  Asosiasi Ibu Menyusui Indonesia (The Association of Indonesian Breastfeeding Mothers)
AO  Administrative Order
ASEAN  Association of Southeast Asian Nations
BMS  Breast-milk Substitutes
BPOM  Badan Pengawas Obat dan Makanan (Indonesian National Agency of Drug and Food Control)
CAMCONTROL  Cambodia Import-Export Inspection and Fraud Repression Directorate-General
C0I  Conflict of Interest
COVID-19  Coronavirus Disease 2019
DDF  Department of Drugs and Food
DHO  District Health Office
DOH  Department of Health
DOJ  Department of Justice
DTI  Department of Trade and Industry
EAPRO  East Asia and Pacific Regional Office
EO  Executive Order
EWG  Executive Working Group
FDA  Food and Drug Administration
HCMC  Ho Chi Minh City
HKI  Helen Keller International
IAC  Inter-Agency Committee for the Philippine Milk Code
IBFAN  International Baby Food Action Network
IPNAP  Pediatric Nutrition Association of the Philippines
KII  Key Informant Interview
LGU  Local Government Units
MBFP  Mother-Baby Friendly Philippines
MCH  Maternal and Child Health
MoC  Ministry of Commerce
MoH  Ministry of Health
MoHS  Ministry of Health and Sports
NGO  Non-governmental organization
NNC  National Nutrition Centre
NNP  National Nutrition Programme
OB  Oversight Board
PHD  Provincial Department of Health
PHO  Provincial Health Offices
POS  Point-of-sale
RIRR  Revised Implementing Rules and Regulations of the Philippine Milk Code
SOP  Standard Operating Procedure
SUN  Scaling Up Nutrition Movement
<table>
<thead>
<tr>
<th>Acronym</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>SUN CSA</td>
<td>Scaling Up Nutrition Civil Society Alliance</td>
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<td>TWG</td>
<td>Technical Working Group</td>
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<tr>
<td>UNICEF</td>
<td>United Nations Children’s Fund</td>
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<tr>
<td>US</td>
<td>United States</td>
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<tr>
<td>VFA</td>
<td>Vietnam Food Administration</td>
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<tr>
<td>VND</td>
<td>Vietnamese Dong</td>
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<tr>
<td>WASH</td>
<td>Water Sanitation and Hygiene</td>
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<tr>
<td>WHA</td>
<td>World Health Assembly</td>
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<td>WHO</td>
<td>World Health Organization</td>
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Executive summary

What, when and how children are fed, particularly in the first two years of life, is critical to health, development and survival. Exclusive breastfeeding, feeding infants nothing but breastmilk for the first six months of life, is the safest and healthiest option for children everywhere and has great potential to save lives. However, good nutrition in the earliest years is a collective responsibility that requires government leadership and contributions from key sectors – including health, agriculture, water and sanitation, social protection and education – as well as workplaces, communities and families, to support mothers in providing their children with the nutrition they need. The International Code of Marketing of Breast-milk Substitutes (hereafter referred to as “the Code”) is crucial to protect and promote breastfeeding by prohibiting the promotion of breast-milk substitutes (BMS) such as infant formula, follow-up formula, growing-up milks as well as bottles and teats that are marketed as suitable for feeding infants and young children.

BMS Code law monitoring and enforcement is called for in several key global documents with relevance to nutrition, including the original 1981 Code, which was adopted by WHO Member States to protect, promote and support breastfeeding. In 2002, the WHO/UNICEF Global Strategy for Infant and Young Child Feeding reiterated the importance of comprehensive national policies that protect, promote and support appropriate infant and young child feeding practices. The Strategy makes clear that an effective feeding policy consistent with efforts to promote overall household food security requires “implementing and monitoring existing measures to give effect to the International Code of Marketing of Breast-milk Substitutes and to subsequent relevant Health Assembly resolutions, and, where appropriate, strengthening them or adopting new measures”. It also explicitly reiterated that manufacturers and distributors of products within the scope of the Code are responsible for monitoring their marketing practices and ensuring that they do not undermine breastfeeding. More recently, in 2016, the WHO/UNICEF/IBFAN Status Report on National Implementation of the International Code noted that very few countries had legal measures in place to facilitate the establishment of formal monitoring and enforcement mechanisms and that information on, and actual existence of, formal monitoring and enforcement mechanisms remains very limited. Lastly, the 2020 Status Report emphasized that governments should establish robust and sustainable monitoring and enforcement mechanisms to implement national laws and regulations and apply deterrent sanctions in the case of violations of national Code legislation.

With this background information in mind, the specific aims of the report are to:

- Identify the main barriers and bottlenecks to successful monitoring and enforcement of Code law systems in five Association of Southeast Asian Nations (ASEAN) countries: Cambodia, Indonesia, Myanmar, Philippines, and Viet Nam;

- Provide recommendations to create strengthened and sustainable Code law monitoring and enforcement systems

In each country, a stakeholder mapping was undertaken and a standardized methodology was developed for key informant interviews and desk reviews of all BMS Code legislation and legal documents related to monitoring and enforcement of the Code law. To identify and prioritize perceived implementation barriers to monitoring and enforcement, a bottleneck analysis matrix was developed around priority categories.
In aggregate, the report shows that the main barriers and bottlenecks to successful Code monitoring and enforcement are strikingly similar across countries. Specifically, government leadership, legislation and policies, human resource capacities, and industry influence were highlighted as priority areas. The recommendations developed are directed at governments as primary duty bearers; however, it is recognized that civil society also plays an important role in successful Code implementation.

A key resource to further address current bottlenecks and strengthen existing systems is the NetCode Ongoing Monitoring System Protocol. This protocol has already been piloted in Cambodia with the assistance of WHO. It provides a framework and tools to improve systems and establish sustainable structures that are able to monitor, detect, and report violations of national Code laws and to take enforcement actions. Instituting the NetCode Ongoing Monitoring System Protocol across the region would be a major step towards holding Code violators accountable for their behaviours and practices that undermine breastfeeding and place the health of infants and young children at risk.

Even 40 years after its adoption, the Code remains as relevant as ever to prohibit the promotion of BMS and to protect and promote breastfeeding. We hope that the recommendations provided in this report will be used to strengthen Code monitoring systems in the five countries examined so that children can enjoy the full benefits of breastfeeding and have the best possible start to life.
Introduction

Exclusive breastfeeding – feeding infants only breastmilk for the first six months of life – is the safest and healthiest option for children everywhere. Yet in every region of the world, rates of exclusive breastfeeding decline steadily from birth to 5 months of age. Globally, just 41 per cent – or two out of five – of the world’s infants under 6 months of age are exclusively breastfed, and there has been little progress over the past 15 years. Part of the explanation for this is that breastfeeding is not a one-woman job. Women who choose to breastfeed need support from their governments, health systems, workplaces, communities and families to make it work. The International Code of Marketing of Breast-milk Substitutes, adopted by the World Health Assembly (WHA) in May 1981, and subsequent relevant WHA resolutions (known together as ‘the Code’) aim to protect and promote breastfeeding by prohibiting the promotion of breastmilk substitutes, including infant formula, bottles, teats, follow-up formulas and growing-up milks marketed for feeding infants and young children up to the age of 3 years. By integrating the Code’s provisions into national legislation, governments can help protect mothers and health-care workers from the commercial pressures that seek to undermine breastfeeding.

As of April 2020, 136 (70 per cent) of 194 WHO Member States (“countries”) had enacted legal measures with provisions to implement the Code. Of these, 25 countries had measures substantially aligned with the Code; a further 42 had measures which are moderately aligned; 69 had only included some of the provisions and 58 had no legal measures at all.

While these figures represent remarkable progress in implementing the Code, enactment of robust national legal measures is only one part of the equation necessary to ensure that parents and other caregivers are protected from inappropriate and misleading information and the continued and aggressive marketing of BMS.

In order to protect, promote and support breastfeeding, measures at many levels are needed. These extend far beyond legal and policy directives, and include supportive social attitudes, comprehensive maternity protection, and workplace breastfeeding support. While we now see that the vast majority of countries have enacted legal measures covering some provisions of the Code, very few have functioning monitoring and enforcement systems. In fact, information on, and actual existence of, formal monitoring and enforcement mechanisms remain very limited. Globally, only 32 countries reported having an operational monitoring and enforcement mechanism. Of these, just six countries reported having dedicated budgets and funding for monitoring and enforcement. As a result, unethical and inappropriate marketing of BMS continues.

This report seeks to shed light on the main barriers and bottlenecks to successful Code law monitoring and enforcement in five Association of Southeast Asian Nations (ASEAN) countries: Cambodia, Indonesia, Myanmar, Philippines and Viet Nam.

It presents information on what stakeholders in these countries provided during key informant interviews (KII) and offers insight into challenges unique to each country. Although it is well known that the inappropriate marketing of BMS undermines breastfeeding and harms child and maternal health, few reports have investigated the functioning of Code law monitoring and enforcement systems and the consequences for effective Code implementation. This report provides information on the efforts made by these five ASEAN countries to monitor and enforce the Code through the establishment of formal mechanisms.

It aims to improve the understanding of how countries are implementing the Code and identify implementation challenges. For each country, it provides tailored recommendations and potential new approaches to improve implementation of Code law monitoring and enforcement systems.
At the time of this writing, the COVID-19 pandemic was spreading across the globe, clearly posing a serious threat to food and nutrition security and the progress made on many nutrition indicators, including exclusive breastfeeding.

Diminished or suspended breastfeeding promotion and nutrition counselling activities, together with mothers’ fears around COVID-19 infection, may result in increased utilization of BMS. The pandemic also spurred opportunistic marketing of BMS, making the adoption and enforcement of the Code even more important.
Objectives and research methodology

Objectives

The objectives of the bottleneck analysis are to:

01 Identify the main barriers and bottlenecks to successful monitoring and enforcement of Code law systems in the five ASEAN countries Cambodia, Indonesia, Myanmar, Philippines and Viet Nam.

02 Provide recommendations to address the main barriers and bottlenecks to Code implementation.

Research methodology

Information and relevant legal documents were collected from the Ministries of Health of Cambodia, Indonesia, Myanmar, Philippines and Viet Nam with assistance from UNICEF Country Offices. The research methodology used to carry out the analysis is summarized in the diagram below (Figure 1).

The overall research methodology was split into the following activities:

- Stakeholder mapping in coordination with UNICEF country offices,
- Standardized data collection through desk reviews and KII, and
- Completion of the BMS Code Monitoring Systems Bottleneck Analysis Matrix by every interviewee.

The following documents were collated:

(1) BMS Code legislation, (2) food labelling and food safety legislation, and (3) advertising legislation (where available).

A desk review covering all BMS Code legislation and legal documents related to monitoring and enforcement of the Code law within each of the five country’s health systems as well as at retail points-of-sale (POS) was conducted in 2018-2019.

Based on the desk review of legislation and the gaps discovered, a list of structured questions to be administered during key KII was developed. Questions focused on areas where little information was available from the desk review.

KII were conducted with country-level stakeholders including from governments (Ministry of Health (MOH), Ministry of Trade and Industry, and National Agency for Food and Drug Control), and development partners to seek clarification on gaps in the information gathered, and to gain insights into system bottlenecks.
Figure 1. Diagram detailing research workflow

OVERVIEW OF RESEARCH WORKFLOW

1. **Data collection**
   - Desk review of existing laws and policies related to the Code in Cambodia, Indonesia, Myanmar, Philippines and Viet Nam
   - Key informant interviews (KII) based on gaps in information collected through the desk review
   - BMS Code Monitoring Systems Bottleneck Analysis Matrix

2. **Data management**
   - Code law summary document created for each country to ensure all legal measures encompassing a country's Code law were evaluated
   - KII summary documents which are collated notes from KII

3. **Outputs**
   - BMS Code Monitoring Systems Bottleneck Analysis Matrices
   - Key recommendations based on findings from KII's and Bottleneck Analysis Matrices

A BMS Code Monitoring Systems Bottleneck Analysis Matrix was completed with each interviewee during face-to-face KII, when possible. If the circumstances of the interview did not allow for completion of the matrix, instructions to the interviewee were provided and the matrix was sent to them via email with a deadline for completion.

This analysis was informed by numerous KII. From November 2018 to February 2020, separate missions to Cambodia, Indonesia, Myanmar, Philippines and Viet Nam were conducted during which the interviews were carried out in person.

These country visits provided an opportunity for in-depth interviews with government representatives, UNICEF Country Office colleagues, NGOs and others. The sampling process for interviews was snowball sampling, a process whereby the researcher makes initial contact with people identified as relevant to the research, and through this initial contact other potential interviewees are identified and contacted. The initial stakeholder mapping of interviewees...
happened with the support of UNICEF Country Offices. The criteria used were: (1) knowledge of in-country BMS Code monitoring and enforcement systems and (2) whether an individual was directly or indirectly involved in Code law monitoring and enforcement activities.

To identify and prioritize perceived implementation barriers to monitoring and enforcement, a bottleneck analysis matrix was developed. The matrix consisted of a series of structured questions developed around 8 categories (Figure 2).

If a bottleneck was identified by respondents, the level was assessed as mild, moderate or significant. Supporting information from respondents on why these categories were a bottleneck and the severity of the bottleneck were collected as notes.

After reviewing the findings from the KII and bottleneck analysis matrices, it was decided to group the recommendations into the areas of advocacy, leadership, capacity development, program implementation, data and reporting, financing and human resources, monitoring and enforcement, and legislation for each country.
Findings

The effective implementation of the Code and subsequent relevant WHA Resolutions remains a challenge in Cambodia, Indonesia, Myanmar, Philippines and Viet Nam.

Major general challenges include:

- Lack of political will to monitor and enforce existing Code laws.
- Continued interference from the infant feeding industry in government efforts to initiate or strengthen Code monitoring and enforcement measures.
- Competing priorities within the health care system.
- Limited national financial and human resources for legislation, monitoring and enforcement.

In addition to these general challenges, the countries discussed in the report all have weaknesses in their respective Code regulations that are explored in greater detail in the next section of the report. It is also important to highlight that the 2016 WHA Resolution 69.9 and its associated WHO Guidance raised the bar in terms of clarifying that the Code should apply to all milk products marketed for children up to the age of 36 months, cross promotion and ending conflicts of interest (COI). Consequently, all countries examined should be incorporating the recommendations contained in the WHA 69.9 Guidance into their national laws in order to bring them fully in line with the Code and latest WHA Resolutions.

As of May 2021, none of the five countries evaluated have fully functioning Code law monitoring systems and enforcement actions have been rare.

Based on interviews undertaken, the report explores the key issues preventing Code law monitoring from being embedded within government systems and the reasons for weak enforcement.
Strengthening Implementation of the Breast-milk Substitutes Code in Southeast Asia:

Putting Child Nutrition First

FINDINGS
Cambodia
3.1 Cambodia

01 Background

According to the 2020 WHO Status Report, Cambodia’s Code law is classified as “moderately aligned with the Code”. This designation is conferred when countries have enacted legislation or adopted regulations, decrees or other legally binding measures encompassing a majority of provisions of the Code.\(^5\)

Cambodia’s Code law

is comprised of two key documents:

1. **Sub-Decree 133 (2005)**, which was enacted to curb the aggressive marketing of BMS.

2. **Joint Prakas 061 (2007)**, which identified the line ministries in charge of implementing the Sub-Decree and their key mandates.

The law covers the marketing of infant and young child feeding products intended for infants and young children 0-24 months of age, feeding bottles, teats and pacifiers. It also applies to their labelling, quality and availability, and to information concerning their use. Sub-Decree 133 prohibits pictures/text idealizing BMS, but falls short of creating a strict prohibition on the marketing of BMS because it allows for the provision of free/low cost supplies to health facilities and the giving of product samples, gifts or company-produced materials with MoH approval.

In 2014, an Oversight Board (OB) was established to oversee the implementation of the Sub-Decree, and in 2015 a more operational body was created, the Executive Working Group (EWG), for which clear terms of reference and a set of monitoring guidelines were developed and endorsed. The OB is a high-level body led by the MoH; however, four additional line ministries (Health, Commerce, Information, and Industry and Handicraft) are also represented by their Secretaries. Article 7 of Joint Prakas 061 mandates that the OB meet on a quarterly basis, but this has not happened. Stakeholders noted that the OB has only met once since it was established five years ago in 2014 due to a lack of high-level political support.

The more operational EWG, composed of key officers from the different line ministries and representatives from relevant offices of the MoH, has been meeting more frequently (3-4 times per year) but suffers from limited financial resources and scheduling issues according to the minutes of its May 2018 meeting. Stakeholders noted that a Technical Working Group (TWG) was also established in 2018 to improve coordination efforts and meets in Phnom Penh on a monthly basis.

Both Sub-Decree 133 and Joint Prakas 061 address the monitoring and enforcement of Cambodia’s Code law. Sub-Decree 133,

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Chapter VI on “Management and Monitoring Authority” states that MoH is responsible for facilitating the collaboration of the line ministries involved in infant and young child feeding. However, it offers few details on MoH’s actual monitoring and inspection powers and duties. Article 17 says that MoH bears the responsibility for issuing directives to inspection officers and mandates that it handle issues concerning implementation as well as reports of violations without further explanation. It also makes clear that MoH is the agency responsible for requesting and sending nutritional specimens to the national laboratory to ensure food safety and quality testing for infant and young child feeding products, as required. Enforcement is addressed briefly in Article 18, which states that penalties for violation of Sub-Decree 133 shall be subject to the provisions of the “Law on Management of Quality and Safety of the Products, Goods and Services” or other relevant laws in force. No further information on sanctions or enforcement measures is provided in the Sub Decree.

Joint Prakas 061 briefly addresses monitoring and enforcement in Article 7, which mandates that the OB accept and consider reports on the implementation of the Sub Decree from the MoH, the Ministry of Commerce (MoC) and the Ministry of Industry as well as from international organizations, non-governmental organizations, health personnel and the public on the breaching of the Sub Decree. Article 7 further instructs the OB to compile and disseminate annual reports on the breaches and actions taken for resolution. However, since the OB is not fully active, stakeholders confirmed that it has not carried out any of these tasks or duties.

While the provisions of Cambodia’s Code law reflect many of the minimum standards embodied by the Code and subsequent WHA Resolutions, a few noteworthy gaps remain. These include the following:

1. Article 13 of Sub-Decree 133 states that manufacturers and distributors shall not promote infant and young child feeding products without prior permission from the MoH, which falls short of creating a strict prohibition on the marketing of BMS as required by the Code.

2. Article 14 of Sub-Decree 133 states that manufacturers and distributors shall not donate samples of designated products, distribute equipment or materials to health facilities, offer gifts to health workers, sponsor events or provide scholarships without authorization from the MoH which falls short of creating a strict prohibition on the giving of product samples, gifts and company-produced materials as required by the Code and subsequent relevant WHA resolutions, including WHA 69.9.

3. Labelling provisions do not ban nutrition and health claims on infant and young child feeding products; require a recommended age of introduction; or mandate a warning message that infant/follow-on formula is not a sterile product and may contain pathogenic micro-organisms.

4. There is no prohibition on provision of free/low cost supplies of BMS to health facilities.
02 Monitoring and inspection activities

In 2016, a pilot of the monitoring system was developed using the NetCode Protocol and key agencies within the MoH (Department of Drugs and Food [DDF] and the National Nutrition Programme [NNP]) in addition to the MoC’s Cambodia Import-Export Inspection and Fraud Repression Directorate-General (CamControl) received support from development partners to carry out monitoring visits at health facilities and inspections at retail POS.

The pilot was intended to systematically monitor BMS product labels and promotions at POS and health facilities in four pilot zones and to monitor audio-visual promotions and advertisements on television, radio, printed media, and the Internet as outlined in Sub-Decree 133. In addition, the pilot was enacted to test the reporting system, to screen and review the process for submitting violations, and to act against violators.

During the pilot, 85 monitors were trained, 392 site visits were made, 2,377 monitoring checklists were completed, and 11 warning letters were issued to violators. Half of the completed checklists (52.9 per cent) indicated Code violations, however the number of violation reports submitted was zero. When evaluating the actions taken in relation to the identified Code violations, it is interesting to note that all of the alleged violations were handled in a similar way by the different agencies. A “soft” approach was taken that involved discussing each violation with the respective person in-charge of the health facility or shop owner in an attempt to ensure that they understood the requirements of Sub-Decree 133 before any formal penalties were issued.

There was consensus amongst stakeholders that the pilot monitoring activities were an important step towards implementing a Code monitoring and enforcement system in Cambodia. However, the pilot also revealed that modifications to the monitoring system were needed and it highlighted significant challenges involved in the sustainability of such a system. The key challenges that emerged were: the checklist developed using the NetCode Protocol was too long and complicated for inspection teams to implement it successfully; there was limited training content available to monitors to help build their capacity; there were no violation reports submitted; and there was an insufficient number of monitors available at the sub-national level. Stakeholders also mentioned that the pilot had been fully funded by development partners and that the government had limited financial resources for continuing Code monitoring activities.

Since the pilot ended in 2017, there has been limited Code monitoring carried out by NNP, DDF and CamControl. However, despite the existing challenges, a number of monitoring visits did take place in 2018 and 2019 and violations of Sub-Decree 133 were documented and reported in the following provinces: Battambang, Siem Reap, Sihanoukville, Pursat, Kratie and Phnom Penh. Those interviewed acknowledged that Code monitoring in Cambodia remains weak, but they were optimistic about the progress achieved to date. They pointed to efforts taken by MoH, MoC and the EWG over the past year to enact a joint work plan to revise the existing monitoring tools and processes based on lessons learned during the pilot, and explained that this was a direct result of the Government of Cambodia’s commitment to the effective implementation of the Code and Sub-Decree 133.

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7 Ibid.
8 Ibid.
03 Enforcement

According to UNICEF Cambodia, a total of seven companies have now been fined 2.5 million Cambodian Rels (~ US$ 615) each for repeat activities promoting infant and young child feeding products in violation of Sub-Decree 133 during 2019.

The MoH, DDF, has confirmed the names of two of the companies: Nutrilatt Master LM Co., Ltd and SAM Business Group. However, the names of the five most recent companies to receive fines have not yet been released.

The events that led to the imposition of these sanctions remain unclear. However, various stakeholders said that they did not think the fines were a result of the NetCode pilot monitoring activities that took place in 2017, and, instead, were at least partially related to the routine monitoring and inspection activities of DDF, which sits within the MoH.

UNICEF and Helen Keller International (HKI) both agreed that an online group chat hosted on the encrypted mobile application Telegram, might offer a partial explanation. Multiple discussions confirmed that the chat group includes about 20 key individuals in Cambodia involved in infant and young child feeding from Government, development partners and NGOs. One advantage of the Telegram group, that was highlighted during discussions, is that it allows Code violations to be reported immediately to all stakeholders in real-time. Those interviewed felt that reports of Code violations exchanged via Telegram likely helped provide the evidence necessary to convince the Government to impose sanctions on the seven companies that received fines in 2019.

In addition to the confirmed penalties previously discussed, 32 cases of confirmed violations of Sub-Decree 133 were filed by the Scaling Up Nutrition (SUN) Civil Society Alliance to the EWG according to the SUN 2018 Joint-Assessment. As a result, 16 warning letters of unknown effect were issued to the alleged violators.

The decisions to impose fines may have been facilitated by a confluence of factors, such as advocacy efforts, increased monitoring visits undertaken by CamControl, NNP and DDF, reports of Code violations with photographic evidence submitted through the Telegram group chat and continued pressure from NGOs.

In conclusion, there is insufficient evidence to determine what recently led the Government of Cambodia to move away from its “soft” approach to reports of Code violations and impose fines for violations of Sub-Decree 133 in 2019.
04 Major bottlenecks

1. **Budget and financing**
   
   As of October 2019, there is no specific budget allocated by the MoH or the other Ministries to support monitoring activities related to Sub-Decree 133 and Joint Prakas 061. The pilot monitoring activities that took place in 2017 were financed by the WHO and HKI.

2. **Leadership, political will and governance**
   
   Until 2019, the Government followed a “soft” approach to Code enforcement which involved writing warning letters and did not include formal sanctions. In 2019 seven companies were fined for violating Sub-Decree 133, but it is too early to say if this represents a temporary or permanent increase in political support for implementation and improved coordination between the Ministries of Health, Commerce, Information, and Industry and Handicraft.

3. **Human resources**
   
   Institutional human resource capacity is weak in the ministries involved in Code monitoring and enforcement and many officials lack appropriate training and qualifications to effectively carry out their jobs. This is especially true for the Ministry of Information and the Ministry of Industry and Handicraft. Stakeholders said that the MoH and the MoC had better human resource capacity and management, but still experienced challenges with low capacity.
05 Recommendations for addressing the barriers to implementation of Code law monitoring and enforcement systems in Cambodia

Based on discussions with stakeholders, the following recommendations are made to address the perceived bottlenecks and barriers to implementation of Code monitoring and enforcement systems in Cambodia:

<table>
<thead>
<tr>
<th>Category</th>
<th>Recommendation</th>
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<tbody>
<tr>
<td>Capacity development</td>
<td>Build the capacity of national and sub-national monitors in the MoH (DDF and NNP) and the MoC (CamControl) to monitor and enforce Sub-Decree 133 effectively.</td>
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<tr>
<td>Financing and human resources</td>
<td>Identify existing financial and human resources within the MoH and MoC to scale up Code monitoring and inspection activities.</td>
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<tr>
<td>Monitoring and enforcement</td>
<td>Improve the integration of Code monitoring activities into routine ministry operations by adding Code monitoring trainings to the existing training curricula for the DDF, NNP and CamControl.</td>
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<td></td>
<td>Revise and simplify the training content for Sub-Decree 133 monitoring used to train national and sub-national monitors and streamline the reporting form for submitting violations of Sub-Decree 133 to facilitate effective monitoring and enforcement.</td>
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<tr>
<td>Legislation</td>
<td>Amend existing Code legislation to address the gaps that prevent full compliance with the minimum standards embodied by the Code and subsequent WHA Resolutions, including WHA Resolution 69.9.</td>
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FINDINGS

Indonesia
3.2 Indonesia

01 Background

According to the 2020 WHO Status Report, Indonesia’s Code law is classified as “moderately aligned with the Code”. This designation is conferred when countries have enacted legislation or adopted regulations, decrees or other legally binding measures encompassing a majority of provisions of the Code.9

Indonesia’s Code law covers infant and follow-up formula milk for infants 0-12 months and other baby products, which include all forms of milk and other baby food, baby bottles, baby teats and pacifiers.

However, Indonesia’s Code law is spread out among multiple legal instruments, making it difficult to interpret and complex to implement. In fact, it is necessary to review around ten separate legal documents (enumerated below) to have a full understanding of the extent and scope of the country’s Code law.

*See Figure 3 for Hierarchy of relevant Indonesian legislation

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## Figure 3.
Hierarchy of relevant Indonesian legislation (from highest to lowest)

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<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Constitution (1945)</td>
<td>Regulates the fundamental rights of everyone to live and grow and guarantees that every child has the right to survival, to grow and to develop […]</td>
</tr>
<tr>
<td>2</td>
<td>Laws</td>
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<tr>
<td></td>
<td>Law No. 36 of 2014 concerning Health Workers</td>
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<td></td>
<td>Law No. 18 of 2012 concerning Food</td>
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<td></td>
<td>Law No. 36 of 2009 concerning Health</td>
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<td></td>
<td>Law No. 8 of 1999 concerning Consumer Protection</td>
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<tr>
<td>3</td>
<td>Government Regulation</td>
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<tr>
<td></td>
<td>Government Regulation No. 33 of 2012 concerning Exclusive Breastfeeding</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Implements elements of Law No.36 of 2009 concerning health and covers exclusive breastfeeding, restriction of advertisements for BMS intended for infants under 6 months old and makes the establishment of nursing rooms for mothers at workplaces mandatory.</td>
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<tr>
<td></td>
<td>Government Regulation No. 69 of 1999 concerning Food Labels and Ads</td>
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<tr>
<td></td>
<td>▪ Regulates the information that must be included on a label of processed food intended for infants, young children and children under 5 years, as well as pregnant and lactating women. The Regulation bans advertisements of baby food intended for infants under 12 months old in the mass media.</td>
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<tr>
<td>4</td>
<td>President’s Instruction</td>
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<td></td>
<td>Presidential Instruction No. 1 of 2017 on Germas (Community Movement for Healthy Life)</td>
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<tr>
<td></td>
<td>▪ Takes a multi-sectoral approach to the National public health program and involves 18 line ministries and institutions.</td>
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<tr>
<td>5</td>
<td>Ministerial Decree</td>
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<td></td>
<td>Regulation of the Minister of Health No. 58 of 2016 concerning Sponsorship for Healthcare Professionals</td>
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</tr>
<tr>
<td></td>
<td>▪ Seeks to prevent COI, improve transparency and render non-partial health services. Requires any pharmaceutical/healthcare company that would like to give sponsorship, that falls under Regulation 58, to any healthcare professional in Indonesia to report this to the Corruption Eradication Commission (known as Komisi Pemberantasan Korupsi or KPK) within 30 days of any sponsorship being received.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Regulation of the Minister of Health No. 15 of 2014 concerning Procedures for Imposing Administrative Sanctions for Health Workers, Health Service Facilities, Health Education Unit Administrators, Health Professional Organizations, and Manufacturers and Distributors of Infant Formula Milk and/or Other Baby Products that can hinder the Success of Exclusive Breastfeeding</td>
<td></td>
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<tr>
<td></td>
<td>▪ Explains the obligations of health workers with regards to contributing to the success of exclusive breastfeeding and not acting as channels for the distribution or promotion of infant formula through the health system. Specifies that the Government, through heads of offices at the provincial, district and/or city levels, has the authority to receive reports of violations of this regulation and impose administrative sanctions in the form of verbal or written warnings as well as the revocation of business licenses.</td>
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<tr>
<td></td>
<td>Regulation of the Minister of Health No. 39 of 2013 concerning Infant Formula Milk and Other Baby Products</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Addresses Government’s duties and responsibilities to increase knowledge and awareness of exclusive breastfeeding and supervise advertisement and promotion of infant formula milk and other baby products.</td>
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</tbody>
</table>
One key area of weakness in Indonesia’s existing Code legislation regards monitoring and enforcement systems. When comparing Article 200 of Health Law No. 36 and Article 11 of the Code “Implementation and Monitoring,” the weaknesses of Indonesia’s Code law in terms of enactment of monitoring systems to control the marketing of BMS are clear. Article 200 states that any person who deliberately hinders exclusive breastfeeding programs by failing to provide sufficient time and special facilities to a baby’s mother to enable her to breastfeed shall be sentenced to a maximum prison term of one year and a maximum fine of 100 million Rupiah (approximately US$ 7,000). However, no government agency is given the authority to monitor or enforce this provision. In fact, the law is silent as to who is responsible for monitoring Article 200.

In addition, Regulation of the Minister of Health No. 15 of 2014 concerning “Procedures for Imposing Administrative Sanctions on Health Workers” specifies the obligations of health workers with regards to contributing to the success of exclusive breastfeeding and not acting as channels for the distribution or promotion of infant formula through the health system. It also makes clear that the Government, through heads of offices at the provincial, district and/or city levels, can receive reports of violations of this regulation and impose administrative sanctions in the form of verbal or written warnings and has the authority to revoke business licenses for serious violations. However, no monitoring or enforcement efforts have been carried out by local government or the MoH since the regulation was enacted six years ago.

In practice, according to stakeholders interviewed, monitoring and reporting of Code violations in Indonesia happens on a voluntary basis and is largely carried out by breastfeeding advocates and NGOs. Furthermore, there are many loopholes in the regulation when it comes to the monitoring of Code violations committed by formula companies. This is particularly concerning as it indicates that even though Indonesia has a strong legal basis to support mothers in their efforts to breastfeed their children, the inadequacies of the law itself allow violations to persist.

Government Regulation No. 33 of 2012 concerning exclusive breastfeeding states that: “The community must support the success of exclusive breastfeeding either individually or organized. Community support is done in an organized approach, among others: ... report violations of ethics code of marketing breast milk substitutes”. This approach represents a gap in the system for Code monitoring and enforcement within Indonesia. As no government authority bears responsibility for monitoring and enforcement under Government Regulation No. 33 of 2012, an unstructured system of monitoring and reporting Code violations has developed that is reliant on community volunteers. This has hindered any real implementation of the Code.

As mentioned above, Indonesia’s Health Law currently provides for a fine of 100 million Rupiah (approximately US$ 7,000) and up to one-year imprisonment for “any person who deliberately hinders exclusive breastfeeding programs as referred to in Article 128 paragraph (2)”. However, political commitment on this issue is lacking. As a result, no budget or human resources have been allocated for effective monitoring and enforcement of the existing law or the establishment of the necessary structures and data gathering/information systems to actually hold violators accountable.

Due to these gaps and the lack of a comprehensive policy to support monitoring and enforcement efforts, violations of the Code are rampant in Indonesia.

Formula milk advertising continues to heavily influence families’ behaviours when choosing between breastmilk and other milk. Inappropriate marketing of BMS and other Code violations at the point of sale and within private and public hospitals, are carried out by both medical practitioners and industry marketing personnel. According to a 2016 study of violations of the Code in Indonesia
published in *Public Health Nutrition,* 72 per cent of women reported having seen the promotion of BMS at health facilities and samples, gifts and promotions are often used alongside these tactics to persuade mothers to use formula. Improper content of advertisements is also an issue—infant pictures are often used to appeal to mothers and encourage them to purchase products.\(^{10}\)

While the provisions of Indonesia’s Code law reflect a number of the minimum standards embodied by the Code and subsequent WHA Resolutions, noteworthy gaps remain.

These include the following:

1. The law is limited in terms of its scope and falls short of the Code’s updated age limit recommendation of 36 months.
   
   a. Government Regulation No. 33 of 2012 concerning exclusive breastfeeding is limited to protecting exclusive breastfeeding for the first 6 months of life, and only regulates marketing within the health system and not at the retail level where the majority of BMS marketing occurs.
   
   b. Government Regulation No. 69 of 1999 concerning food labels and advertisements only covers BMS and foods intended for feeding infants up to 12 months of age\(^{11}\).

2. Much of the labelling information mandated by the Code is not required on labels of BMS in Indonesia. Under current labelling legislation – Government Regulation No. 69 of 1999 concerning food labels and advertisements – a message on the superiority of breastfeeding and detailed preparation instructions for BMS are not required. In addition, the current law does not prohibit the use of pictures or text on the labels of BMS that idealize these products (e.g. pictures of babies or baby bottles). However, stakeholders are well aware of these gaps and efforts are currently underway to amend the 1999 Labelling Law to include all labelling provisions contained in the Code.

3. Gaps in prohibitions on sponsorship. The law allows BMS companies to fund trainings, scientific research, events and other activities related to the health sector, as long as no product logo or name appears. In addition, the regulation of the MoH on sponsorship allows health workers/members of professional organizations to receive sponsorship from the BMS industry under certain conditions.


\(^{11}\) Article 47 (4) of Government Regulation No. 69 of 1999 concerning Food Labels and Ads states that food advertisements for infants up to the age of 12 months old are forbidden except in cases where approval from the Minister of Health is obtained, and the ad clearly states that the product is not a substitute for breastmilk.
02 Monitoring and inspection activities

Two key government entities bear responsibility for monitoring Indonesia’s complex Code law: MoH and the National Agency of Drug and Food Control (BPOM). However, the law itself is vague and often silent on the roles and responsibilities of each agency with regards to Code monitoring and inspection activities.

This is exacerbated by Indonesia’s decentralized government system which requires local adoption of national laws and regulations at the provincial and district level. This is due to the fact that provincial and district government authorities, and not the central government, are responsible for implementation and monitoring of laws and regulations.12

Stakeholder interviews revealed that neither MoH or BPOM is carrying out routine Code monitoring and inspection activities. Of the two agencies, BPOM’s monitoring capability appeared to be the strongest and they confirmed that they conduct food safety inspections at manufacturing facilities for products, including BMS, as part of their routine activities. In addition, BPOM is responsible for monitoring the labelling of processed food intended for older infants, young children and children under 5 years, as well as pregnant and lactating women under Government Regulation No. 69 of 1999 concerning food labels and advertisements. However, BPOM did not confirm how many of these inspections had been carried out in the past at BMS manufacturing sites or retail points of sale. Furthermore, those interviewed confirmed that neither BPOM nor MoH inspectors have ever received training on Code monitoring.

The challenges facing MoH were highlighted during meetings with the Legal and the Nutrition Units in Jakarta, where it became clear that there was a lack of cross-sectoral policy coherence and a systemic absence of coordination among stakeholders within MoH on the Code. Roles and responsibilities are not clearly defined, and the issue did not appear to have strong political commitment from within MoH. The systemic issues observed at the central level provide some explanation as to why there are currently no Code law monitoring or enforcement activities being carried out within Indonesia’s health system at the provincial or district levels.

The complexity of the Indonesia situation stood out among the countries evaluated for this report. Ten separate meetings were held with various stakeholders in which they all confirmed that monitoring related to products within the scope of the Code was not taking place. It was not until the final meeting with BPOM officials themselves that it became clear that BMS products were being included in their routine food safety and quality checks. While BPOM confirmed that they were not conducting dedicated Code law monitoring and inspection visits, they were including BMS and foods for children up to 12 months in inspections for label compliance, expiration dates and nutrient content.

BPOM clarified that it carries out three types of inspection activities: 1) sampling of food products to ensure safety, 2) label compliance and 3) advertisement compliance. None of these activities are specific to BMS products, and any monitoring of BMS products that currently takes place in Indonesia is part of BPOM’s routine monitoring activities and not a focused effort to enforce its Code law. BPOM confirmed that no Code training has been carried out for BPOM inspectors and they do not have standardized tools for Code monitoring.

12 See Regulation of the Minister of Health No. 15 of 2014 concerning Procedures for Imposing Administrative Sanctions for Health Workers, Health Service Facilities, Health Education Unit Administrators, Health Professional Organizations, and Manufacturers and Distributors of Infant Formula Milk and /or Other Baby Products that can hinder the Success of Exclusive Breastfeeding.
According to BPOM, Indonesia has major budget and human resource constraints when it comes to food inspectors – there are only 500 inspectors for the entire country of 264 million people. As a result, a decision was taken at the national level in 2015-2016 to shift the focus of their activities to self-control and industry self-regulation to ensure food safety. This means that BPOM does fewer actual inspections at manufacturing sites and has ceded authority to the food industry to self-regulate. Under this system, BMS products are categorized as ‘high risk’, which means that they receive the highest level of prioritization and are subject to periodic testing and sampling by BPOM inspectors using standardized criteria developed to ensure food safety. BPOM was not forthcoming on the frequency of the testing and sampling it conducts to ensure the safety of BMS products but confirmed that an inspection schedule for high-risk products exists and changes on a monthly basis.

03 Enforcement

Enforcement of Indonesia’s Code law has been extremely limited for two key reasons: (1) the law itself is complex, hindering implementation and (2) neither MoH or BPOM carry out dedicated Code monitoring and inspection activities.

While there was no evidence that financial penalties had ever been imposed for violations, BPOM confirmed that there are currently ten producers of BMS products in Indonesia and that one of them does not have a good track record and has been issued warning letters for unspecified food safety violations. Although the name of the BMS company that had repeatedly violated food safety laws was not disclosed, BPOM confirmed that multiple warning letters to infant feeding companies for Code specific violations of labelling laws (one of which was discovered via a major e-commerce platform) were issued. However, penalties or sanctions for violations of advertisement compliance provisions had not been issued due to a lack of human resources and capacity to carry out such monitoring.
04 Major bottlenecks

1. Legislation and policies
   - Existing Code law is spread out among multiple legal instruments, making it difficult to interpret and complex to implement.
   - Decentralization is a major issue and local government has broad latitude to legislate. Decisions made at national government level often do not get implemented due to the decentralized government system which requires local adoption of national laws and regulations at the provincial and district level. Furthermore, it is the provincial and district government authorities, and not the central government, that are responsible for implementation and monitoring of laws and regulations.

2. Leadership, political will and governance
   - Code law implementation and enforcement efforts have been almost nonexistent due to gaps in leadership at the MoH, a systemic absence of coordination among stakeholders within MoH and overall weak coordination between MoH and BPOM on monitoring and enforcement actions.

3. Human resources
   - Institutional human resource bottlenecks and weak capacity at both MoH and BPOM have prevented effective monitoring and enforcement of existing Code legislation, in addition to roles and responsibilities not being clearly defined.
   - BPOM has offices in 33 provinces, but their staff has not received training to enable them to carry out effective monitoring and enforcement of Indonesia’s Code law and is not involved in Code monitoring at the provincial level.
   - Provincial Health Offices (PHO) and District Health Offices (DHO) are not involved in Code monitoring at provincial and district level due to competing priorities and insufficient numbers of trained staff. Furthermore, no formal system has been established within PHOs and DHOs that permits staff to enforce existing provincial and district-level legislation on marketing of BMS and the protection of breastfeeding.
Industry influence

- Aggressive marketing of BMS has impacted negatively on knowledge practices and attitudes toward infant and young child feeding in the community and has helped create the perception that formula contains equivalent or superior nutrition when compared with breastmilk.

- Industry acts as an upstream bottleneck to enacting improved legislation in order to bring Indonesia’s law fully in line with the Code and latest WHA Resolutions. It is also a risk for industry to be involved in Indonesia’s Codex delegation where their representatives encourage the adoption of pro-industry positions.

- Inadequate checks and balances on industry-funded research and sponsorship of health workers and academic institutions, resulting in conflicts of interest with the infant feeding industry.

05 Recommendations for addressing the barriers to implementation of Code law monitoring and enforcement systems in Indonesia

Based on discussions with stakeholders and the feedback received, the following recommendations are made to address the perceived bottlenecks and barriers to implementation of Code monitoring and enforcement systems in Indonesia:

Advocacy

Develop a comprehensive strategy to raise awareness on the Code among the public, key stakeholders in the healthcare system, civil society organizations and government line ministries.

Advocate for the allocation of budget resources for training and capacity building of MoH and Indonesian FDA staff on the Code and strengthened monitoring and enforcement activities.

Monitoring and enforcement

Consider establishing regional code monitoring teams using the methodology contained in the NetCode Ongoing Monitoring System Protocol to monitor Code violations at the subnational level in locations with strong stakeholder engagement and government support.

Legislation

Draft a comprehensive and overarching Code law that addresses the weaknesses of the current legislation and brings Indonesia’s law fully in line with the Code and subsequent relevant WHA Resolutions, including WHA Resolution 69.9.
Strengthening Implementation of the Breast-milk Substitutes Code in Southeast Asia: Putting Child Nutrition First

FINDINGS
Myanmar
3.3 Myanmar

01 Background

According to the 2020 WHO Status Report, Myanmar’s Code law is classified as “moderately aligned with the Code”. This designation is conferred when countries have enacted legislation or adopted regulations, decrees or other legally binding measures encompassing a majority of provisions of the Code.\(^\text{13}\)

Myanmar’s Code law is comprised of a single comprehensive document:

**The Order of Marketing of Formulated Food for Infant and Young Child (the Order of Marketing)** which was issued in 2014 by the Food and Drug Board of Authority under the National Food Law.

The legislation covers infant formula marketed for children up to the age of 6 months, follow-up formula marketed for children up to the age of 24 months, formulated complementary foods for children 6-24 months (including BMS), feeding bottles and teats. It includes provisions on labelling, marketing, information and education, and monitoring and enforcement.

The law contains strict labelling provisions that prohibit the use of language implying that BMS are superior to breastmilk and it includes detailed guidelines to ensure the appropriate labelling of products within its scope; mandating warnings of the health hazards of inappropriate preparation and storage of BMS as well as improperly sterilized feeding utensils.

Myanmar’s Code law prohibits all kinds of marketing of BMS and formulated complementary foods at retail outlets including POS advertising, discount coupons, gifts, direct and indirect promotions to the general public and the giving of samples to mothers and families of infants and young children. In addition, companies are also prohibited from incentivizing marketing personnel and/or establishing sales quotas. In regard to health care professionals and the health system, the law specifies that manufacturers and distributors of products within its scope are generally prohibited from providing free samples, low cost supplies, donating equipment or office materials and providing fellowships, research grants, funding for meetings or sponsorship of events.

However, Chapter 4, Article 10 of the Order of Marketing falls short of creating an absolute prohibition on these practices because it allows for them if prior approval has been

received from the Myanmar Food and Drug Board of Authority (FDA) or the Ministry of Health and Sports (MoHS).

In respect of information and education on infant and young child feeding, the Order of Marketing requires that anyone publishing materials do so in the local language and include information on the benefits and superiority of breastfeeding. Specifically, any materials on infant and young child feeding must include how and why any introduction of bottle feeding or early introduction of complementary foods negatively affects breastfeeding; the importance of introducing complementary foods from the age of six months and easy preparation of complementary foods at home using local ingredients; and stress the importance of maternal nutrition and preparation for and maintenance of breastfeeding. In addition, these information and education materials must not use any text or images that encourage bottle feeding, contain any brand names or logos, encourage the use of any designated food or give an impression that feeding any designated food is equivalent to or superior to breastmilk or breastfeeding.

Myanmar’s Code law addresses monitoring and enforcement in chapters six and seven of the Order of Marketing. Chapter 6 gives the FDA the power to delegate any organization with full responsibilities for monitoring and implementation, but it does not provide any guidance on the procedures and actions required to do this. The section also directs all state, region and township Food and Drug Supervisory Committees to monitor and implement the Order of Marketing and to take action on any violations of its provisions. It also delegates responsibility to the health care system and health care providers to monitor and implement the Order of Marketing within the health system. However, all stakeholders interviewed confirmed that, at present, the Order of Marketing is not routinely monitored or enforced within or outside the health system. Therefore, although the law itself allows for the Food and Drug Supervisory Committees, as well as “any organization” to be delegated the responsibility to investigate Code violations and impose sanctions, this is not being done and remains a key area in need of improvement.

While the provisions of Myanmar’s Code law reflect many of the minimum standards embodied by the Code and subsequent WHA Resolutions, a few noteworthy gaps remain. These include the following:

1. Chapter 4, Article 10 of the Order of Marketing states that manufacturers and distributors of products within its scope shall not provide low cost or free samples; donate or distribute equipment or office materials; offer any gifts, fellowships, research grants or funding for local or international meetings or other contributions to health professionals or the health care system; or sponsor events relating to reproductive health, pregnancy, maternal nutrition or infant and young child feeding without prior approval from the MOHS or the FDA, which falls short of creating a strict prohibition on the marketing of BMS as required by the Code.

2. Labeling provisions do not require a warning message that infant/follow-on formula is not a sterile product and may contain pathogenic micro-organisms.

3. Criteria for the monitoring mechanism contained in Chapter 6 of the Order of Marketing does not require that monitoring be independent and transparent and free from commercial influence.
02 Monitoring and inspection activities

As of May 2021, the Government of Myanmar has done some limited monitoring of the 2014 Order of Marketing in public health facilities, but no reporting or enforcement measures have been taken.14

Two government entities are involved in monitoring the Order of Marketing: the FDA and the National Nutrition Centre (NNC). The NNC is responsible for monitoring marketing within the public health system as well as information and education materials (it does not have oversight authority in the private health system) and the FDA bears responsibility for monitoring labelling and marketing outside the health system and at retail points of sale. The FDA is also the authoritative body for enforcement action of the Order of Marketing. According to WHO and WFP officials interviewed for this report, routine monitoring of the Order of Marketing is not currently taking place in Myanmar and there is no existing mechanism to conduct such monitoring within either the NNC or FDA.15 Various stakeholders confirmed that monitoring of the Order of Marketing is sporadic and mainly takes place when the Government is pressured by development partners and civil society organizations.

The FDA confirmed that it does not currently monitor the marketing of BMS products, but it does carry out three key activities related to BMS. First, it checks product labels to make sure that they are in the local language. Second, it checks for prohibited statements (e.g. misleading statements that imply that formula is better than breastmilk, health and nutrition claims) and, third, it checks the labels of BMS for appropriate font size.

The FDA also explained that with UNICEF support the agency led a major nationwide BMS surveillance effort undertaken in 2017, the results of which were published in the national press, and that FDA food inspectors received training on the Order of Marketing in 2018 from the International Code Documentation Centre to address gaps in capacity and technical knowledge. Additional BMS surveillance activities have been planned for 2020 with the support of UNICEF, but this will likely be delayed until 2021 due to the COVID-19 crisis. Multiple stakeholders also mentioned that the National Food Law is in the process of being amended and strengthened to address existing weaknesses.

Furthermore, the FDA has recently developed a new standard operating procedure (SOP) that applies to importers of BMS to improve compliance with Myanmar’s labelling requirements, which continues to be a major problem. According to the SOP, if importers of BMS products violate the agreement, then Section 31 of the National Food Law on Sanctions will apply. The FDA expressed confidence that sufficient political will existed at higher levels of Government to implement this new approach which is aligned with the Order of Marketing. However, it remains to be seen how it plays out in practice – at the time of writing this report – labelling violations on product labels of BMS and complementary foods were widespread in Myanmar.

Besides the limited Code law monitoring efforts that have been carried out by the Government, the SUN Civil Society Alliance (SUN CSA) in Myanmar has collected evidence of violations of the Order of Marketing that took place between 2014 and 2017. Their findings have been published in two reports. The first is the ‘BMS Code Monitoring Report - Edition 1’ that covers September 2014 to July 2016 and there is also a report on the ‘Order of Marketing of Formulated Food for Infant and Young Child Violations in Myanmar’ that covers January 2016 to July 2017.

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14 Interview with SUN CSA Myanmar Official, 4 February 2020 in Yangon.
15 Interview with WHO and WFP Officials, 6 February 2020 in Naypyidaw.
The reports document numerous instances of breaches of the Order of Marketing by major international and local brands such as Abbott, Dumex, Dutch Baby, Gold Power, Nestlé, Ninolac, Nutrilatt, and Pigeon in contravention of national law. As illustrated in the reports, between 2014 and 2017 violations took place across multiple channels including TV, social media (Facebook), online, retail shops, health facilities and at trade fairs such as Kid Fair Yangon. Of the 30+ violations documented by the SUN CSA in the two reports, the majority are related to the marketing of BMS and complementary foods, inappropriate or inadequate labelling of designated food products, information and education materials on infant and young child feeding, prohibited contact with mothers from manufacturers and distributors of BMS, and sponsorship of health professionals.

According to Save the Children Myanmar, which serves as the Secretariat for the SUN CSA, many of the violations reported were collected at the community level through the Kobo Collect app, which is a free mobile application available through the Google Play store. Unfortunately, the use of this mobile app has been discontinued because it was too burdensome for many NGOs to use successfully as a reporting mechanism. Another key factor for the discontinuation of regular monitoring at the community level cited by Save the Children was that there was limited follow up on the violations reported between 2014 and 2017.

03 Enforcement

According to all stakeholders interviewed, there have not been any instances of formal enforcement or penalties issued for violating Myanmar’s Code law since it was enacted in 2014.

Although the FDA is the authoritative body for enforcement action of the Order of Marketing, they have struggled to take action even though this authority is clearly granted to them in Chapter 7 which states, “Whoever violates any provisions of this Order shall be taken action with the section 31 of the National Food Law”.

One partial explanation for the lack of enforcement action might be that neither the NNC nor the FDA carry out dedicated monitoring and inspection activities of the Order of Marketing, as there is no existing mechanism to conduct such monitoring.\(^1\) In addition, both the NNC and FDA highlighted their lack of human resources, both in terms of adequate training and technical knowledge as well as the overall number of staff available to carry out such monitoring at health facilities and retail point of sale.

\(^1\) Interview with WHO and WFP Officials, 6 February 2020 in Naypyidaw.
04 Major bottlenecks

- **Limited leadership, political will and governance**
  - As of October 2020, the Government has done some limited monitoring of the 2014 Order of Marketing in public health facilities but no reporting or enforcement measures have been taken. Stakeholders pointed to the top down political situation and the fact that the Order of Marketing is not prioritized by MOHS decision makers as major challenges to implementation at the state/ regional/ township level where officials are not empowered to take action without guidance from Central level.
  
  - No clear instruction or implementation guidance from NNC and FDA to lower level staff on roles and responsibilities under the Order of Marketing and how to take action.
  
  - Stakeholders noted that transparency was lacking in terms of Government decision making, resulting in the absence of operational planning and nutrition-related activities and those within the scope of the Order of Marketing changing and or being cancelled frequently.

- **Institutional human resources capacity**
  - Institutional human resource capacity is weak within the FDA and NNC. Trainings provided to government officials are also lacking.

- **Industry influence**
  - Industry influence with companies being noncompliant on the labeling provisions of imported BMS products and complementary foods.

- **Conflict of interest**
  - Conflict of interest throughout the health system, and between healthcare system and private sector.

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**Leadership, political will and governance**

**Human resources**

**Industry influence**

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law’s labelling provisions, even though they have already had six years. High-level lobbying of central Government officials is a major challenge.

- COI is rampant throughout the health system and many health professionals have relationships with BMS companies that violate the Order of Marketing.
05 Recommendations for addressing the barriers to implementation of Code law monitoring and enforcement systems in Myanmar

Based on discussions with stakeholders, the following recommendations are made to address the perceived bottlenecks and barriers to implementation of Code monitoring and enforcement systems in Myanmar:

<table>
<thead>
<tr>
<th>Category</th>
<th>Recommendation</th>
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<tbody>
<tr>
<td>Advocacy</td>
<td>Continue advocacy for full implementation of the Code, including WHA Resolution 69.9, and improved implementation, monitoring and enforcement of the Order of Marketing.</td>
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<tr>
<td>Capacity development</td>
<td>Develop formal guidance on labelling requirements and prohibitions for BMS and commercial complementary food products to improve compliance with existing legislation by manufacturers, distributors and retailers.</td>
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<tr>
<td>Program implementation</td>
<td>Issue clear MOHS Instruction on the roles and responsibilities of hospital staff and basic health staff under the Order of Marketing to improve compliance within the public health system.</td>
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<tr>
<td>Financing and human resources</td>
<td>Identify existing financial and human resources within the National Nutrition Centre (NNC) and Food and Drug Administration (FDA) and use the methodology contained in the NetCode Ongoing Monitoring System Protocol to establish national and regional teams to monitor the Order of Marketing.</td>
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<tr>
<td>Legislation</td>
<td>Amend existing Code legislation to address the gaps that prevent full compliance with the minimum standards embodied by the Code and subsequent WHA Resolutions, including WHA Resolution 69.9.</td>
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FINDINGS

Philippines
3.4 Philippines

01 Background

According to the 2020 WHO Status Report, the Philippines’ Code law is classified as “substantially aligned with the Code”. This designation is conferred when countries have enacted legislation or adopted regulations, decrees or other legally binding measures encompassing a significant set of provisions of the Code.\(^\text{17}\)

**Philippines Code law**

is comprised of two key documents:

1. **Executive Order (E.O.) 51**
   Also known as the Philippine Milk Code of 1986, and

2. **Administrative Order No. 2006-0012**

The law covers the marketing of BMS when represented to be suitable as a partial or total replacement for breastmilk, feeding bottles and teats. It also applies to their quality and availability, and to information concerning their use. However, it does not cover milk for mothers or complementary foods unless they are explicitly marketed as appropriate for children under 6 months of age, which the law prohibits.

In addition to E.O. 51 and the RIRR of 2006, there are multiple policies of lesser importance that have relevance to the Code in the Philippines. These include:

- Republic Act 11148: Kalusugan at Nutrisyon ng Mag-Nanay Act of 2018. An Act scaling up the national and local health and nutrition programs through a strengthened integrated strategy for maternal, neonatal, child health and nutrition in the first one thousand (1,000) days of life.
- AO No. 2007-0026: Revitalization of the Mother Baby Friendly Hospital Initiative in Health Facilities with Maternity and Newborn Care Services.

The text of E.O. 51 clearly states that the Department of Health (DoH) is principally responsible for the implementation and enforcement of the Milk Code. Section 12 (a) of E.O. 51 establishes an IAC in order to ensure that no advertising, promotion or other marketing materials for products within the scope of the Milk Code are printed, published or broadcast without prior authorization and approval of the committee. The IAC is a powerful entity and is composed of the following members: Secretary of Health (Chairman), Secretary of Trade and Industry (Member), Secretary of Justice (Member) and Secretary of Social Services and Development (Member). Currently, all advertisements, educational and promotional materials falling within the scope of the Milk Code have to be submitted for its approval prior to dissemination.

In 2006, the RIRR of E.O. 51 clarified that DoH would be responsible for the monitoring and enforcement of the Milk Code in health facilities but was silent as to which agency was responsible for monitoring and enforcement of products within the scope of the Milk Code at POS. Although the RIRR calls for the formation of monitoring teams at national and regional levels, stakeholders confirmed that these teams never materialized as envisioned. Various explanations were offered for the absence of DoH-led monitoring teams, including: competing priorities within the health care system both at national and regional levels; overburdened health offices at provincial, city and barangay levels with far-reaching mandates but too few human resources to complete them successfully; and an absence of leadership within the DoH itself.

Discussions with stakeholders revealed a strong consensus that the IAC was the best functioning part of the Milk Code monitoring and enforcement system. However, individuals noted that this was a relatively recent development and attributed it to two factors: a committed and proactive chairperson newly appointed by DoH in 2018 and the provision of external administrative support by World Vision to the IAC Secretariat. Stakeholders said that the IAC was effective in ensuring that advertisements and other marketing materials submitted for authorization and approval of the Committee complied with the Milk Code. However, they noted that the IAC does not currently have the authority to impose penalties for Milk Code violations or conduct retroactive monitoring of advertisements once they are printed, published or broadcast. As of February 2020, DoH is amending the RIRR (2006) to address identified weaknesses and gaps in the legislation. This process is expected to be finalized sometime in Q2 2020 and is supported by a Technical Working Group that includes UNICEF and select development partners.

While the provisions contained in the Philippines’ Code law are generally strong and reflect the minimum standard represented by the Code and subsequent WHA Resolutions, a few noteworthy gaps remain. These include the following:

1. No age range is specified for the term “breast-milk substitute” in E.O. 51 (1986) or the RIRR (2006), resulting in confusion and differing views on interpretation of the term among industry, government and non-profit organizations.

2. Inadequate checks and balances on industry-funded research and sponsorship of health workers and professionals, academic institutions, and even other government line agencies contained in Rule IV of the RIRR (2006), resulting in COI with the infant feeding industry.

3. Definition of “total effects” provision remains vague and is still open for discussion. As such, it is an inadequate safeguard against cross-promotion as defined by WHO.

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18 E.O. 51 stipulates that the members of the IAC may designate their duly authorized representative to every meeting of the Committee. In practice, the secretaries themselves do not attend and they send technical experts on their behalf.
02 Monitoring and inspection activities

To date, monitoring and enforcement of the Milk Code has been exceptionally limited.

As mentioned in the previous section, the DoH bears the primary responsibility for the Milk Code implementation but it has never established the monitoring teams mandated in the RIRR (2006) and does not currently conduct Milk Code monitoring or inspection activities, whether routinely or periodically.

In the absence of a formal Government Milk Code monitoring system, civil society and non-profit organizations have tried to fill the gap and have carried out some project-based monitoring activities.

In November 2016, international humanitarian organization World Vision launched the Crowd-Based Monitoring of Milk Code Compliance Project, otherwise known as Mother-Baby Friendly Philippines (MBFP). The project aimed to improve the implementation of E.O. 51, and its RIRR (2006) by encouraging crowd-sourced monitoring and by developing reporting channels where the public could report non-compliance to the mentioned laws. In October 2017, the DoH and World Vision signed a memorandum of agreement that formalized their partnership in the MBFP project and established three pilot sites – Malabon, Manila, and Quezon City. In order to operationalize the crowd-based monitoring of the Milk Code, the MBFP project committee launched three reporting channels for the public: (1) the Mother-Baby Friendly Philippines website, (2) Mother-Baby Friendly Philippines mobile application, and (3) the Mother-Baby Friendly Philippines SMS or texting mechanism.

Based on interviews with World Vision in Quezon City conducted in September 2018 and February 2019, 190 reports of Milk Code violations were received via the mobile app and the website, with very few violations submitted by SMS. Out of 190 total reports, World Vision verified 109 of them as confirmed violations, which were then submitted to DoH for further action. According to the DoH, they processed the confirmed violations and forwarded them to the Food and Drug Administration (FDA) of the Philippines, which sits within the DoH.

The FDA is the agency responsible for ensuring food safety and conducting monitoring within food manufacturing facilities. It is also responsible for enforcement of the Milk Code and the imposition of penalties and sanctions on violators. However, besides limited routine food safety inspections at BMS product manufacturing sites they do not currently conduct any dedicated Milk Code monitoring. In fact, the law does not require it, as neither E.O. 51 nor the RIRR (2006) specifies a monitoring function for the FDA. Instead, the RIRR (2006) defines the role of the FDA in Rule 11, Section 39 as follows:

“The FDA shall investigate and verify reports of violations; when appropriate, apply administrative sanctions against the violators; and/or file criminal complaints against persons and entities found to have violated, singly or repeatedly, the provisions of the Milk Code or these implementing rules and regulations.”

This is consistent with what those interviewed stated about the role and function of the FDA as related to the Milk Code. The FDA representative confirmed that the organization

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19 Criminal complaints must be forwarded by the FDA to the Department of Justice (DOJ). As of July 2019, no criminal complaints for violations of the Milk Code have ever been filed in the Philippines.
sees its role as limited to participation in the IAC and related to investigation and verification of reports of violations and the subsequent application of sanctions, if necessary.

All key informants interviewed confirmed that routine Milk Code monitoring is not taking place in the Philippines. The crowd-sourced monitoring facilitated by World Vision through the MBFP project has been the largest monitoring effort to date and has produced mixed results. Stakeholders reported that the idea of crowd-sourced monitoring never caught on and failed to generate interest among the general public beyond established breastfeeding advocates such as Latch, Breastfeeding Pinays and Arugaan. Although the project provided 109 verified reports of Milk Code violations to the DoH, as of October 2019, those reports have not resulted in any enforcement actions or sanctions being imposed on Milk Code violators by the FDA. It is also important to note that there have been no efforts to address the existing institutional human-resource bottlenecks within FDA to complement improvements in monitoring and reporting systems. The MBFP project ended in 2019, and, as of the time of writing this report, there were no plans for its continuation.
03 Enforcement

According to stakeholders, there have been few formal issuances of sanctions for violating the Philippine Milk Code.

In January 2012, the Undersecretary of Health acting as Chairperson of the IAC issued a “Cease and Desist Order” to a major international BMS company based on reports that products within the scope of the Milk Code were included in the distribution of relief goods to Cagayan de Oro City in the wake of Tropical Storm Sendong.

The Cease and Desist Order noted a prima facie violation of Section 6(b) of E.O. 51 and Sections 21, 51 and 52 of the RIRR (2006).

Section 6(b) of E.O. 51 provides that: “Manufacturers and distributors shall not be permitted to give, directly or indirectly, samples and supplies of products within the scope of this Code or gifts of any sort to any member of the general public, including members of their families, to hospitals and other health institutions, as well as to other personnel within the health care system, save as otherwise provided in this Code.”

Sections, 21, 51 and 52 of the RIRR (2006) provide as follows:

Section 21. “Gifts of any sort from milk companies/manufacturers, distributors and representatives of products within the scope of this Code, with or without company name or logo or product or brand name shall not be given to any member of the general public, to hospitals and other health facilities, including their personnel and members of their families.”

Section 51. “Donations Within the Scope of This Code. Donations of products, materials defined and covered under the Milk Code and these implementing rules and regulations, shall be strictly prohibited.”

Section 52. “Other Donations by Milk Companies Not Covered by this Code. Donations of products, equipment, and the like, not otherwise falling within the scope of this Code or these Rules, given by milk companies and their agents, representatives, whether in kind or in cash, may only be cours ed through the IAC, which shall determine whether such donation be accepted or otherwise.”

Besides the issuance of the Cease and Desist Order in January 2012, there have been few formal sanctions imposed on violators of the Milk Code since its inception in 1986. Consequently, enforcement efforts can be characterized as very weak and in need of improvement.
04 Major bottlenecks

1. Legislation and policies
   - The scope of the existing Code law is ambiguous, which has led to differing interpretations amongst stakeholders (e.g., there is a split between those who believe the law covers milk products intended for 0-24 month old infants and young children and those who believe the law covers milk products intended for 0-36 month old infants and young children).
   - Inadequate checks and balances on industry-funded research and sponsorship of health workers and academic institutions contained in Rule IV of the RIRR (2006), resulting in COI with the infant feeding industry.
   - The existing Code law does not mandate that the FDA monitor promotional activities (special prices, special offers and free gifts) for products within the scope of the Code sold on e-commerce platforms or at physical retail outlets.

2. Leadership, political will and governance
   - The Monitoring Teams envisioned in the RIRR (2006) at national and regional/provincial/city/municipal/barangay levels (in collaboration with their respective Local Government Units (LGUs)) never materialized due to a lack of high-level political support and leadership within the DoH, as well as a lack of commitment from LGUs.
   - Code enforcement efforts have been limited and unsustainable due to gaps in leadership, the roles and responsibilities of relevant line ministries not being well defined (i.e., DoH for health workers'/health facilities’ violations and FDA for industry violations), and overall weak coordination between the DoH, FDA and the Department of Justice (DoJ) on enforcement.

3. Human resources
   - Institutional human resource bottlenecks at both the DoH and the FDA have rendered previous attempts at improving Milk Code...
monitoring (Mother-Baby Friendly Philippines project) and enforcement systems ineffective.

- Legal expertise required to process confirmed Code violations is lacking at the FDA.

**Industry influence**

- Industry involvement is common in professional associations, within pre-and-in-service training programs for health workers (including nutritionists and dieticians), and within government entities that are major stakeholders in guiding national nutrition policy (e.g. Food and Nutrition Research Institute).

- The infant feeding industry has set up a SEC-registered company, the Infant and Pediatric Nutrition Association of the Philippines or IPNAP (www.ipnap.org.ph) to conduct educational activities for health professionals, which creates a COI with the potential to seriously undermine the professional responsibility of health workers to ensure optimal infant and young child nutrition.

- Initiatives such as the HiPP sponsored Project Mom offer resources and activities for mothers. Project Mom holds seminars on nutrition for women (pregnant and lactating) and their babies, which result in COI and inappropriate product promotion.

- Infant feeding industry participation is common at medical exhibitions in the Philippines. According to one BMS-producing company, the purpose of participating at the Philippines Medical Expo 2014 was "to find new potential specialised partners in Southeast Asia, especially in the Philippines where the population and birth rate are high". This statement shows the company’s obvious interest in creating opportunities to enter the health care system, where it can promote the use of its products.20

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05 Recommendations for addressing the barriers to implementation of Code law monitoring and enforcement systems in the Philippines

Based on discussions with stakeholders and the feedback received, the following recommendations are made to address the perceived bottlenecks and barriers to implementation of Code monitoring and enforcement systems in the Philippines:

Capacity Development

Orient key legal and technical staff at the FDA on Executive Order No. 51 and its associated Revised Implementing Rules and Regulations, with emphasis on their enforcement role and responsibilities under the Milk Code.

Provide technical assistance and training at the subnational level on the use of the NetCode Ongoing Monitoring System Protocol to establish and test a new approach to Code monitoring.

Monitoring and enforcement


Draft a Manual of Operations on Milk Code monitoring and inspection procedures to facilitate implementation of the Milk Code at health facilities and retail points of sale.

Legislation

Amend existing Code legislation to address the gaps that prevent full compliance with the minimum standards embodied by the Code and subsequent WHA Resolutions, including WHA Resolution 69.9.
Strengthening Implementation of the Breast-milk Substitutes Code in Southeast Asia: Putting Child Nutrition First

FINDINGS

Viet Nam
3.5 Viet Nam

01 Background

According to the 2020 WHO Status Report on National Implementation of the International Code (hereafter referred to as “the WHO Status Report”) Viet Nam’s Code law is classified as “moderately aligned with the Code”. This designation is conferred when countries have enacted legislation or adopted regulations, decrees or other legally binding measures encompassing the majority of provisions of the Code.21

Viet Nam’s Code law
(Decree 100/ND-CP in 2014)
covers BMS for children up to 24 months
and complementary foods for children up
to 6 months of age, feeding bottles and
artificial pacifiers.

It is comprised of two key documents:

1. **Decree 21/ND-CP (2006)**, which regulates the marketing of BMS for children up to 12 months, complementary food for children under 6 months and artificial feeding bottles and teats.

2. **Law on Advertising (2012)**, which bans the advertising of BMS intended for infants and young children under 24 months old.

In addition, the law prohibits the marketing of complementary foods specifically marketed for infants under-6-months of age and the use of images of infants and young children in advertisements for milk products for pregnant women. The law also specifies roles and responsibilities of health staff in breastfeeding support, specifies that information and educational materials on infant and young child feeding cannot contain pictures or words encouraging the use of BMS or discouraging breastfeeding; compare formula for young children as being equivalent to or better than breastmilk; or include names or logos of specific nutritional products for infants and young children.

In addition, there are multiple decrees of lesser importance that impact the monitoring and enforcement system in Viet Nam. These include:

- Decree 158 on Penalties for Administrative Violations Pertaining to Culture, Sports, Tourism and Advertising (2013).
- Decree 176 on Sanctions for Administrative Violations of Public Health (2013).22
- Decree 122 on Health Inspection Procedure (2014).

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22 As of August 2019, there is an amendment to Decree 176 on Penalties for Administrative Violations Against Trading and Using Products for Infants, Artificial Feeding Bottles and Pacifiers awaiting approval.
Decree 115 on Penalties for Administrative Violations of Food Safety Regulations (2018).

In terms of monitoring and enforcement, Decree 100, Article 14 on Management Responsibilities makes it clear that the MoH is primarily responsible for implementation. According to the Decree, MoH controls the use of nutritional products for infants, the quality and safety management of nutritional products for young children and is tasked with monitoring and enforcement duties. Stakeholders explained that there are three key agencies within MoH that are involved in conducting monitoring/inspection visits and enforcing the Code in Viet Nam: Department of Food Safety (VFA), the Health Inspection Department, and the Maternal and Child Health (MCH) Department.

Article 14 also notes that the Ministry of Culture, Sports and Tourism (“Ministry of Culture”) has a role in monitoring and enforcing the Decree. They are expected to manage the advertisement of nutritional products for young children in coordination with relevant line ministries.

According to Viet Nam’s legal system, roles and responsibilities of relevant agencies are defined based on the content of the specific legal provision. For example, the Ministry of Culture, Sport and Tourism is responsible for everything relating to advertisements, while the Vietnam Food Administration is in charge of food safety. As such, specific information on the roles and responsibilities of relevant agencies can be found in other legal documents or laws, but Decree 100 itself does not provide operational details on the roles and responsibilities of the agencies involved in Code monitoring and enforcement - it simply states which relevant ministry bears which duties and responsibilities for implementation and enforcement of the Decree. Additional details on roles, obligations, and responsibilities of the assigned ministries/agencies are stated in other relevant umbrella laws and guidance related to the functioning and operations of each agency.

Decree 122 on Health Inspection Procedure (2014) offers more specifics on the monitoring and inspection process. It states that there is an Annual Health Inspection Plan developed by the MoH Inspectorate and approved by the MoH at the national level. Based on this plan, MoH establishes inspection teams made up of individuals with the necessary expertise to effectively carry out that year’s plan. As part of this process, various departments within the MoH are assigned to perform specialized inspection functions. MoH departments that have specialized inspection functions implement their inspection plans in coordination with the MoH Inspectorate at the provincial level, which oversees the conclusions, recommendations and decisions resulting from the inspections.

Decree 100 necessarily involves monitoring and enforcement both within the health care system and the retail food environment. According to the MoH Legislation Department, the national agency responsible for performing medical inspections and imposing sanctions for violations within the health care system is the MoH Inspectorate. When it comes to the retail food environment and food manufacturing facilities, the VFA carries out inspections and may involve the Market Control Administration (Ministry of Industry and Commerce) and handles violations. At the provincial level, most provinces split responsibilities for Code implementation between the MoH Inspectorate, which is responsible for implementing and enforcing Decree 176 on Sanctions for Administrative Violations of Public Health (2013) and the relevant Provincial DoH or the VFA, which serves as the focal point for the monitoring and enforcement of Decree 100.

The handling of violations in advertising is addressed in Article 11 of the Law on Advertising. The law states that organizations committing violations of the law are liable to administrative sanctions and compensation for damages (if any) as prescribed by law.

23 See Decree 158 on Penalties for Administrative Violations related to the functioning and operations of each agency.

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Individuals committing violations are liable to disciplinary action, administrative sanctions or criminal prosecution depending on the nature and extent of the violations, and compensation for damages (if any) as prescribed by law\textsuperscript{24}. The law does not go into specifics on the magnitude of possible penalties. Instead, it simply states “The Government shall specify the acts of violations, forms and rates of administrative sanctions against the violations of advertising.”\textsuperscript{3} Therefore, a new Government Decree that regulates the detailed penalties/sanctions for Decree 100 violations has been developed. At the time of writing this report, the draft decree was under review.

While the provisions contained in Viet Nam’s Code law are generally strong and were significantly strengthened with the adoption of Decree 100/ND-CP in 2014, now reflecting a “full provisions” Code law, especially the very tight and inclusive definition of BMS, a few noteworthy gaps remain compared to relevant WHA Resolutions. These include the following:

1. No prohibition on the provision of free or low-cost supplies of BMS in the health care system as stipulated by WHA Resolution 39.28 (1986) and WHA Resolution 47.5 (1994).

2. No warning required on labels of BMS regarding pathogenic micro-organisms as stipulated by WHA Resolution 58.32 (2005).
02 Monitoring and inspection activities

As described in the previous section, MoH is primarily responsible for monitoring Viet Nam’s Code law. However, the Ministry of Culture, Sports and Tourism also plays a role when it comes to managing the advertisement of nutritional products for young children.

Within MoH the responsibilities for monitoring Decree 100 are divided as follows:

- **VFA**: monitors food safety, product registration and product labelling at pharmacies, retail POS, supermarkets, and BMS manufacturing sites.

- **Health Inspection Department**: performs inspections within the health care system to ensure compliance of health facilities, physicians and health workers with national legislation.

- **MCH Department**: participates in inspections within the health care system to ensure that health facilities, physicians and health workers comply with national legislation related to maternal and child health.

It was not possible to interview the Ministry of Culture, Sports and Tourism authorities responsible for monitoring the ban on advertising of BMS intended for children under 24 months old, artificial feeding bottles and pacifiers. However, a 2015-2016 media audit conducted by Alive & Thrive (A&T) and published in the *Journal of Public Health Nutrition* confirmed that there were no advertisements of BMS products for children under 24 months old found on television or in online/print media in Viet Nam. According to stakeholders, this is because licenses are necessary to advertise in Viet Nam, and the Ministry of Culture, Sports and Tourism has sufficient knowledge of Viet Nam’s Code law and the 2012 Law on Advertising that they do not approve licenses for advertising BMS products for children less than 24 months old.

However, A&T and other stakeholders noted that the absence of BMS advertisements was confined to traditional media, and newer forms of media, such as e-commerce platforms and social media, which are out of MoH’s current inspection scope, commonly advertise products in violation of Decree 100 and the Code. In fact, the International Baby Food Action Network (IBFAN) and A&T have kept a database of Code violations in Viet Nam since 2014. Upon review, the database largely contained photographic evidence of labelling violations and promotional activities on e-commerce websites and at POS, such as discounted prices, special offers or free gifts, in violation of Decree 100 and the Code.

It is important to point out that Viet Nam’s current Code legislation does not specify agencies to monitor and inspect the law’s violations on e-commerce websites, social media (e.g. Facebook, Instagram) or in POS advertising.

Based on multiple discussions and interviews, this appears to be a loophole in the monitoring and enforcement of the legislation that the infant feeding industry is exploiting. While the industry cannot promote BMS products for children under 24 months old in traditional media, evidence suggests that they are promoting BMS for children aged 0-36 months via e-commerce platforms, social media and at POS in violation of Article 5.1 of the Code. Therefore, it is recommended that a guiding document for detailing the implementation of Decree 100 is considered to be developed by the Government of Viet Nam to prevent industry from promoting BMS products for children under 24 months old on social media, e-commerce platforms, and at POS.
**Code law monitoring within the health system**

The MoH Health Inspection Department is the lead agency in charge of conducting inspections within the healthcare system to ensure compliance of health facilities, physicians and health workers with national legislation, policies and procedures. According to Decree 122 on Health Inspection Procedure (2014) and stakeholder interviews, inspections are conducted based on an annual plan developed by the MoH Inspectorate and approved by the Minister of Health. Once the annual plan is finalized and approved, MoH establishes inspection teams made up of individuals with the requisite expertise to effectively carry out the inspections in health facilities and hospitals. Inspection teams are comprised of 3-5 people per team and are guided by an inspection manual.

In terms of the Code, interviews suggested that Decree 100 is monitored as part of the routine inspection system developed by the MoH Inspectorate. However, due to the lack of available data and reporting on health inspection activities and enforcement measures, it is not possible to determine how well Decree 100 monitoring is functioning within those existing government systems. Because there is no data, it is impossible to know how many health inspections are taking place, what areas of the health system are being covered or how many of them include Decree 100. Furthermore, it is very difficult to find data on how many violations of Decree 100 have been documented and what was done to address these violations, because it is not made publicly available. A&T noted that because the MoH Inspection Department is tasked with monitoring almost everything within the health system, competing priorities are a big problem. This results in health inspections, including those that cover Decree 100, being assigned to the provincial departments of health (PHDs) for the majority of hospitals where they are not routinely conducted due to a scarcity of inspectors.

One positive development, however, is that in 2013 MoH introduced a set of Hospital Quality Assessment Criteria to improve services and increase patient satisfaction. There are 83 criteria, one of which is related to breastfeeding and requires compliance with Decree 100.

Each year, every hospital in Viet Nam self-administers the hospital standard assessment and ranks its performance on the 83 criteria. This is followed by a re-assessment conducted by the Medical Service Administration of MoH and the PHDs to verify the self-assessment results.

This monitoring is a routine mechanism within the health system and has the potential to be revised to further strengthen the regulatory environment around breastfeeding protection, promotion and support.

Between 26-28 November 2018, UNICEF had the opportunity to accompany a MoH inspection team on Decree 100 inspection visits to hospitals in HCMC and witnessed Code law monitoring within the health system first-hand. The team was comprised of individuals from the MoH Inspection Department, the MCH Department, the Ho Chi Minh City (HCMC) DoH in addition to the UNICEF Nutrition Specialist.

In the course of these visits, two public and two private hospitals were inspected, and numerous violations of Decree 100 were found and documented. Impressive was the caliber of the team and the quality of their inspections. Standardized monitoring tools and reporting procedures were utilized, and they completed the inspections thoroughly and quickly. After each inspection, there was a joint meeting with hospital administration officials and the MoH inspection team and the hospital was provided with a copy of the inspection report. In cases where violations of Decree 100 were discovered, the hospital was given two weeks by MoH to provide a plan of action to fix the violations and avoid financial penalty. No issuance of any sanctions or penalties for violations of Decree 100 were observed.
Based on numerous discussions with stakeholders and first-hand experience, it appears that Code law monitoring in Viet Nam’s health system has a few bright spots but overall is weak and in need of strengthening. Monitoring and inspection activities related to maternal and child health, including Decree 100, are infrequent and under-funded. Furthermore, the issuance of formal sanctions for violations is rare.

This assessment was confirmed by the findings in a report issued by MoH’s Legislation Department in July 2018 that assessed the implementation of Decree 100 and Decree 176 five years after commencement and noted weaknesses and challenges in implementation.

**Code law monitoring within the retail food environment**

In Viet Nam, the VFA conducts inspections to ensure food safety and periodic monitoring visits to enforce Decree 43 on Labelling. Monitoring and inspection visits are conducted according to an annual inspection plan developed by the MoH Inspectorate and approved by the Minister of Health. According to VFA officials, efforts are currently focused on the three largest cities in Viet Nam: Ho Chi Minh City, Hanoi and Da Nang. Inspections are comprised of 3-5 people per inspection team and are guided by an inspection manual.

In terms of the Code, VFA’s role is to monitor conformity with food safety regulations and the labelling requirements for BMS and complementary foods as well as feeding bottles, teats, and pacifiers outlined in Decree 100.

According to stakeholders, the VFA does not currently monitor other promotional activities at POS covered by Decree 100 and the Code such as special prices, special offers or free gifts, nor is this mandated in existing legislation.

Neither VFA officials nor other stakeholders were able to provide the confirmed number of inspection visits or details of the annual monitoring plan that covers products within the scope of Decree 100 within the retail food environment. However, multiple stakeholders confirmed that there is no government funding for dedicated Decree 100 monitoring and inspection visits, so any monitoring that is happening is integrated into the routine activities of the VFA and is likely insufficient to document and uncover labelling violations of BMS. It was also not possible to obtain a copy of the annual inspection plan that governs inspections to verify if and how frequently products within the scope of Decree 100 are scheduled for inspection.
03 Enforcement

Enforcement of Viet Nam’s Code law has been limited both in terms of the total number of formal sanctions imposed for violations and the predictability of the enforcement plan. However, MoH has recently developed a new government decree that includes detailed penalties and sanctions for Decree 100 violations, so this may improve in the near future.

While enforcement of the Code law and the issuance of penalties have been rare, there have been a few notable cases. For example, in January 2019 MoH issued a 25 million Vietnamese Dong (VND) (equivalent to ~US$ 1,075) fine for violations of Decree 176 and in 2013 five separate BMS companies were fined 25 million VND (~US$ 1,075) each for not conducting product safety testing. In addition to imposing fines, MoH has forced companies to take remedial measures to stop promoting BMS products in contravention of Viet Nam’s Code law.

The MoH Inspectorate is responsible for issuing sanctions and penalties for violations of Decree 100 in Viet Nam. However, it faces a number of challenges in terms of human-resource constraints and being overstretched. In 2010, there were a total of 70 health inspectors in the MoH inspectorate unit and about 5 in each inspectorate unit of the PHDs.25 Furthermore, stakeholders noted that at the provincial level, PHDs were hesitant to take enforcement actions and impose sanctions believing that the Ministry of Industry instead of MoH should be responsible for penalizing companies for their transgressions.

There is also evidence that the VFA, which is responsible for ensuring food safety and enforcing Decree 43 on Labelling, has pro-industry leanings. Its own website published a 2016 article on “Why nutritional products for children should be clinically validated”. The article notes that although breastmilk is always the best choice for the development of babies and young children, in many cases mothers are unable to provide this natural source of milk and must use formula milk to ensure their babies’ adequate nutrition.26 The article provides examples of situations where mothers may need to supplement breastmilk with BMS to ensure the development of children in the early years of life, and even suggests that using BMS products with docosahexaenoic acid (and arachidonic acid will improve their children’s brain development.27 These are the same deceptive tactics used by the BMS industry to undermine breastfeeding by spreading false or biased information and eroding mothers’ confidence in their ability to feed their children and have no place on an official website of a department of the MoH.

In terms of the Law on Advertising, the Ministry of Culture is responsible for implementation and issuing sanctions as mandated by Decree 158 on Penalties for Administrative Violations Pertaining to Culture, Sports, Tourism and Advertising (2013).

Decree 158, Article 50 covers goods and services banned from advertising and states that advertising milk for children under 24 months of age as a substitute for breastmilk or complementary food for children under 6 months of age, baby bottles or artificial nipples is subject to a fine of 40,000,000 VND to 50,000,000 VND (~US$ 1,720 - $2,150). At the time of writing the report, there was no evidence that such a fine had ever been imposed upon a company operating in Viet Nam.

27 Ibid.
04 Major bottlenecks

1. Lack of available data on health inspection activities and enforcement measures

Government data on health inspection activities and routine monitoring and enforcement efforts carried out as part of the Annual Health Inspection Plan developed by the MoH Inspectorate is not currently available. Therefore, it is not possible to know how many health inspections are taking place, what areas of the health system are being covered or how many of them include Decree 100. Furthermore, there is no data publicly available on how many violations of Decree 100 have been documented and what was done to address these violations.

2. Budget and financing

There is not enough budget allocated by the MoH to support routine monitoring and inspection of all health activities including Decree 100 implementation at health facilities. Therefore, general health inspection visits by MoH’s Health Inspection Department are only conducted at a small number of hospitals annually.

3. Industry influence

- Public-private partnerships focusing on pregnant women and lactating mothers such as the Projects for Nutrition Improvement sponsored by Abbott, are a means for these companies to use high profile ‘support of breastfeeding and infant and young child nutrition’ tactics to increase sales.
- COI persist and BMS companies continue to make donations to the health care system and sponsor medical conferences and professionals for continuing education.
- Dairy producers and BMS companies make inappropriate use of trade fairs and exhibitions to market BMS in violation of Decree 100 and the Code.

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Stakeholders in Viet Nam repeatedly emphasized the challenge the lack of available data on health inspection activities and enforcement measures presented to improving Code law monitoring and enforcement systems. Although the Bottleneck Analysis Matrix tool developed to guide key informant interviews did not explicitly state this as a separate category, it has been included accordingly.
05 Recommendations for addressing the barriers to implementation of Code law monitoring and enforcement systems in Viet Nam

Based on discussions with stakeholders and the feedback received, the following recommendations are made to address the perceived bottlenecks and barriers to implementation of Code monitoring and enforcement systems in Viet Nam:

<table>
<thead>
<tr>
<th>Advocacy</th>
<th>Consider engagement of line ministries beyond the MoH to conduct breastfeeding advocacy efforts and increase awareness of the Code and relevant national legislation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leadership</td>
<td>Establish a coalition to end COI related to the infant feeding industry’s involvement in maternal and child health issues in the healthcare system.</td>
</tr>
<tr>
<td>Data and reporting</td>
<td>Compile, analyse, and publish in health inspection reports the data on health inspection activities conducted and enforcement measures taken in relation to Decree 100 as part of the routine inspection system.</td>
</tr>
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<td></td>
<td>Develop a database to track routine monitoring and enforcement activities within the health system to strengthen accountability and ensure routine monitoring is taking place.</td>
</tr>
<tr>
<td>Monitoring and enforcement</td>
<td>Prioritize monitoring and inspection activities related to maternal and child health, including Decree 100, in the Annual Health Inspection Plan developed by the MoH Inspectorate.</td>
</tr>
<tr>
<td></td>
<td>Develop standardized Code monitoring tools/checklists using the NetCode Ongoing Monitoring System Protocol to support the capacity development of Nursing Units and Quality Control Units of hospitals.</td>
</tr>
</tbody>
</table>
Conclusion

This report on *Strengthening Implementation of the Breast-milk Substitutes Code in Southeast Asia: Putting Child Nutrition First* shows that existing Code law monitoring and enforcement systems in Cambodia, Indonesia, Myanmar, Philippines and Viet Nam need to be strengthened. It also demonstrates that the main barriers and bottlenecks to successful Code law monitoring and enforcement are strikingly similar in the countries examined.

Despite efforts to stop the harmful promotion of BMS, countries all over the world, including in Southeast Asia, are still falling short in protecting parents from misleading information on infant and young child feeding. UNICEF and WHO recommend that babies be fed nothing but breastmilk for their first six months, after which they should continue breastfeeding – as well as eating other nutritious and safe foods – until two years of age, or beyond. Babies who are exclusively breastfed are 14 times less likely to die than those who are not according to the 2020 WHO Status Report. Yet, only 41 per cent of infants 0–6 months old are exclusively breastfed, a rate WHO Member States have committed to increase to at least 50 per cent by 2025.

Inappropriate marketing of BMS continues to undermine efforts to improve breastfeeding rates. Therefore, the Code bans all forms of promotion of BMS, including advertising, gifts to health workers and distribution of free samples. Labels cannot make nutritional and health claims or include images that idealize infant formula. Instead, they must carry messages about the superiority of breastfeeding over BMS and the risks of not breastfeeding. Having a strong Code law in place helps ensure that health care systems can act to boost parents’ confidence in breastfeeding without industry influence.

In line with this, in four out of five countries examined in this report, leadership, political will and governance were reported to be key issues inhibiting successful Code law monitoring and enforcement.

To strengthen the implementation of the BMS Code in Southeast Asia, the report therefore provides:

- Recommendations to strengthen government leadership
- Recommendations to improve Code-related legislation and policies
- Recommendations to address human resource capacity challenges
- Recommendations to limit and prevent industry influence
01 Recommendations to strengthen government leadership

Evidence shows that strong and well-enforced national Code legislation can reduce the unethical marketing of BMS, bottles and teats, and ensure support for breastfeeding. However, as demonstrated in this report, even where the Code has been adopted in legislation, enforcement is often weak, and violations frequently occur. Government leadership is therefore needed to develop and strengthen Code law monitoring and enforcement systems.

- **Prioritize monitoring and inspection activities**
  
  Prioritize monitoring and inspection activities related to maternal and child health, including Code monitoring, in annual inspection plans developed by relevant line ministries.

- **Improve integration of Code monitoring activities**
  
  Improve the integration of Code monitoring activities into routine ministry operations by adding Code monitoring trainings to the existing training curricula for food, health and consumer protection inspectors.

- **Establish Milk Code monitoring teams**
  

02 Recommendations to improve Code-related legislation and policies

Another key area that was identified by countries examined in this report as a bottleneck to improved monitoring and enforcement was Code-related legislation and policies. Only one out of five countries currently has Code legislation that is “substantially aligned with the Code”. This is largely a consequence of national legislations failing to meet various provisions of the Code that prohibit the promotion of BMS to the general public and in health care facilities; ban all gifts and other forms of inappropriate engagement between manufacturers of BMS and health care workers; enable authorized government entities to impose sanctions when violations have been identified and validated; and explicitly include milk products intended and marketed as suitable for feeding young children up to at least 36 months of age in the scope of their national legislation.

- **Amend existing Code legislation**
  
  Amend existing Code legislation to address the gaps that prevent full compliance with the minimum standards embodied by the Code and subsequent WHA Resolutions, including WHA Resolution 69.9.

- **Ensure the establishment of monitoring and enforcement mechanisms**
  
  Ensure that robust and sustainable monitoring and enforcement mechanisms to implement national laws and regulations are established that include the possibility of applying deterrent sanctions in the case of violations of national Code legislation.

- **Clearly define roles and responsibilities**
  
  Clearly define the roles and responsibilities of the agencies involved in Code monitoring and enforcement in Code legislation and policies.

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03 Recommendations to address human resource capacity challenges

Legislation must be supported by allocation of adequate budgets and human resources to enable full implementation in relevant sectors. A common bottleneck across the countries examined in this report was weak institutional human resource capacity in the ministries involved in Code monitoring and enforcement. KII noted that many officials lacked appropriate training and qualifications to effectively carry out their jobs, and there were too few human resources overall, which made implementation of existing monitoring activities difficult.

| Identify existing financial and human resources | Identify existing financial and human resources within the key ministries involved in Code monitoring and enforcement in order to scale up Code monitoring and inspection activities. |
| Provide capacity development and training | Provide capacity development and training to key technical staff at the ministries involved in Code monitoring and enforcement on national Code legislation, with emphasis on their enforcement role and responsibilities. |

04 Recommendations to limit and prevent industry influence

The fourth area that emerged as a common bottleneck across the countries examined in this report was industry influence. Specifically, the widespread use of digital marketing strategies for the promotion of BMS is a cause of growing concern for countries in Southeast Asia. Modern marketing methods that were unavailable when the Code was written in 1981 are now used regularly to reach young women and their families with messages that normalize artificial feeding and undermine breastfeeding. Tactics such as industry-sponsored online social groups, individually-targeted Facebook advertisements, paid blogs and vlogs, online magazines, and discounted internet sales are used increasingly. Industry sponsorship of meetings of health professionals or scientific groups was also cited as an area of concern by numerous KII.

| Ensure that national Code legislation includes adequate checks and balances | Ensure that national Code legislation includes adequate checks and balances on industry-funded research and sponsorship of health workers and academic institutions, to prevent COI with the infant feeding industry. |
| Strengthen existing Code legislation | Strengthen existing Code legislation to include monitoring and enforcement of any violations on e-commerce websites (Lazada, Shopee) and social media (e.g. Facebook, Instagram, TikTok, etc.). |
| Amend existing Code legislation | Amend existing Code legislation to prevent inappropriate product promotion by industry to the general public or within health care systems. |
The main purpose of a Code law monitoring and enforcement system is to identify violations and, where these are verified to be actionable offences, the relevant agency can be called upon to take enforcement action. Furthermore, NGOs, civil society, consumers and citizens should also be provided with information on how to identify and report alleged Code violations. Countries such as Myanmar and the Philippines have already developed digital platforms where civil society can report observed violations of their national Code laws, and these types of efforts should be encouraged and strengthened in the future by governments and development partners. As of this writing, Indonesia was also in the process of developing such a system where consumers will easily be able to report violations of the Code observed via social media and other channels. Even though government systems are ultimately responsible for effective monitoring and enforcement of national Code laws, the digital platforms described may augment existing government systems and offer an innovative solution to addressing the barriers and bottlenecks to successful Code law monitoring.

A key resource to further address the bottlenecks identified in this report and strengthen existing systems is the NetCode Ongoing Monitoring System Protocol. This protocol has already been piloted in Cambodia with the assistance of WHO and provides a framework and tools to improve existing systems and establish sustainable structures that are able to monitor, detect, and report violations of national Code laws. Having such systems in place subsequently enables relevant enforcement actions to be taken. Instituting the NetCode Ongoing Monitoring System Protocol across the region would be a major step towards holding Code violators accountable for their behaviours and practices that undermine breastfeeding and place the health of infants and young children at risk.

Celebrated in 2021, the 40th anniversary of the Code provides an opportunity to reflect on the achievements made and on remaining and emerging challenges. Building on an analysis of barriers and bottlenecks, this report provides recommendations to improve Code monitoring and enforcement in five ASEAN countries. It is hoped that the report can strengthen the implementation of the Code in the countries concerned so that children can enjoy the full benefits of breastfeeding and have the best possible start to life.
# Annex A

List of KII respondents

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
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<tbody>
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<td>Etienne Poirot</td>
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<td>Doddy Izwardy</td>
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<td>Adhi Lukman</td>
<td>Chairman</td>
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<td>Wiyarni Pambudi</td>
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<td>Jee Hyun Rah</td>
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<td>Theresia Sembiring</td>
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<td>Sri Sukotjo</td>
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<td>Sundoyo</td>
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<td>Nia Umar</td>
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<td>Chan Myae Aung</td>
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<td>Htet Aung</td>
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<td>Sanjay Kumar Das</td>
<td>Nutrition Specialist</td>
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<td>Saw Eden</td>
<td>Nutrition Advisor</td>
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<tr>
<td>Lwin Mar Hlaing</td>
<td>Acting Director, National Nutrition Centre</td>
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<tr>
<td>Zar Ni Htet Hlaing</td>
<td>Nutrition Advocacy Advisor</td>
<td>SUN Civil Society Alliance</td>
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*Strengthening Implementation of the Breast-milk Substitutes Code in Southeast Asia: Putting Child Nutrition First*
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<thead>
<tr>
<th>Name</th>
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<tbody>
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<td>Sabel Htet Htoo</td>
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<tr>
<td>Swe Tint Kyu</td>
<td>Director, Department of Consumer Affairs</td>
<td>Ministry of Commerce</td>
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<td>Kyaw Win Sein</td>
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<tr>
<td>May Moe Thu</td>
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<td>Food and Drug Administration</td>
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<tr>
<td>Ohnmar Soe Win</td>
<td>Director, Food Control Division</td>
<td>Food and Drug Administration</td>
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<tr>
<td>Philippines</td>
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<tr>
<td>Kristine Jane Atienza</td>
<td>Health &amp; Nutrition Team</td>
<td>World Vision</td>
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<tr>
<td>Anthony Calibo</td>
<td>Lead Child Health Officer and Child Health</td>
<td>Department of Health</td>
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<td>Specialist</td>
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<td>Maria Evelyn Carpio</td>
<td>Nutrition Specialist</td>
<td>UNICEF</td>
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<tr>
<td>Atty. Ruth B. Castello</td>
<td>Undersecretary for Consumer Protection Group</td>
<td>Department of Trade and Industry</td>
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<tr>
<td>Aya Escobar</td>
<td>Supervising Health Program Officer</td>
<td>Department of Health</td>
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<tr>
<td>Maria Victoria S. Guevara</td>
<td>Co-Founder</td>
<td>Breastfeeding Pinays</td>
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<tr>
<td>Wigdan Madani</td>
<td>Chief, Health and Nutrition</td>
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<td>Mary Jane Paez</td>
<td>Medical Specialist, Bureau of Health Facilities and Services Standards Division</td>
<td>Department of Health</td>
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<tr>
<td>Lilian Salonga</td>
<td>Chief Trade &amp; Industry Specialist</td>
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<tr>
<td>Rosalyn Tomimbang &quot;Bibi&quot;</td>
<td>Food and Drug Regulations Officer</td>
<td>Food and Drug Administration</td>
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<tr>
<td>Carleneth San Valentin</td>
<td>Health &amp; Nutrition Technical Programme Manager</td>
<td>World Vision</td>
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<tr>
<td>Maria Rosario S. Vergeire</td>
<td>Assistant Secretary of Health, Public Health Services Team</td>
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<tr>
<td>Paul Zambrano</td>
<td>Regional Technical Specialist</td>
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<td>Viet Nam</td>
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<tr>
<td>Le Thuc Lan</td>
<td>Head of Inspection Division</td>
<td>Ministry of Health</td>
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<tr>
<td>Anh Nguyen</td>
<td>Division of Legislation and International</td>
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